



**CROHN'S  
& COLITIS**  
FOUNDATION

# Understanding **IBD Medications** and Side Effects



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If you or someone you know has just been diagnosed with Crohn's disease or ulcerative colitis, you may feel a bit overwhelmed by the news. In fact, you may not have even heard of these illnesses before. But now that you have, or even if you have been living with inflammatory bowel diseases for quite a while, you will want to learn as much as possible about them—including which medications can help control the diseases. That is the purpose of this brochure.

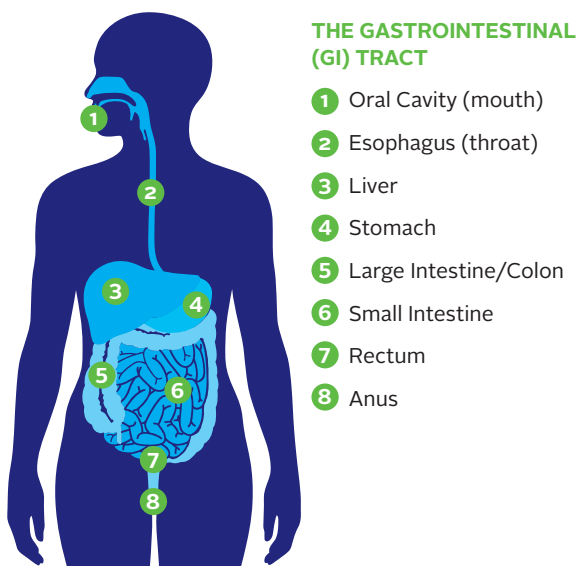
# About Crohn's Disease and Ulcerative Colitis

**Crohn's disease** and **ulcerative colitis** belong to a group of conditions known as **inflammatory bowel diseases**, or IBD. These disorders affect the **gastrointestinal (GI) tract**, the area of the body where digestion takes place. As the name implies, these diseases cause **inflammation** of the **intestine**. When a part of the body is inflamed, it becomes swollen. Sores, or **ulcers**, may also form within the walls of the intestine. The ongoing inflammation leads to symptoms that may already be familiar to you: abdominal pain, cramping, **diarrhea**, **rectal** bleeding, and fatigue. For some people, their symptoms are not just restricted to the GI tract. They may experience signs of IBD in other parts of the body, such as the eyes, joints, skin, bones, kidneys, and liver. These are referred to as **extraintestinal complications** of IBD, because they occur outside of the intestine.

Although Crohn's disease and ulcerative colitis share a lot of symptoms, they do have some marked differences. While inflammation related to Crohn's disease may involve any part of the GI tract from the mouth to the **anus** (including the esophagus, stomach, **small intestine**, and **large intestine**), ulcerative colitis is limited to just the large intestine (including the **colon** and **rectum**). Another distinguishing feature of ulcerative colitis is that it starts in the rectum and extends from there in a continuous area of inflammation. In contrast, Crohn's disease may appear in "patches," affecting some areas of the GI tract while leaving other sections in between completely untouched. These are known as "skip" areas. These differences are important for deciding whether inflammation of the intestinal tract is from Crohn's disease or ulcerative colitis. In 10 percent of cases there are overlapping features

of both ulcerative colitis and Crohn's disease, a condition called indeterminate colitis.

On average, people are more frequently diagnosed with IBD between the ages of 15 and 35, although the disease can occur at any age. The number of IBD patients has significantly increased over the last 50 years. While multiple contributing factors have been found, the exact cause of these diseases is unknown and currently there are no cures for Crohn's disease and ulcerative colitis. This makes the role of the Crohn's & Colitis Foundation in supporting research so critical. The Foundation has pioneered the research of these difficult to understand digestive diseases for over a half-century. Some of our major projects include our Genetics Initiative (research studies focused on the genes associated with IBD), Microbiome Initiative (studying bacterial, viral, and fungal species that reside in the gut and can affect the course of disease), and Environmental Triggers Initiative (research into the impact of lifestyle, psychological stress, nutrition, and other external factors).



# Treatment

To date, there is no known cause of or cures for IBD, but fortunately there are many effective treatments to help control the symptoms of these diseases. The two main goals of treatments for IBD are:

- Achieving **remission** (defined as the absence of symptoms)
- Maintaining remission (defined as preventing **flare-ups** of disease)

These goals may be achieved with a combination of over-the-counter and prescription medications or surgery, depending on each individual case. For more on surgery, visit [www.crohnscolitisfoundation.org](http://www.crohnscolitisfoundation.org).

When considering medication options, it is important to work together with your provider to make the best choice of treatment that aligns with your personal goals and preferences.

Please keep in mind the following:


- Symptoms of these long-term diseases may range from mild to severe and may include, but are not limited to, diarrhea, abdominal cramping, nausea, pain, rectal bleeding, and fever.
- People will go through periods in which the illness is active and is flaring. These episodes are usually followed by times of remission. Remission occurs when symptoms either disappear completely or lessen considerably and good health returns. These remission periods can last months or even years.
- Because each person with IBD is different, the treatment used to control his or her illness is unique. Doctors will customize treatment to the individual's needs based on the type and severity of symptoms. Medications may be given in different dosages, formulations, and for different lengths of time.

- Medications can be given in **oral** form (by mouth), intravenously (through a vein), or **subcutaneously** (by injection under the skin). Topical therapies are administered rectally, as suppositories, enemas, creams, and ointments.
- A person's therapeutic needs may change over time. What works at one point during the disease may not be effective during another stage. It is important for the patient and doctor to thoroughly discuss which course of therapy is best, balancing the benefits and risks of each treatment option.
- With the right treatment, patients may possibly achieve a life with minimal symptoms. Patients should have an open dialogue with their doctor and inform them if they are still experiencing IBD symptoms or a change in symptoms while on treatment. During these discussions, patients should feel comfortable asking their doctor about other available treatment options.

## Over-the-Counter (OTC) Medications

Prescription medications reduce intestinal inflammation and form the core of IBD treatments. Even so, these important prescription medications may not eliminate all of your symptoms. Naturally, you may want to take over-the-counter medications in an effort to feel better. Before doing so, speak with your doctor, as sometimes these symptoms may indicate a worsening of the inflammation that may require a change in your prescription.

Other times these symptoms do not reflect a worsening of the condition and can be treated with over-the-counter medications. For example, your doctor may recommend loperamide (Imodium®) to relieve diarrhea, or anti-gas products for bloating. To reduce joint pain or fever, your doctor may recommend acetaminophen (Tylenol®) or non-steroidal anti-inflammatory drugs (**NSAID**)—such as aspirin, ibuprofen



(Motrin<sup>®</sup>, Advil<sup>®</sup>), or naproxen (Aleve<sup>®</sup>). NSAIDs will work to alleviate joint symptoms but can irritate the GI tract, thus promoting inflammation. NSAIDs should be used with great care. Make sure that you follow instructions with all OTC products, but again, speak with your healthcare professional before you take any of these medications.

## Prescription Medications

Some medications used to treat Crohn's disease and ulcerative colitis have been around for years. Others are more recent breakthroughs. The most commonly prescribed medications fall into the following categories:

- **Aminosalicylates:** These include medications that contain 5-aminosalicylic acid (5-ASA) such as sulfasalazine, balsalazide, mesalamine, and olsalazine. These medications work by inhibiting certain pathways that produce substances that cause inflammation. They can work at the level of the lining of the GI tract to decrease inflammation. They are thought to be effective in treating mild-to-moderate episodes of IBD, and are useful as a maintenance treatment in preventing relapses of the disease. They work best in the colon and are not particularly effective if the disease is limited to the small intestine. These are often given orally in the form of delayed release tablets to target the colon, or rectally as enemas or suppositories.
- **Corticosteroids:** These medications, which include prednisone, prednisolone, methylprednisolone, and budesonide, affect the body's ability to begin and maintain an inflammatory process. In addition, they work to keep the immune system in check. Prednisone and prednisolone are used for people with moderate-to-severe Crohn's disease and ulcerative colitis. Budesonide is used for people with mild-to-moderate ileal Crohn's disease, and right-sided colon Crohn's disease. They can be administered orally, rec-



tally, or intravenously. They are effective for short-term control of disease activity (flares); however, they are not recommended for long-term or maintenance use because of their side effects such as swelling, weight gain, hair growth, and acne. Long-term steroid use can also lead to weakened bones (osteoporosis). If you cannot come off steroids without a relapse of symptoms, your doctor may add some other medications to help manage your disease. It is important not to suddenly stop taking this medication. If you stop suddenly, you may experience symptoms such as severe fatigue, weakness, body aches, joint pain, nausea, or a decrease in appetite.

- **Immunomodulators:** These include azathioprine, 6-mercaptopurine (6-MP), methotrexate, cyclosporine, and tacrolimus. This class of medications modifies the body's **immune system** so that it cannot cause ongoing inflammation. Usually given orally (methotrexate can also be injectable), immunomodulators are typically used in people for whom aminosalicylates and corticosteroids haven't been effective, or have been only partially effective. They may be useful in reducing or eliminating reliance on corticosteroids. They also may be effective in maintaining remission in people who haven't responded to other medications given for this purpose. Immunomodulators may take up to three months to begin working. All patients on immunomodulators need to be monitored closely for side effects, such as bone marrow problems as well as irritation of the liver or pancreas.



- **Biologic therapies:** These therapies are bio-engineered drugs that target very specific molecules involved in the inflammatory process. These are not drugs but antibodies (types of proteins) that target the action of other proteins that cause inflammation.

These medications are indicated for people with moderately to severely active disease. They also are effective for reducing **fistulas**. Fistulas, which may occur with Crohn's disease, are small tunnels connecting the intestine to another area of the body to which it is not usually connected.

Biologics may be an effective strategy for reducing steroid use, as well as for maintaining remission. While on biologics, you should not receive any live vaccines. Be sure to speak with your healthcare provider about appropriate vaccinations before starting these medications.

Biosimilars are similar, near identical copies of other already approved biologic therapies, known as the reference product or originator biologic. They are drugs that act just like a reference product, having the same effectiveness and safety in the patient population that it treats. Examples of this class of therapy include infliximab biosimilars: infliximab-abda, infliximab-axxq, infliximab-dyyb, and infliximab-qbtx.

- **Antibiotics:** Antibiotics may be used when infections—such as an **abscess** (pocket of pus)—occur. They treat Crohn's disease, **perianal** Crohn's disease, and ulcerative colitis. They are also used to treat **pouchitis**, which is an inflammation of the ileal pouch (also known as a j-pouch, a surgically constructed internal pouch for those who have had their large intestine removed), and for prevention of recurrent Crohn's disease after surgery.

- **Targeted synthetic small molecules:**

These medications help reduce inflammation by specifically targeting parts of the immune system that play a role in inflammation in the intestine and other organs. There are currently three FDA approved targeted synthetic small molecules to treat adults with moderate-to-severe ulcerative colitis and they are taken orally in pill form.

## Off-Label

Sometimes doctors will prescribe medications that the Food and Drug Administration (**FDA**) has not specifically approved for the treatment of Crohn's or ulcerative colitis. Nonetheless, these medications have been shown to be very effective in reducing symptoms. Prescribing medications for other than FDA-approved conditions is known as “**off-label**” use. Your health-care provider may have to obtain prior approval from insurance companies before prescribing a medication for off-label use. Patients should be aware that they or their doctor might need to make a special appeal in order for their insurance company to pay for an off-label medication.

## Complementary therapies

Some people living with Crohn's disease and ulcerative colitis look toward complementary therapies to use together with conventional therapies to help ease their symptoms. These therapies may work in a variety of ways. They may help to control symptoms and ease pain, enhance feelings of well-being and quality of life, and possibly boost the immune system. Speak with your doctor about the best therapies for your situation.

*For further information about complementary therapies, visit: [www.crohnscolitisfoundation.org](http://www.crohnscolitisfoundation.org).*


# Pediatric IBD Patients

Customizing treatment for the individual with IBD is critical, including when that patient is a child or teenager.

Most pediatric treatment choices were developed after initial research on adults. As a result, drug dosages for a child must be carefully tailored to suit their age, size, and weight—in addition to existing symptoms, location of inflammation, and previous response to treatment.

The same medications that are used to treat adults with IBD are also used for children. Still, there are some special considerations in treatment because children and teenagers are going through a period of physical and emotional growth and development. Here are some of the recommendations for the various medication categories:

- **Aminosalicylates:** These compounds that contain 5-aminosalicylic acid (5-ASA) are generally the first step in therapy for children with mild-to-moderate ulcerative colitis or mild Crohn's disease of the colon. Mesalamine, balsalazide, and olsalazine have fewer side effects than sulfasalazine. Drugs can be given either orally or rectally. The number of pills may be as many as 10 or more per day, which your doctor will advise how to handle with respect to your child's school schedule. Also, some children have trouble swallowing pills. In cases where swallowing capsules is a concern, your child's doctor may advise that specific capsules be opened and the contents mixed with food. You can download a pill-swallowing handout that will provide information on how to teach your child how to swallow pills at [www.crohnscolitisfoundation.org](http://www.crohnscolitisfoundation.org).
- **Corticosteroids:** When a child has not responded to treatment with a 5-ASA, or if their disease is more severe at onset, oral corticosteroids may be prescribed. For severe




cases, intravenous corticosteroids may be used—necessitating a hospital stay. Once remission is achieved, corticosteroid dosage is tapered gradually. When patients are tapered off of corticosteroids, a strict schedule should be followed in order to minimize side effects that can occur if patients are weaned off too quickly. Long-term steroid use in children can also lead to growth problems and weakened bones (osteoporosis). To minimize the chance of osteoporosis, adequate calcium and vitamin D intake is essential.

- **Immunomodulators:** While immunomodulators can be prescribed for children with Crohn's disease and ulcerative colitis the approach to their use as a treatment can vary. Immunomodulators may often be prescribed as a combination therapy with biologics. All patients on immunomodulators need to be monitored closely for side effects, such as bone marrow problems as well as irritation of the liver or pancreas. Live vaccines are not recommended for IBD patients taking immunomodulators.
- **Biologic therapies:** Biologic therapies are commonly used in the treatment of pediatric IBD. Some of these therapies have been specifically approved by the FDA for use in children ages 6-17. Examples include infliximab, and adalimumab, which are approved for children with moderate-to-severe Crohn's disease and ulcerative colitis. Other biologic therapies are being tested in children and are currently used in specific situations.

Live vaccines are not recommended for IBD patients taking biologic medications. It is important to talk to your health care provider about which vaccines are safe for your child to receive.

- **Antibiotics:** Metronidazole is used in children and teenagers with perianal Crohn's disease. It may also be used as an alternative treatment to 5-ASA or steroids for Crohn's colitis.



Another antibiotic option is ciprofloxacin, which has been shown to be effective in adults with Crohn's colitis and inflammatory changes around the anus, including fistulas and abscesses in Crohn's disease. The use of ciprofloxacin and other drugs in the same class, called fluorquinolones, has been associated with an increased risk of tendonitis and joint discomfort or pain. Their use in children has been controversial in the past, although studies have not demonstrated any increased risk of complications in children compared to adults.

## Making the Most of Your Treatment

Crohn's disease and ulcerative colitis are long-term, **chronic** diseases. This means that people with these conditions may need to take medication indefinitely. While not every person with IBD will be on medication all of the time, most people will require therapy most of the time to get well and stay well.

For many individuals this may seem like a major concern, especially when some of those medications produce unwanted side effects. Side effects can vary and your doctor will explain which side effects are serious and require immediate attention, and which side effects are more mild and common. If you are experiencing unpleasant side effects or interactions with other drugs, don't stop taking your prescribed medication. Speak with your doctor and ask about possible adjustments that might reduce those effects.

Even when there are no side effects, taking medication as prescribed by your doctor can seem like a nuisance, but it is an important step in helping manage your disease. Remember, taking medication to maintain remission can significantly reduce the risk of flares in both Crohn's disease and ulcerative colitis.

## Tips to Help You Manage Your Medications

- Taking medication correctly means more than just taking the right amount at the right time. Talk to your doctor or pharmacist and learn as much as possible about the medications you take and how they may affect you. For example, sometimes medications should be taken with food and other times on an empty stomach.
- Some medications require close monitoring for side effects. This may require blood work and follow-up visits as requested by your doctor.
- If possible, use the same pharmacy every time you get your prescription filled. Pharmacies can help you keep track of what you are taking.
- Don't take any medications that have expired.
- Don't take anyone else's medications or share yours with others.
- Tell your doctor or pharmacist about all medicines, supplements, or other things you may be taking for your health, including OTC medications, vitamins, and herbs.
- Use the medication log at the end of this brochure or an online tracker tool.
- Immunomodulators and biologics can increase the risk of upper respiratory and lung infections. Therefore it is recommended that you be up-to-date on certain vaccinations. Be aware that live virus vaccines might be contraindicated in these situations.

If you are having trouble affording your medications, do not stop taking your medications. Alert your healthcare provider who may be able to help you find a solution. It is important that you take medications as prescribed, as some cannot be safely stopped abruptly. If the cost of treatment presents a problem for you, or if you have an insurance change, there may be



a number of patient assistance programs that can help. Visit [www.crohnscolitisfoundation.org/managingcosts](http://www.crohnscolitisfoundation.org/managingcosts).

## **What to Ask Your Healthcare Provider About Your Medications**

It is only natural that you will have some concerns about the treatment that you will be receiving for IBD. What should you ask your doctor? What do you need to know about your treatment? The following are some of the questions you may want to ask:

- Why is this medication necessary?
- How long will I need to take this medication?
- How does this medication work?
- How long does it take for this medication to start working?
- Can I take vitamins, minerals, herbs, or other supplements while using the medication?
- Can I take OTC medications for joint pain, diarrhea, or abdominal pain?
- Can I get vaccines while I am on my IBD medication?



- What kind of side effects might I experience? Which are cause for alarm, and what should I do if these occur?
- What kind of interactions does this IBD medication have with other medications I may be taking for other conditions?
- What should I do if I miss a dose?
- What should I do if I have a negative reaction immediately after taking my medication?
- Is it safe to drink alcoholic beverages while on this medication?


## **Remember to Tell the Doctor**

Before starting new medications, it is important for you to tell your doctor and other healthcare providers (including dentists or emergency room staff) about other medications you may be taking. Tell them whether you:

- Have taken this drug before (even if there was no unusual reaction).
- Have had an unusual or allergic reaction to this drug, or other medications.
- Have or have had any other medical conditions.
- Take any other medication or drugs (prescription or OTC), how long you have been taking them, your dose, and any side effects you may have.
- Take any vitamins, minerals, herbs, or other supplements.

## **Pregnancy and Male Fertility**

With careful supervision of both a gastroenterologist and an obstetrician, most women with IBD can have a healthy pregnancy and a healthy baby. If you are considering becoming pregnant, it is recommended to try to have your IBD in remission before you do so.



Recent studies have shown that women do better during pregnancy if their disease is not active at the time of conception. Most experts agree that the major threat to pregnancy seems to come from the active disease itself, rather than the medication being used to treat the disease. Having active disease during pregnancy can increase the risk of having a baby born prematurely or with a low birth weight.


If you are pregnant and have IBD symptoms, your doctor will advise you as to which of the medications mentioned previously are safe to take. In most cases, medication schedules are maintained during pregnancy. However, there are some considerations and exceptions. It is also important to note that if a woman's condition changes, drugs or dosages may be altered. Here are some of the recommendations for the various medication categories:

- **Aminosalicylates.** Sulfasalazine (Azulfidine®) and other 5-ASA compounds such as mesalamine (Asacol® HD, Pentasa®, Rowasa®, Canasa®, Lialda®), balsalazide (Colazal®), and olsalazine (Dipentum®) do not appear to increase complications or harm the fetus. Sulfasalazine may cause nausea and heartburn. As sulfasalazine lowers folic acid levels, women should be on at least 2 mg of folic acid daily. Women can breastfeed while taking a 5-ASA compound.
- **Corticosteroids.** Prednisone and other corticosteroids are low risk during pregnancy. Corticosteroids are not recommended for planned maintenance therapy in pregnant women, but talk to your doctor about use during flares in pregnancy. If a woman becomes pregnant while on steroids, the doctor usually tries to minimize the dose. Nursing infants of women on moderate-to-high dosages of prednisone should be monitored by a pediatrician.

- **Immunomodulators.** Dosing of immunomodulators should be monitored during pregnancy. Although many immunomodulators may appear as low risk, there is limited data in pregnancy. Both men and women should avoid methotrexate as it is known to cause birth defects.
- **Biologics.** Most biologics, such as infliximab (Remicade®), adalimumab (Humira®), and certolizumab (Cimzia®), are considered low risk. They also do not appear in breast milk. However, both adalimumab and infliximab cross the placenta in high levels late in pregnancy, so your doctor may want to give the last dose in the middle of your third trimester.
- **Antibiotics.** Antibiotics are not recommended for planned maintenance therapy in IBD during pregnancy.
- **Targeted synthetic small molecules.** There is currently limited data in pregnancy. It is advised to consider other options, particularly in the first trimester.

Because pregnancy is such a personal matter and there are so many factors that go into how a pregnancy may turn out, the choice of what





medicines to take before and during pregnancy should be discussed with the healthcare provider treating your disease, as well as your obstetrician and your maternal fetal medicine specialist.

While most of the recommendations regarding medication use and pregnancy focus on women, there are some for men as well. For three months before conception, men should avoid taking methotrexate. Also, because the medication sulfasalazine decreases sperm count and therefore may cause infertility, a man taking this drug should switch to another 5-ASA compound (with his doctor's approval). Discuss all medications with your doctor.


For more information on Pregnancy and IBD, view our pregnancy fact sheet at [www.crohnscolitisfoundation.org/brochures](http://www.crohnscolitisfoundation.org/brochures).

## Participation in Clinical Trials

Researchers working in laboratories all over the world are devoted to the scientific investigation of Crohn's disease and ulcerative colitis in the hope of finding cures.

That is good news when it comes to the development of new therapies for these diseases. New discoveries over the past decade have led to huge strides in the fields of immunology (the study of the body's immune defense system), microbiology (the study of microscopic organisms with the power to cause disease), and genetics (the study of how various tendencies and traits—including diseases—are passed from one generation to another).

With new information being gathered all the time, there is good reason to be hopeful about future treatment for IBD. While we all wish for better treatments today, it's important




to understand that it takes a long time for a promising development in the laboratory to become a drug ready for consumer use. In fact, the process of getting a drug to market, from first testing to final approval by the Food and Drug Administration (FDA), may take as long as 10 years.

Before a new drug or a new type of treatment is approved, it must go through a series of clinical trials. Clinical trials are well-organized studies that evaluate the treatment's efficacy and safety. Most clinical trials are classified into one of three phases:

- **Phase I** trials evaluate how a new drug should be given (by mouth, injected into the blood, or injected into the muscle), how often, and what doses are safe to use.
- **Phase II** trials test the safety of the new drug, as well as evaluate how well the drug works.
- **Phase III** trials test how well the new drug works and the best dose. Trial participants are divided into groups where one receives the medication and a “control” group receives a placebo (no chemical properties) or standard-of-care therapy.

With the ever-increasing number of clinical trials of potential new IBD therapies, there is an even greater need for patient participation to see if these experimental therapies work. Patients often find participation in a clinical trial a rewarding experience. Anyone can participate as long as they meet the criteria for that particular trial. Those criteria may include type of symptoms, location or stage of disease, and age.

Should you participate in a clinical trial of a new drug for Crohn's disease or ulcerative colitis? To make that decision, you need to be fully informed about that trial and the drug that is being tested. All clinical trials have both benefits and risks associated with them. The



advances in current IBD treatment are possible only because people before you participated in clinical trials. Find out more about clinical trials through the Foundation's Clinical Trials Community at [www.crohnscolitisfoundation.org/clinical-trials-community](http://www.crohnscolitisfoundation.org/clinical-trials-community).

## Improving Quality of Life

The Crohn's & Colitis Foundation has established a range of educational materials and programs designed to increase awareness about Crohn's and ulcerative colitis.

We know living with IBD can be difficult, but the right resources and support can make day-to-day living more comfortable. That's why the Foundation has developed a comprehensive, free online community ([www.crohnscolitiscommunity.org](http://www.crohnscolitiscommunity.org)) to provide the support individuals need in managing their condition. In-person support groups are also available in many locations nationwide. Find groups in your area at [www.crohnscolitisfoundation.org](http://www.crohnscolitisfoundation.org), or call 1-888-694-8872.

We recognize the importance of distributing unbiased, accurate, and authoritative information in order to provide education of the finest quality. One avenue used to accomplish this is the Irwin M. and Suzanne R. Rosenthal IBD Resource Center (IBD Help Center). Through a toll-free number (1-888-694-8872), e-mail, or live chat on our website ([www.crohnscolitisfoundation.org](http://www.crohnscolitisfoundation.org)), master's degree level health education professionals answer questions and direct people to resources that are important to help improve their quality of life.

# IBD Medications

You and your healthcare team share one important goal: to get your IBD under control and keep it that way.

One of the best ways to accomplish that is by carefully following the medication regimen your doctor has prescribed for you. Included on the next page are medication profiles. The profiles include information about commonly used IBD medications. The information in this brochure is current as of the date of printing.

These profiles do not contain all available information about the risks, benefits, and additional warnings for each medication listed. Please speak with your healthcare team for more detailed information. This information is not intended to replace medical advice from your doctor or other healthcare provider.

For a complete listing of all currently available IBD medications, please visit our IBD Medication Guide on our website [www.crohnscolitis-foundation.org](http://www.crohnscolitis-foundation.org) or contact the IBD Help Center at [info@crohnscolitisfoundation.org](mailto:info@crohnscolitisfoundation.org) for more information and resources.

## Aminosalicylates (5-ASA)

<b>Generic Name:</b> Balsalazide
<b>Brand Name(s):</b> Colazal, <sup>®</sup> Giazol <sup>™</sup>
<b>Drug Class:</b> Aminosalicylates (5-ASA)
<b>Recommendations for Pregnancy:</b> Low risk
<b>How Taken:</b> Oral
<b>Used for:</b> Mild-to-moderate ulcerative colitis
<b>Medication Indication:</b> Used to treat the signs and symptoms of mildly-to-moderately active ulcerative colitis in patients five years of age and older. Also, prescribed for off-label use for treatment of Crohn's disease.
<b>Most Common Side Effects:</b> Headaches, abdominal pain, diarrhea, nausea, vomiting, respiratory infection, and arthralgia.
<b>Other:</b> Avoid balsalazide if you are allergic to medicines containing salicylates, such as aspirin, or mesalamine (Rowasa, <sup>®</sup> Asacol <sup>®</sup> HD, Pentasa, <sup>®</sup> Canasa, <sup>®</sup> Lialda, <sup>™</sup> Apriso, <sup>™</sup> and Delzicol <sup>™</sup> ). Kidney <b>toxicity</b> has been rarely reported. Use caution if there is active renal disease.

<b>Generic Name:</b> Mesalamine
<b>Brand Name(s):</b> Apriso, <sup>™</sup> Asacol <sup>®</sup> HD, Canasa, <sup>®</sup> Delzicol, <sup>™</sup> Lialda, <sup>™</sup> Pentasa, <sup>®</sup> Rowasa <sup>®</sup>
<b>Drug Class:</b> Aminosalicylates (5-ASA)
<b>Recommendations for Pregnancy:</b> Limited human data: Low risk
<b>How Taken:</b> Oral or rectal
<b>Used for:</b> Mild-to-moderate ulcerative colitis
<b>Medication Indication:</b> Mesalamine delayed-release tablets or capsules and extended-release capsules may be used to treat ulcerative colitis that affects any part of the colon. Mesalamine suppositories and enemas can be used to treat inflammation of the lower part of the colon. Also used as off-label treatment of Crohn's disease, although the benefits are unproven.
<b>Most Common Side Effects:</b> Headache, muscle or joint pain, aching, tightness or stiffness, back pain, nausea, vomiting, heartburn, burping, constipation, gas, dry mouth, sore throat, cough, flu-like symptoms, stuffy head, runny nose, ear pain, anxiety, sweating, acne, slight hair loss, and diarrhea.
<b>Other:</b> Caution should be used for individuals with pre-existing liver disease or renal impairment.



<b>Generic Name:</b> Olsalazine
<b>Brand Name(s):</b> Dipentum®
<b>Drug Class:</b> Aminosalicylates (5-ASA)
<b>Recommendations for Pregnancy:</b> Low risk
<b>How Taken:</b> Oral
<b>Used for:</b> Ulcerative colitis
<b>Medication Indication:</b> For the maintenance of remission of ulcerative colitis in patients who are intolerant of sulfasalazine.
<b>Most Common Side Effects:</b> Stomach upset, bloating, loss of appetite, blurred vision, headache, pain in joints, and dizziness.
<b>Other:</b> Avoid Dipentum® if you are allergic to medicines containing salicylates, such as aspirin, or mesalamine.

<b>Generic Name:</b> Sulfasalazine
<b>Brand Name(s):</b> Azulfidine®
<b>Drug Class:</b> Aminosalicylates (5-ASA)
<b>Recommendations for Pregnancy:</b> Considered low risk, give folate 2mg daily
<b>How Taken:</b> Oral
<b>Used for:</b> Ulcerative colitis
<b>Medication Indication:</b> For the treatment of mild-to-moderate ulcerative colitis, and as adjunctive therapy in severe ulcerative colitis, and for the prolongation of the remission period between acute attacks of ulcerative colitis. Also, off-label use for treatment of Crohn's disease.
<b>Most Common Side Effects:</b> Diarrhea, headache, loss of appetite, upset stomach, vomiting, and stomach pain.
<b>Other:</b> Low sperm count and infertility have been observed in men treated with sulfasalazine; however, withdrawal of the drug appears to reverse these effects.

## Antibiotics

<b>Generic Name:</b> Ciprofloxacin
<b>Brand Name(s):</b> Cipro, <sup>®</sup> Proquin <sup>®</sup>
<b>Drug Class:</b> Antibiotics
<b>Recommendations for Pregnancy:</b> Avoid; potential toxicity to cartilage
<b>How Taken:</b> Oral and intravenous (IV)
<b>Used for:</b> Active Crohn's disease and pouchitis
<b>Medication Indication:</b> May help control symptoms of IBD by reducing intestinal bacteria. Effective as a long-term therapy for some patients with Crohn's disease who have fistulas or recurrent abscesses near their anus. Also effective for people who develop pouchitis.
<b>Most Common Side Effects:</b> Nausea, vomiting, stomach pain, indigestion, diarrhea, headache, nervousness, agitation, anxiety, and difficulty falling asleep or staying asleep.
<b>Other:</b> Contains fluoroquinolone, an ingredient associated with an increased risk of tendonitis and tendon rupture. It may also cause worsening of myasthenia gravis (a disease that causes muscle weakness).

<b>Generic Name:</b> Metronidazole
<b>Brand Name(s):</b> Flagyl <sup>®</sup>
<b>Drug Class:</b> Antibiotics
<b>Recommendations for Pregnancy:</b> Would avoid in first trimester only, given limited efficacy in IBD and risk of cleft palate
<b>How Taken:</b> Oral
<b>Used for:</b> Active Crohn's disease and pouchitis
<b>Medication Indication:</b> Off-label use of metronidazole may help control symptoms of IBD by reducing intestinal bacteria. Effective as a long-term therapy for some patients with Crohn's disease who have fistulas or recurrent abscesses near their anus. Also effective for people who develop pouchitis.
<b>Most Common Side Effects:</b> Nausea, vomiting, loss of appetite, a metallic taste, diarrhea, dizziness, headaches, <b>peripheral neuropathy</b> , and discolored urine (dark or reddish brown).

## Biologics

<b>Generic Name:</b> Adalimumab
<b>Brand Name(s):</b> Humira®
<b>Drug Class:</b> Biologics
<b>Recommendations for Pregnancy:</b> Low risk
<b>How Taken:</b> Injection under the skin (subcutaneous)
<b>Used for:</b> Moderate-to-severe Crohn's disease and ulcerative colitis in adults and pediatric patients age 6 and older.
<b>Medication Indication:</b> Reduces signs and symptoms and induces and maintains clinical response in patients with moderate-to-severely active Crohn's disease and ulcerative colitis who have had an inadequate response to conventional therapy.
<b>Most Common Side Effects:</b> Injection site reactions such as redness, rash, swelling, itching, pain, or bruising; upper respiratory infections (including sinus infections); headaches, rash, and nausea.
<b>Other:</b> There have been reports of serious infections associated with adalimumab, including tuberculosis (TB) and other infections, such as viruses, fungi, and other bacteria that have spread throughout the body. On rare occasions, certain types of cancer, including lymphoma, have been reported.

**Generic Name:** Certolizumab pegol

**Brand Name(s):** Cimzia®

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Low risk

**How Taken:** Injection under the skin (subcutaneous)

**Used for:** Moderate-to-severe Crohn's disease

**Medication Indication:** Reduces signs and symptoms, and maintains clinical response, in adult patients with moderately-to-severely active Crohn's disease who have had an inadequate response to conventional therapy.

**Most Common Side Effects:** Swelling, weight gain, rash, upper respiratory tract infection, urinary tract infection, and joint pain.

**Other:** There have been reports of serious infections associated with certolizumab pegol, including tuberculosis (TB) and other infections such as viruses, fungi, and other bacteria that have spread throughout the body. On rare occasions certain types of cancer, including lymphoma, have been reported.

**Generic Name:** Golimumab

**Brand Name(s):** Simponi®

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Low risk

**How Taken:** Injection under the skin (subcutaneous)

**Used for:** Moderate-to-severe ulcerative colitis in adults

**Medication Indication:** Induces and maintains a clinical response in patients with moderate-to-severe active ulcerative colitis when certain other medications have not worked well enough or cannot be tolerated, or if it is necessary to continue taking steroid medications.

**Most Common Side Effects:** Upper respiratory infections, such as runny nose, sore throat, hoarseness or laryngitis; injection site reactions, such as redness, swelling, itching, pain, bruising and tingling; and viral infections, such as flu and oral cold sores.

**Other:** There have been reports of serious infections while taking golimumab, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that spread throughout the body. Lymphoma and other malignancies have been reported in children and adolescent patients treated with TNF blockers, of which golimumab is a member.

**Generic Name:** Infliximab

**Brand Name(s):** Remicade®

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Low risk

**How Taken:** Intravenous (IV) infusion

**Used for:** Moderate-to-severe Crohn's disease and ulcerative colitis

**Medication Indication:** Indicated for reducing signs and symptoms, and inducing and maintaining clinical remission, in adult and pediatric patients over the age of 6 with moderately-to-severely active Crohn's disease and ulcerative colitis who have had an inadequate response to conventional therapy. Infliximab is also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulae and maintaining the fistulizing closure in patients with Crohn's disease.

**Most Common Side Effects:** Infusion reactions, such as hives, redness, chest pressure, itching and swelling of the lips and throat and shortness of breath; respiratory infections, such as sinus infections and sore throat; headache; coughing; stomach pain; nausea; and back pain.

**Other:** There have been reports of serious infections associated with infliximab, including tuberculosis (TB) and other infections such as viruses, fungi, and other bacteria that have spread throughout the body. On rare occasions certain types of cancer, including lymphoma, have been reported.

**Generic Name:** Infliximab-abda

**Brand Name(s):** Renflexis® (this drug is a biosimilar to Remicade®)

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Low risk

**How Taken:** Intravenous (IV) infusion

**Used for:** Moderate-to-severe Crohn's disease and ulcerative colitis

**Medication Indication:** Indicated for reducing signs and symptoms, and inducing and maintaining clinical remission, in adult and pediatric patients over the age of 6 with moderately-to-severely active Crohn's disease and ulcerative colitis who have had an inadequate response to conventional therapy. Infliximab-abda is also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulae and maintaining the fistulizing closure in patients with Crohn's disease.

**Most Common Side Effects:** Infusion reactions such as hives, redness, chest pressure, itching and swelling of the lips and throat and shortness of breath, respiratory infections, such as sinus infections and sore throat; headache; coughing; stomach pain; nausea; and back pain.

**Other:** There have been reports of serious infections associated with infliximab products, including tuberculosis (TB) and other infections such as viruses, fungi, and other bacteria that have spread throughout the body. On rare occasions certain types of cancer, including lymphoma, have been reported.

**Generic Name:** Infliximab-axxq

**Brand Name(s):** Avsola® (this drug is a biosimilar to Remicade®)

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Low risk

**How Taken:** Intravenous (IV) infusion

**Used for:** Moderate-to-severe Crohn's disease and ulcerative colitis

**Medication Indication:** Indicated for reducing signs and symptoms, and inducing and maintaining clinical remission, in adult and pediatric patients over the age of 6 with moderately-to-severely active Crohn's disease and ulcerative colitis who have had an inadequate response to conventional therapy. Infliximab-axxq is also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulae and maintaining the fistulizing closure in patients with Crohn's disease.

**Most Common Side Effects:** Infusion reactions such as hives, redness, chest pressure, itching and swelling of the lips and throat and shortness of breath, respiratory infections, such as sinus infections and sore throat; headache; coughing; stomach pain; nausea; and back pain.

**Other:** There have been reports of serious infections associated with infliximab products, including tuberculosis (TB) and other infections such as viruses, fungi, and other bacteria that have spread throughout the body. On rare occasions certain types of cancer, including lymphoma, have been reported.

**Generic Name:** Infliximab-dyyb

**Brand Name(s):** Inflectra™ (This drug is a biosimilar to Remicade®)

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Low risk

**How Taken:** Intravenous (IV) infusion

**Used for:** Moderate-to-severe Crohn's disease and ulcerative colitis

**Medication Indication:** Indicated for reducing signs and symptoms, and inducing and maintaining clinical remission, in adult and pediatric patients over the age of 6 with moderately-to-severely active Crohn's disease and ulcerative colitis who have had an inadequate response to conventional therapy. Infliximab-dyyb is also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulae and maintaining the fistulizing closure in patients with Crohn's disease.

**Most Common Side Effects:** Infusion reactions, such as hives, redness, chest pressure, itching and swelling of the lips and throat and shortness of breath; respiratory infections, such as sinus infections and sore throat; headache; coughing; stomach pain; nausea; and back pain.

**Other:** There have been reports of serious infections associated with infliximab products, including tuberculosis (TB) and other infections such as viruses, fungi, and other bacteria that have spread throughout the body. On rare occasions certain types of cancer, including lymphoma, have been reported.



**Generic Name:** Infliximab-qbtx

**Brand Name(s):** IXIFI™ (This drug is a biosimilar to Remicade®)

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Low risk

**How Taken:** Intravenous (IV) infusion

**Used for:** Moderate-to-severe Crohn's disease and ulcerative colitis

**Medication Indication:** Indicated for reducing signs and symptoms, and inducing and maintaining clinical remission, in adult and pediatric patients over the age of 6 with moderately-to-severely active Crohn's disease and ulcerative colitis who have had an inadequate response to conventional therapy. Infliximab-qbtx is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulae and maintaining the fistulizing closure in patients with Crohn's disease.

**Most Common Side Effects:** Infusion reactions, such as hives, redness, chest pressure, itching and swelling of the lips and throat and shortness of breath; respiratory infections, such as sinus infections and sore throat; headache; coughing; stomach pain; nausea; and back pain.

**Other:** There have been reports of serious infections associated with infliximab products, including tuberculosis (TB) and other infections such as viruses, fungi, and other bacteria that have spread throughout the body. On rare occasions certain types of cancer, including lymphoma, have been reported.

**Generic Name:** Unbranded Infliximab

**Brand Name(s):** No brand name associated—known as unbranded Infliximab

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Low risk

**How Taken:** Intravenous (IV) infusion

**Used for:** Moderate-to-severe Crohn's disease and ulcerative colitis

**Medication Indication:** Indicated for reducing signs and symptoms, and inducing and maintaining clinical remission, in adult and pediatric patients over the age of 6 with moderately-to-severely active Crohn's disease and ulcerative colitis who have had an inadequate response to conventional therapy. Unbranded Infliximab is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulae and maintaining the fistulizing closure in patients with Crohn's disease.

**Most Common Side Effects:** Infusion reactions, such as hives, redness, chest pressure, itching and swelling of the lips and throat and shortness of breath; respiratory infections, such as sinus infections and sore throat; headache; coughing; stomach pain; nausea; and back pain.

**Other:** There have been reports of serious infections associated with infliximab products, including tuberculosis (TB) and other infections such as viruses, fungi, and other bacteria that have spread throughout the body. On rare occasions certain types of cancer, including lymphoma, have been reported.

**Generic Name:** Natalizumab

**Brand Name(s):** Tysabri®

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Based on animal data, may cause fetal harm

**How Taken:** Intravenous (IV) infusion

**Used for:** Moderate-to-severe Crohn's disease

**Medication Indication:** Reduces signs and symptoms, and induces and maintains clinical remission in adult patients with moderately-to-severely active Crohn's disease who have had an inadequate response to conventional therapy, including inhibitors of TNF-alpha.

**Most Common Side Effects:** Infections such as in the urinary tract or upper respiratory tract, headache, tiredness, depression, joint pain, diarrhea, and stomach area pain.

**Other:** Natalizumab increases the risk of progressive multifocal leukoencephalopathy (PML), a rare brain infection that usually causes death or severe disability. Your chance of getting PML increases if you have been exposed to John Cunningham Virus (JCV). Your doctor may do a blood test to check if you have been exposed to JCV before you start receiving natalizumab or during your treatment. The risk of PML is higher in patients who are virus carriers (anti-JCV positive), have received other immunosuppressives, or have been on natalizumab for a long time, especially longer than two years. Natalizumab may also cause liver damage and allergic reactions.

**Generic Name:** Risankizumab-rzaa

**Brand Name(s):** Skyrizi®

**Drug Class:** Biologics

**Recommendations for Pregnancy:** Insufficient trial data. Monoclonal antibodies may be transported across the placenta.

**How Taken:** Intravenous (IV) infusion for first three doses; subcutaneous (under skin) injection after

**Used for:** Moderate-to-severe Crohn's disease

**Medication Indication:** This medication is an interleukin-23 antagonist prescribed for the treatment of moderate-to-severe Crohn's disease in adults.

**Most Common Side Effects:** This medication may increase risk of infections including upper respiratory or urinary tract infections. Other side effects may include injection site reactions, abdominal pain, headache, and joint pains. Liver injury has been reported (liver enzymes and bilirubin levels should be monitored).

**Other:** Patients should be evaluated for tuberculosis (TB) prior to starting this medication and should not be given Risankizumab-rzaa if there is active TB. If there is a hypersensitivity reaction or anaphylaxis (life threatening allergic reaction) occurs, discontinue medication and start appropriate therapy immediately. Avoid use of live vaccines.

<b>Generic Name:</b> Ustekinumab
<b>Brand Name(s):</b> Stelara®
<b>Drug Class:</b> Biologics
<b>Recommendations for Pregnancy:</b> Limited human data; No adverse effects or risks in animal studies
<b>How Taken:</b> Intravenous (IV) for initial dosages, injection for maintenance therapy
<b>Used for:</b> Moderate-to-severe Crohn's disease
<b>Medication Indication:</b> For the treatment of adults with moderate-to-severe active Crohn's disease who've had an inadequate response to conventional therapy
<b>Most Common Side Effects:</b> Upper respiratory infection, headache, tiredness, itching, vomiting, vaginal yeast infection, urinary tract infection, and redness at injection site
<b>Other:</b> Rare side effects include reversible posterior leukoencephalopathy syndrome (this is a reversible syndrome that can include headache, altered mental functioning, seizures, and loss of vision).

<b>Generic Name:</b> Vedolizumab
<b>Brand Name(s):</b> Entyvio®
<b>Drug Class:</b> Biologics
<b>Recommendations for Pregnancy:</b> No human data; Likely low risk
<b>How Taken:</b> Intravenous (IV) infusion
<b>Used for:</b> Moderate-to-severe Crohn's disease and ulcerative colitis
<b>Medication Indication:</b> For the treatment of adults with moderate-to-severe active Crohn's disease and ulcerative colitis who have had an inadequate response with, lost response to or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulatory or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.
<b>Most Common Side Effects:</b> Injection site reactions, nasopharyngitis, headache, pain in joints, nausea, fever, upper respiratory infection, and fatigue.

## Corticosteroids

<b>Generic Name:</b> Budesonide
<b>Brand Name(s):</b> Entocort® EC, UCERIS™
<b>Drug Class:</b> Corticosteroids
<b>Recommendations for Pregnancy:</b> Low risk: limited human data
<b>How Taken:</b> Oral
<b>Used for:</b> Mild-to-moderate active Crohn's disease and ulcerative colitis
<b>Medication Indication:</b> Entocort® EC is used for the treatment of mild-to-moderate active Crohn's disease involving the ileum and/or the ascending colon. UCERIS™ is used for induction of remission in active mild-to-moderate ulcerative colitis.
<b>Most Common Side Effects:</b> Headache, respiratory infection, nausea, and symptoms of hypercorticism (too many steroids in your body). These symptoms include an increase in the size of the face and neck, acne, bruising, and weight gain.
<b>Other:</b> Budesonide is a nonsystemic corticosteroid, which means it is released primarily in the gastrointestinal (GI) tract, therefore causing fewer side effects. Avoid eating grapefruit or drinking grapefruit juice regularly as it can increase the amount of budesonide in your body.

<b>Generic Name:</b> Methylprednisolone
<b>Brand Name(s):</b> A-Methapred®, Depo-Medrol®, Medrol Dosepak®, Solu-Medrol®
<b>Drug Class:</b> Corticosteroids
<b>Recommendations for Pregnancy:</b> Low risk: possible increased risk of cleft palate, adrenal insufficiency, premature rupture of membranes
<b>How Taken:</b> Oral or intravenous
<b>Used for:</b> Moderate-to-severe Crohn's disease and ulcerative colitis
<b>Medication Indication:</b> For the management of active Crohn's disease and ulcerative colitis to reduce signs and symptoms.
<b>Most Common Side Effects:</b> Upset stomach, stomach irritation, vomiting, headache, dizziness, insomnia, restlessness, depression, anxiety, and acne.

<b>Generic Name:</b> Prednisolone
<b>Brand Name(s):</b> Oraped, <sup>®</sup> Prelone, <sup>®</sup> and PEDIAPRED <sup>®</sup>
<b>Drug Class:</b> Corticosteroids
<b>Recommendations for Pregnancy:</b> Low risk: possible increased risk of cleft palate, adrenal insufficiency, premature rupture of membranes
<b>How Taken:</b> Oral
<b>Used for:</b> Moderate-to-severe Crohn's disease and UC
<b>Medication Indication:</b> Management of active Crohn's disease and UC to reduce signs and symptoms.
<b>Most Common Side Effects:</b> Upset stomach, stomach irritation, vomiting, headache, dizziness, insomnia, restlessness, depression, anxiety, and acne.

<b>Generic Name:</b> Prednisone
<b>Brand Name(s):</b> Deltasone <sup>®</sup>
<b>Drug Class:</b> Corticosteroids
<b>Recommendations for Pregnancy:</b> Low risk: possible increased risk of cleft palate, adrenal insufficiency, premature rupture of membranes
<b>How Taken:</b> Oral
<b>Used for:</b> Moderate-to-severe Crohn's disease and UC
<b>Medication Indication:</b> For the management of active Crohn's disease and ulcerative colitis to reduce signs and symptoms.
<b>Most Common Side Effects:</b> Headache, dizziness, difficulty falling asleep or staying asleep, inappropriate happiness, extreme changes in mood, changes in personality, bulging eyes, and acne.

## Immunomodulators

<b>Generic Name:</b> Azathioprine
<b>Brand Name(s):</b> Azasan, <sup>®</sup> Imuran <sup>®</sup>
<b>Drug Class:</b> Immunomodulators
<b>Recommendations for Pregnancy:</b> Data in IBD transplant literature suggest low risk
<b>How Taken:</b> Oral, not given by intravenous (IV) for IBD
<b>Used for:</b> Ulcerative colitis and Crohn's disease
<b>Medication Indication:</b> Off-label use for the management of moderate and active inflammatory bowel disease to reduce signs and symptoms.
<b>Most Common Side Effects:</b> Upset stomach, vomiting, diarrhea, and muscle aches.
<b>Other:</b> Periodic blood work is necessary when taking Imuran to monitor the liver and blood counts. Infections, including lymphoma and pancreatitis, have been rarely reported.

<b>Generic Name:</b> Cyclosporine
<b>Brand Name(s):</b> Gengraf, <sup>®</sup> Neoral, <sup>®</sup> Sandimmune <sup>®</sup>
<b>Drug Class:</b> Immunomodulators
<b>Recommendations for Pregnancy:</b> Low risk
<b>How Taken:</b> Oral and intravenous (IV) infusion
<b>Used for:</b> Ulcerative colitis
<b>Medication Indication:</b> Off-label use for the management of moderate-to-severe ulcerative colitis
<b>Most Common Side Effects:</b> Headache; diarrhea; heart-burn; gas; increased hair growth; acne; flushing; shaking of a part of your body that you cannot control; burning or tingling in the hands, arms, feet, or legs; muscle or joint pain; cramps.
<b>Other:</b> Avoid drinking grapefruit juice or eating grapefruit, as this can alter drug levels. Due to increased risk for hypertension and kidney dysfunction, close monitoring is needed. Small increased risk for lymphoma, skin cancer, and other cancers. Small increased risk for infections and liver dysfunction.



<b>Generic Name:</b> Mercaptopurine (6-MP)
<b>Brand Name(s):</b> Purinethol®
<b>Drug Class:</b> Immunomodulators
<b>Recommendations for Pregnancy:</b> Data in IBD transplant literature suggests low risk
<b>How Taken:</b> Oral
<b>Used for:</b> Ulcerative colitis and Crohn's disease
<b>Medication Indication:</b> Off-label use for the management of moderate and active inflammatory bowel diseases to reduce signs and symptoms.
<b>Most Common Side Effects:</b> Headache, weakness, or achiness; darkening of the skin; loss of appetite or weight.
<b>Other:</b> Periodic blood work is necessary when taking mercaptopurine to monitor the liver and blood counts. Infection, a small risk of lymphoma, and a small risk of pancreatitis have been noted.

<b>Generic Name:</b> Methotrexate
<b>Brand Name(s):</b> Rheumatrex®
<b>Drug Class:</b> Immunomodulators
<b>Recommendations for Pregnancy:</b> Contraindicated: teratogenic
<b>How Taken:</b> Oral and injection under the skin (subcutaneous); It can be administered intramuscularly in Crohn's disease
<b>Used for:</b> Active Crohn's disease
<b>Medication Indication:</b> Off-label use for the management of active Crohn's disease to reduce signs and symptoms.
<b>Most Common Side Effects:</b> Nausea, hair loss, fatigue, headache, dizziness, drowsiness, and mouth sores.
<b>Other:</b> It is not recommended for individuals with pre-existing conditions. Methotrexate is known to cause birth defects; it is recommended for patients to stop taking methotrexate at least three months prior to planned conceptions. Additionally, methotrexate reduces the absorption of folic acid so supplementation may be necessary.

## Targeted Synthetic Small Molecules

<b>Generic Name:</b> Ozanimod
<b>Brand Name(s):</b> Zeposia®
<b>Drug Class:</b> Targeted Synthetic Small Molecules
<b>Recommendations for Pregnancy:</b> Do not use if pregnant or plan to become pregnant.
<b>How Taken:</b> Oral
<b>Used for:</b> Moderate-to-severe ulcerative colitis
<b>Medication Indication:</b> To reduce signs and symptoms of moderate-to-severe ulcerative colitis in adults.
<b>Most Common Side Effects:</b> Common side effects may include respiratory infections, elevated liver test, headaches, urinary tract infections, low blood pressure, high blood pressure or back pain.
<b>Other:</b> You should avoid this medication if you have severe heart failure, recent heart attack or stroke, heart block that is not treated with a pacemaker, uncontrolled abnormal heart rhythms (arrhythmia), or untreated sleep apnea.

<b>Generic Name:</b> Tofacitinib
<b>Brand Name(s):</b> Xeljanz®, Xeljanz XR®
<b>Drug Class:</b> Targeted Synthetic Small Molecules
<b>Recommendations for Pregnancy:</b> Risks associated to mother and fetus in pregnancy. Pregnancy planning should be considered in women of reproductive age.
<b>How Taken:</b> Oral
<b>Used for:</b> Moderate-to-severe ulcerative colitis
<b>Medication Indication:</b> To reduce signs and symptoms of moderate-to-severe ulcerative colitis in adults.
<b>Most Common Side Effects:</b> Common side effects may include infections in nose or sinus, headache, nausea, diarrhea, rash, throat irritation, high cholesterol, gastroenteritis, anemia, upper respiratory infection. Risks of lymphoma and other cancers are rare.
<b>Other:</b> Patients should be tested for tuberculosis prior to starting tofacitinib. Avoid taking live vaccines while taking tofacitinib.

**Generic Name:** Upadacitinib

**Brand Name(s):** RINVOQ®

**Drug Class:** Targeted Synthetic Small Molecules

**Recommendations for Pregnancy:** Do not use if pregnant or plan to become pregnant. Based on animal studies, upadacitinib may harm your unborn baby. You should use effective birth control to avoid becoming pregnant during treatment with upadacitinib and for 4 weeks after your last dose.

**How Taken:** Oral

**Used for:** Moderate-to-severe ulcerative colitis

**Medication Indication:** To reduce signs and symptoms of moderate-to-severe ulcerative colitis in adults.

**Most Common Side Effects:** Common side effects may include headache, common cold, and sinus/throat infection.

**Other:** There have been reports of serious infections such as herpes zoster or shingles with upadacitinib. Upadacitinib may cause an increase in cardiovascular events in people greater than 50 years old with at least one heart disease risk factor, especially in current or former smokers. There may be a risk of blood clots while taking this medication.

## Glossary

**Abscess:** A collection of pus (dead white blood cells) that has accumulated in a cavity formed by the tissue because of an infectious process (usually caused by bacteria, fungi, or parasites).

**Aminosalicylates:** See page 6.

**Antibiotics:** Drugs that fight infections, such as metronidazole and ciprofloxacin.

**Anus:** Opening at the end of the rectum that allows solid waste to be eliminated.

**Biologic therapies:** See page 8.

**Chronic:** Long lasting or long term.

**Colon:** The large intestine.

**Corticosteroids:** See page 6.

**Crohn's disease:** A chronic inflammatory disease that primarily involves the small and large intestine, but that can affect other parts of the digestive system as well. It is named for Dr. Burrill Crohn, the American gastroenterologist who first described the disease in 1932.

**Diarrhea:** Passage of excessively frequent or excessively liquid stools.

**Extraintestinal complications:** Complications that occur outside of the intestine, such as arthritis or skin rashes. In some people, these may actually be the first signs of IBD, appearing even before the bowel symptoms. In others, they may occur right before a flare-up of the disease.

**FDA:** The U.S. Food and Drug Administration.

**Fistula:** A tunnel starting from the intestine to another area of the body, such as another area of the intestine, bladder, vagina, or skin.

**Flare or flare-up:** Presence of inflammation and symptoms.

**Gastrointestinal:** Adjective referring collectively to the stomach and small and large intestines.

**GI tract:** Short for gastrointestinal tract.

**Immune system:** The body's natural defense system that fights against disease.

**Immunomodulators:** See page 7.

**Inflammation:** A response to tissue injury that causes redness, swelling, and pain.

**Inflammatory bowel diseases (IBD):** A term referring to a group of disorders, including Crohn's disease (inflammation anywhere in the gastrointestinal tract) and ulcerative colitis (inflammation limited to the colon).


**Intestine:** The long, tubelike organ in the abdomen that completes the process of digestion. It consists of the small and large intestines.

**Large intestine:** Also known as the colon. Its primary function is to absorb water and get rid of solid waste.

**NSAIDs:** Nonsteroidal anti-inflammatory drugs such as aspirin, ibuprofen, ketoprofen, and naproxen.

**Off-label:** Use of an FDA-approved drug for an indication other than that for which the drug was approved originally.

**Oral:** By mouth.



**Perianal:** Located around the anus, the opening of the rectum, to the outside of the body.

**Peripheral neuropathy:** Nerve damage in the hands or feet that can result in weakness, numbness, or pain.

**Pouchitis:** Inflammation of the lining of the internal pouch (formed from the small intestine).

**Rectal:** Having to do with the rectum.

**Rectum:** Lowest portion of the colon.

**Remission:** Periods in which symptoms disappear or decrease and good health returns.

**Small intestine:** Connects to the stomach and large intestine; absorbs nutrients.

**Subcutaneous:** Injected under the skin.

**Targeted synthetic small molecules:**

See page 9.

**Teratogenic:** Capable of causing birth defects.

**Toxicity:** The degree to which a substance is harmful.

**Ulcer:** A sore on the skin or in the lining of the GI tract.

**Ulcerative colitis:** A relatively common disease that causes inflammation of the large intestine (the colon).

# About the Crohn's & Colitis Foundation

Established in 1967, the Crohn's & Colitis Foundation is a non-profit, volunteer-driven organization dedicated to finding the cures for Crohn's disease and ulcerative colitis, and improving the quality of life of children and adults affected by these diseases.

Since our founding, the Foundation has remained at the forefront of research in Crohn's disease and ulcerative colitis. Today, we fund cutting-edge studies at major medical institutions, nurture investigators at the early stages of their careers, and finance underdeveloped areas of research.

In addition, the Crohn's & Colitis Foundation provides a comprehensive series of education programs, printed and online resources, support services and advocacy programs to members of the IBD community, including patients and caregivers.

## **We can help! Contact us at:**

888-MY-GUT-PAIN

(888-694-8872)

[info@crohnscolitisfoundation.org](mailto:info@crohnscolitisfoundation.org)

[www.crohnscolitisfoundation.org](http://www.crohnscolitisfoundation.org)

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The Crohn's & Colitis Foundation is a nonprofit organization that relies on the generosity of private contributions to advance its mission to cure Crohn's disease and ulcerative colitis, and to improve the quality of life of children and adults affected by these diseases.

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