

Understanding IBD Medications

and Side Effects



CROHN'S & COLITIS
FOUNDATION OF AMERICA

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Medication information is up to date as of the time of printing. Due to rapid advances and new findings, there may be changes to this information over time. You should always check with your doctor to get the most current information. This information should not replace the recommendations and advice of your doctor.

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, 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, the diseases cause inflammation of the intestine. When a part of the body is inflamed, it becomes red and 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, 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, kidney, and liver. These are referred to as *extraintestinal manifestations* 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 line of inflammation. In contrast, Crohn's disease may appear in "patches," affecting some areas of the GI tract while leaving other sections in between com-

pletely 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.

Although you may have never heard of these diseases, approximately 1.4 million American adults and children suffer from Crohn’s disease or ulcerative colitis. Most people develop these diseases between the ages of 15 and 35. The number of newly diagnosed people has exploded over the last 50 years. The exact reasons for this increase are unknown. To date, there is no known cause of or cure for Crohn’s disease or ulcerative colitis, and that’s what makes the Crohn’s & Colitis Foundation of America’s (CCFA) research so critical. CCFA has pioneered the field of research into these difficult digestive diseases for nearly a half-century. Some of our major projects have included human genome (study of genes associated with IBD), microbiome (which include bacterial and fungal species), and genetic research.



Treatment

To date, there is no known cause of or cure for IBD, but fortunately there are many effective treatments to help control these diseases.

The three main goals of treatments for IBD are:

- **Achieving remission** (defined as the absence of symptoms).
- **Maintaining remission** (defined as preventing flare-ups of disease).
- **Improving quality of life** (defined personally).

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.ccf.org.*) When considering medication options, you should remember 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 causing *flares*. These episodes are usually followed by times of *remission*. Remission occurs when symptoms either disappear completely or lessen considerably and good health returns. These disease-free 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 illness may not be effective during another stage. It is important for the patient and doctor to discuss thoroughly which course of therapy is best, balancing the benefits and risks of each treatment option.
- With the right treatment, patients should expect to achieve a life without symptoms. Patients should have an open dialogue with their doctor and inform them if they are still experiencing IBD 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 treatment. 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 either hospitalization or a change in your prescription IBD medication.

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

such as aspirin, ibuprofen (Motrin®, Advil®), or naproxen (Aleve®). NSAIDs will work to alleviate joint symptoms but can irritate the gastrointestinal tract (stomach, small intestine, or colon), 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 first 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 five basic categories:

- **Aminosalicylates:** These include aspirin-like compounds that contain 5-aminosalicylic acid (5-ASA), such as sulfasalazine, balsalazide, mesalamine, and olsalazine. These drugs, which can be given either orally or rectally, do not suppress the immune system but decrease inflammation at the inner wall of the intestine itself, and help heal both in the short- and long-term. They are effective in treating mild-to-moderate episodes of IBD. They also are useful in preventing *relapses* (return of symptoms).
- **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, rectally, or intravenously. Effective for short-term control of acute episodes (*flares*), they are not recommended for long-term or maintenance use because of their side effects. If you cannot discontinue steroids without suffering a re-

lapse of symptoms, your doctor may add some other medications to help manage your disease. It is important not to suddenly stop taking this medication.

- **Immunomodulators:** These include azathioprine, 6-mercaptopurine (6-MP), methotrexate, and cyclosporine. This class of medications modifies the body's immune system so that it cannot cause ongoing inflammation. Usually given orally (methotrexate is 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.
- **Biologic therapies:** These therapies are bio-engineered drugs that target very specific molecules involved in the inflammatory process. This class of therapy includes adalimumab, certolizumab pegol, golimumab, infliximab, and natalizumab. These are not drugs but proteins (antibodies) that target the action of certain other proteins that cause inflammation.

These medications are indicated for people with moderately to severely active disease who haven't responded well to conventional therapy. 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 that are usually not connected). Biologics may be an effective strategy for reducing steroid use, as well as for maintaining remission.

- **Antibiotics:** Metronidazole, ciprofloxacin, and other antibiotics may be used when infections—such as an abscess—occur. They treat Crohn's, colitis, and perianal Crohn's disease.

They are also used to treat pouchitis, which is an inflammation of the ileal pouch, and for postoperative prevention of recurrent Crohn's disease.

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 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 healthcare 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 to get third-party insurance payment for off-label medication.

The use of substances found in nature, such as herbs, foods, and vitamins, is considered naturopathic practice. Unlike pharmaceutical products, natural remedies are not regulated by the FDA.

Pediatric IBD Patients

Customizing treatment for the individual with IBD is critical, but it is especially important 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 aspirin-like 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 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 <http://www.cdfa.org/assets/pdfs/PillSwallowing.pdf>.
- **Corticosteroids:** When a child has not responded to treatment with 5-ASA, or if their disease is more severe to begin with, oral corticosteroids may be prescribed on an outpatient basis. For very severe cases, intravenous corticosteroids may be used—necessitating a hospital stay. Once remission is achieved, corticosteroid dosage is tapered gradually. The goal is to discontinue these medications as quickly as possible and thereby minimize side effects, which may include facial swelling, excessive weight gain, hair growth, and acne. 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:** Both azathioprine and 6-mercaptopurine (6-MP) are widely prescribed for children with Crohn's disease, and for patients with ulcerative colitis who do not respond to standard medications such as 5-ASA. They may minimize symptoms and enhance growth. Treatment with azathioprine/6-MP has been shown to work well for controlling active disease in children, as well as reducing or eliminating dependency on corticosteroids. They also may be effective in maintaining remission in people who haven't responded to other medications given for this purpose. Methotrexate is another immunomodulator with similar advantages in limiting corticosteroid use, and it is increasingly being used in children and adolescents with Crohn's disease, though there is less evidence to support its use in ulcerative colitis. 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:** Infliximab is FDA approved for the treatment of children (age 6–17) with Crohn's disease and ulcerative colitis who have failed conventional treatment. Infliximab is often used to treat more advanced or aggressive disease. Other biologic therapies are being tested in children and are currently used in special situations.

Children who are going to receive infliximab or any other biologic should have all their vaccines brought up to date before starting the drug; however, they should not receive any live vaccines while on infliximab or any other biologic.

- **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, have 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.

Pregnancy and Male Fertility

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 the pregnancy seems to come from the active disease itself, rather than the medication.

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. The FDA ranking system for drug safety during pregnancy categorizes all medications from “A” to “D” (safest to least safe), in addition to an extra category, “X.”

- **Category A:** Drugs that are used in pregnancy during the first trimester.
- **Category B:** Drugs used in pregnancy that do not appear to cause birth defects or problems.
- **Category C:** Drugs that have warnings and are more likely to cause a problem for mother or fetus.

- **Category D:** Drugs that have clear health risks, but benefits may outweigh these risks.
- **Category X:** Drugs that cause birth defects and should not be used during pregnancy.

Drugs that fall into this last category have been shown to cause birth defects and should never be taken during pregnancy. Please note: Although the rating system provides valuable information, it will no longer be used in the near future for new drug therapies, as per a March 2008 policy change by the FDA. However, some healthcare professionals are continuing to use this helpful data for existing drug therapies. Information on all known pregnancy and nursing experience will soon appear in the prescribing insert of any medication. [\[See page 18 for recommendations.\]](#)

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.

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 the drug 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.

Making the Most of Your Treatment

Crohn's disease and ulcerative colitis are long-term 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.

For many individuals—particularly children and teenagers—this may seem like a major concern, especially when some of those medications produce unwanted side effects. 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, or just minimal ones, it may still seem like a nuisance to be on a steady regimen of medication. Seek support from your healthcare provider. Remember, though, that taking maintenance medication can significantly reduce the risk of flares in both Crohn's disease and ulcerative colitis. In between flares, most people feel quite well and free of symptoms.

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.
- Take medications as directed. Remember, more is not necessarily better.
- Some medications require close monitoring for side effects. Don't forget to complete blood work and follow-up visits as requested by your provider.
- Read drug labels carefully. If the print on the container is difficult to read, ask your pharmacist if it can be made larger.
- 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 you take, including OTC, vitamins, and herbs.
- Use the medication log at the end of the brochure or our interactive tracker tool, GI Buddy (www.cdfa.org/gibuddy), online or on your mobile device.
- Immunomodulators and biologics can increase the risk of upper respiratory and pulmonary 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.

Above all, do not stop taking your medications without your doctor's approval even if you feel you cannot afford them. 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, that is still not a reason to cut back or discontinue it. A number of patient assistance programs can help. Contact the Crohn's & Colitis Foundation of America (www.cdfa.org) for more information.

What to Ask Your Healthcare Provider About Your Medications

It is only natural that you will have some concerns about the treatment that you (or your child) will be receiving for IBD. What should you ask your doctor? What do you need to know about your treatment or your child's 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?

- Can I take vitamins, minerals, herbs, or other supplements while using the medication?
- Can I take over-the-counter (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?
- Which OTC products would you recommend for me to take if I have pain or other symptoms?
- 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?
- What should I do if I can't afford my 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 over-the-counter).

- Take any vitamins, minerals, herbs, or other supplements.

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 a cure.

That is good news when it comes to the development of new therapies for these conditions. 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 on from one generation to another.

With new information being amassed all the time, there is good reason to be hopeful about future treatment for IBD. While we all wish for better treatments today, we need 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), sometimes 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 drug, as well as evaluate how well the new drug works.
- **Phase III** trials test how well the new drug works and 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.

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. Your healthcare provider may recommend a trial or you can find out about them yourself from CCFA at <http://www.ccfa.org/research/participate-in-research/find-studies-and-clinical-trials/> or other sources including <http://www.clinicaltrials.gov/>. All clinical trials conducted under an investigational new drug application, no matter how big or small, have to be registered with this clinical trials website.

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 offered to participate in clinical trials.

To find out about new treatments, visit www.ccfa.org, call 888-694-8872 or email info@ccfa.org

Table I. Pregnancy Drug Safety Chart

Drug	FDA pregnancy category	Recommendations for pregnancy	Recommendations for breast-feeding
Adalimumab	B	Low risk	Limited human data: probably compatible
Alendronate	C	Limited human data	Safety unknown
Amoxicillin/clavulanic acid	B	Low risk	Probably compatible
Azathioprine/6-mercaptopurine	D	Data in IBD transplant literature suggest low risk	Limited human data: probably compatible
Balsalazide	B	Low risk	No human data: potential diarrhea
Budesonide	C	Low risk in pregnancy: limited human data	Compatible with breastfeeding
Certolizumab pegol	B	Low risk	Limited human data: probably compatible
Ciprofloxacin	C	Avoid: potential toxicity to cartilage	Limited human data: probably compatible
Corticosteroids	C	Low risk: possible increased risk of cleft palate, adrenal insufficiency, premature rupture of membranes	Compatible
Cyclosporine	C	Low risk	Limited human data: potential toxicity
Golimumab	B	Low risk	No human data: probably compatible
Infliximab	B	Low risk	Limited human data: probably compatible
Mesalamine	B	Low risk	Detected in human milk: caution should be used
Mesalamine Asacol® HD	C	Limited human data: Asacol® HD should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus	Detected in human milk: caution should be used
Methotrexate	X	Contraindicated: teratogenic	Contraindicated
Natalizumab	C	Based on animal data, may cause fetal harm	Detected in human milk: effects unknown
Metronidazole	B	Would avoid in first trimester only, given limited efficacy in IBD and risk of cleft palate	Limited human data: potential toxicity
Olsalazine	C	Low risk	Limited human data: potential diarrhea
Rifaximin	C	Animal teratogen: no human data	No human data: probably compatible
Risedronate	C	Limited human data	Safety unknown
Sulfasalazine	B	Considered low risk; give folate 2 mg daily	Limited human data: potential diarrhea
Tacrolimus	C	Use if mother's health mandates	Limited human data: potential toxicity
Thalidomide	X	Contraindicated: teratogenic	No human data: potential toxicity

Improving Quality of Life

CCFA has established a range of educational brochures, fact sheets, and programs designed to increase awareness about these digestive diseases.

We know living with Crohn's or colitis can be difficult, but the right resources and support can make day-to-day living more comfortable. That's why CCFA has developed a comprehensive, free online community (www.ccfacommunity.org) to provide the support individuals need in managing their condition. Support groups are also available in many locations. Find groups in your area at www.ccfa.org/chapters, 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.ccfa.org), master's degree level health education professionals answer questions and direct people to resources important to improve their quality of life. The IBD Help Center has truly become an important lifeline for patients, families, friends, healthcare professionals, and the media.

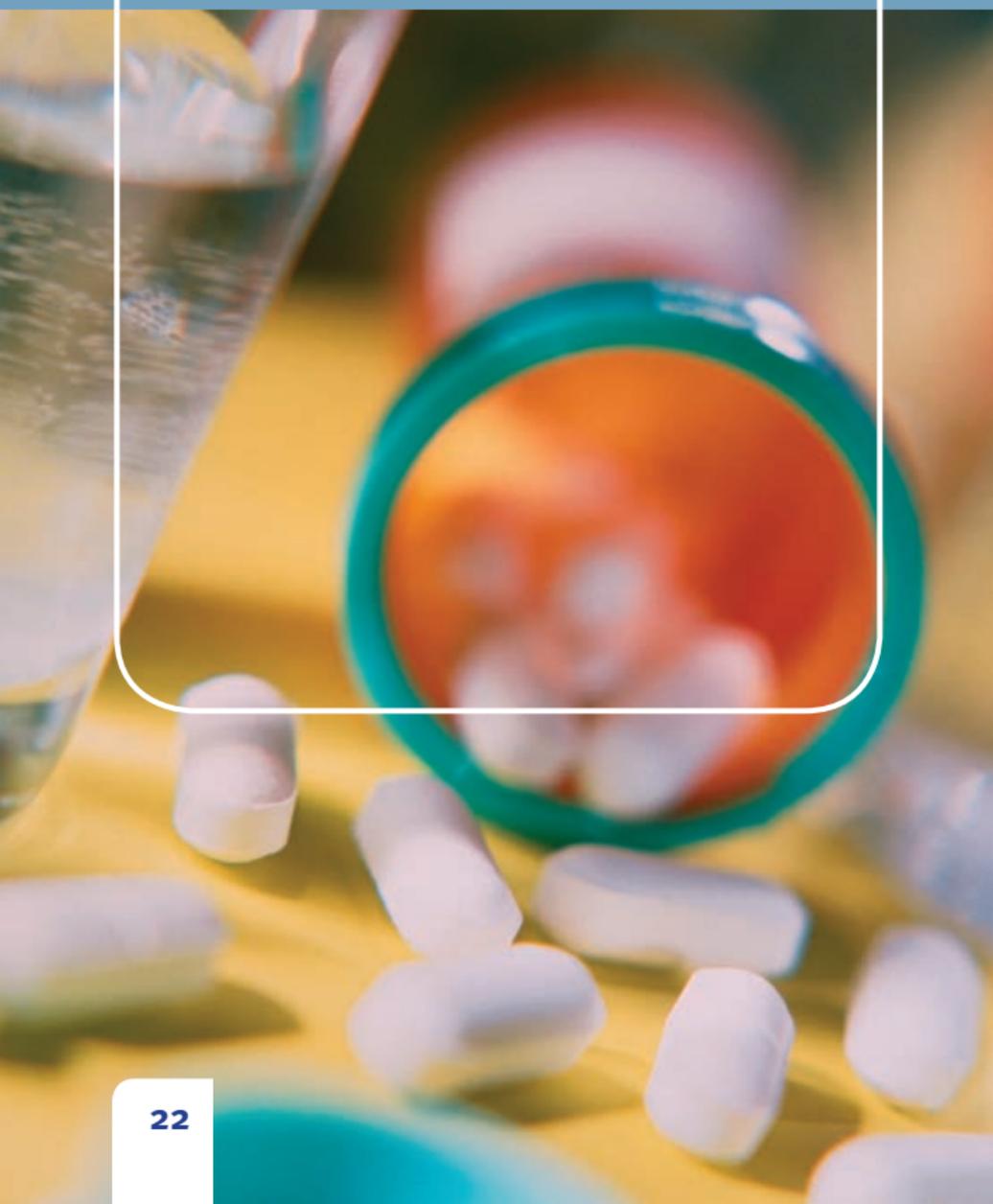
Tools and Resources

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

This is also known as achieving and maintaining remission. One of the best ways to accomplish that is by carefully following the medication regimen your doctor has prescribed for you. To help you, we have provided a medication log toward the end of this brochure to track your treatment and care over time. To use the log, fill in the medication information under each category. You may want to leave blank lines under each medication to enable you to record any changes—such as dosage, times taken, symptoms, or side effects—and additional comments or special directions. We suggest you keep it somewhere handy so you can access it easily. The log also serves as a convenient reference for when you speak with your healthcare providers. Also included on the next page are medication profiles. The profiles include information about commonly used IBD medications.

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

IBD Medication Profiles



Generic Name: Adalimumab**Brand Name(s):** Humira®**Drug class:** Biologics**FDA Pregnancy Category:** B**How taken:** Injection under the skin (subcutaneous)**Used for:** Moderate to severe Crohn's disease and ulcerative colitis**Medication indication:** Reduces signs and symptoms and induces and maintains clinical response in adult patients with moderately to severely active Crohn's disease and ulcerative colitis who have had an inadequate response to conventional therapy.**Most common side effects:** Injection site reactions such as redness, rash, swelling, itching, pain, or bruising; upper respiratory infections (including sinus infections); headaches, rash, nausea.**Other:** 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:** Azathioprine**Brand Name(s):** Azasan®, Imuran®**Drug class:** Immunomodulators**FDA Pregnancy Category:** D**How taken:** Oral, not given by intravenous (IV) for IBD**Used for:** Ulcerative colitis and Crohn's disease**Medication indication:** Off-label use for the management of moderate and active inflammatory bowel disease to reduce signs and symptoms.**Most common side effects:** Upset stomach, vomiting, diarrhea, muscle aches.**Other:** Periodic blood work is necessary when taking Imuran to monitor the liver and blood counts. Infections, including lymphoma and pancreatitis, have been rarely reported.

Generic Name: Balsalazide**Brand Name(s):** Colazal®, Giazio™**Drug class:** Aminosalicylates (5-ASA)**FDA Pregnancy Category:** B**How taken:** Oral**Used for:** Mild-to-moderate ulcerative colitis

Medication indication: Used to treat the signs and symptoms of mildly to moderately active ulcerative colitis in patients five years of age and older. Also, off-label use for treatment of Crohn's disease.

Most common side effects: Headaches, abdominal pain, diarrhea, nausea, vomiting, respiratory infection, and arthralgia.

Other: Avoid balsalazide if you are allergic to medicines containing salicylates, such as aspirin, or mesalamine (Rowasa®, Asacol® HD, Pentasa®, Canasa®, Lialda™, Apriso™, and Delzicol™). Kidney toxicity has been rarely reported. Use caution if there is active renal disease.

Generic Name: Budesonide**Brand Name(s):** Entocort® EC, UCERIS™**Drug class:** Corticosteroids**FDA Pregnancy Category:** C**How taken:** Oral**Used for:** Mild-to-moderate active Crohn's disease and ulcerative colitis

Medication indication: 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.

Most common side effects: Headache, respiratory infection, nausea, and symptoms of hypercorticism (too much steroids in your body). These symptoms include an increase in the size of the face and neck, acne, and bruising.

Other: 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.

Generic Name: Certolizumab pegol

Brand Name(s): Cimzia®

Drug class: Biologics

FDA Pregnancy Category: B

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: Ciprofloxacin

Brand Name(s): Cipro®, Proquin®

Drug class: Antibiotics

FDA Pregnancy Category: C

How taken: Oral and intravenous (IV)

Used for: Active Crohn's disease and pouchitis

Medication indication: 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.

Most common side effects: Nausea, vomiting, stomach pain, indigestion, diarrhea, headache, nervousness, agitation, anxiety, difficulty falling asleep or staying asleep.

Other: 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).

Generic Name: Cyclosporine

Brand Name(s): Gengraf®, Neoral®, Sandimmune®

Drug class: Immunomodulators

FDA Pregnancy Category: C

How taken: Oral and intravenous (IV) infusion

Used for: Ulcerative colitis

Medication indication: Off-label use for the management of moderate-to-severe ulcerative colitis

Most common side effects: 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.

Other: 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.

Generic Name: Golimumab

Brand Name(s): Simponi®

FDA Pregnancy Category: B

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 infection such as runny nose, sore throat, hoarseness or laryngitis; injection site reactions such as redness, swelling, itching, pain, bruising and tingling; 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

FDA Pregnancy Category: B

How taken: Intravenous (IV) infusion

Used for: Moderate-to-severe Crohn's disease and ulcerative colitis in adults and pediatric patients age 6 and older

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 who have had an inadequate response to conventional therapy. Infliximab is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulae and maintaining the fistulizing closure in patients with Crohn's disease.

Infliximab is indicated for reducing signs and symptoms, achieving clinical remission and mucosal healing, and eliminating corticosteroid use, in adult and pediatric patients over the age of 6 with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

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: Mercaptopurine (6-MP)**Brand Name(s):** Purinethol®**Drug class:** Immunomodulators**FDA Pregnancy Category:** D**How taken:** Oral**Used for:** Ulcerative colitis and Crohn's disease**Medication indication:** Off-label use for the management of moderate and active inflammatory bowel diseases to reduce signs and symptoms.**Most common side effects:** Headache, weakness, or achiness; darkening of the skin; loss of appetite or weight.**Other:** 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.**Generic Name:** Mesalamine**Brand Name(s):** Apriso™, Asacol® HD, Canasa®, Delzicol™, Lialda™, Pentasa®, Rowasa®**Drug class:** Aminosalicylates (5-ASA)**FDA Pregnancy Category:** B**FDA Pregnancy Category:** C (Asacol® HD)**How taken:** Oral or rectal**Used for:** Mild-to-moderate ulcerative colitis**Medication indication:** 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 should only 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.**Most common side effects:** 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 or runny nose; ear pain; anxiety; sweating; acne; slight hair loss; and diarrhea.**Other:** Caution should be used for individuals with pre-existing liver disease or renal impairment.

Generic Name: Methotrexate**Brand Name(s):** Rheumatrex®**Drug class:** Immunomodulators**FDA Pregnancy Category:** X**How taken:** Oral and injection under the skin (subcutaneous)**Used for:** Active Crohn's disease**Medication indication:** Off-label use for the management of active Crohn's disease to reduce signs and symptoms.**Most common side effects:** Nausea, hair loss, headache, dizziness, drowsiness, and mouth sores.**Other:**

- Not recommended for individuals with pre-existing liver disease.
- Known to cause birth defects.
- It is recommended for patients to stop methotrexate at least three months prior to planned conception.
- Reduces the absorption of folic acid.

Generic Name: Methylprednisolone**Brand Name(s):** A-Methapred®, Depo-Medrol®, Medrol Dosepak®, Solu-Medrol®**Drug class:** Corticosteroids**FDA Pregnancy Category:** C**How taken:** Oral or intravenous**Used for:** Moderate-to-severe Crohn's disease and ulcerative colitis**Medication indication:** For the management of active Crohn's disease and ulcerative colitis to reduce signs and symptoms.**Most common side effects:** Upset stomach, stomach irritation, vomiting, headache, dizziness, insomnia, restlessness, depression, anxiety, and acne.

Generic Name: Metronidazole

Brand Name(s): Flagyl®

Drug class: Antibiotics

FDA Pregnancy Category: B

How taken: Oral

Used for: Active Crohn's disease and pouchitis

Medication indication: 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.

Most common side effects: Nausea, vomiting, loss of appetite, a metallic taste, diarrhea, dizziness, headaches, peripheral neuropathy, and discolored urine (dark or reddish brown).

Generic Name: Natalizumab

Brand Name(s): Tysabri®

Drug class: Biologics

FDA Pregnancy Category: C

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: Olsalazine

Brand Name(s): Dipentum®

Drug class: Aminosalicylates (5-ASA)

FDA Pregnancy Category: C

How taken: Oral

Used for: Ulcerative colitis

Medication indication: For the maintenance of remission of ulcerative colitis in patients who are intolerant of sulfasalazine.

Most common side effects: Stomach upset, bloating, loss of appetite, blurred vision, headache, pain in joints, and dizziness.

Other: Avoid Dipentum® if you are allergic to medicines containing salicylates, such as aspirin, or mesalamine.

Generic Name: Prednisolone

Brand Name(s): Oraped®, Prelone®, and Pediapred®

Drug class: Corticosteroids

FDA Pregnancy Category: C

How taken: Oral

Used for: Moderate-to-severe Crohn's disease and UC

Medication indication: Management of active Crohn's disease and UC to reduce signs and symptoms.

Most common side effects: Upset stomach, stomach irritation, vomiting, headache, dizziness, insomnia, restlessness, depression, anxiety, and acne.

Generic Name: Prednisone

Brand Name(s): Deltasone®

Drug class: Corticosteroids

FDA Pregnancy Category: C

How taken: Oral

Used for: Moderate-to-severe Crohn's disease and UC

Medication indication: For the management of active Crohn's disease and ulcerative colitis to reduce signs and symptoms.

Most common side effects: Headache, dizziness, difficulty falling asleep or staying asleep, inappropriate happiness, extreme changes in mood, changes in personality, bulging eyes, and acne.

Generic Name: Sulfasalazine

Brand Name(s): Azulfidine®

Drug class: Aminosalicylates (5-ASA)

FDA Pregnancy Category: B

How taken: Oral

Used for: Ulcerative colitis

Medication indication: 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.

Most common side effects: Diarrhea, headache, loss of appetite, upset stomach, vomiting, and stomach pain.

Other: Low sperm count and infertility have been observed in men treated with sulfasalazine; however, withdrawal of the drug appears to reverse these effects.

Generic Name: Tacrolimus

Brand Name(s): Prograf®

Drug class: Immunomodulators

FDA Pregnancy Category: C

How taken: Oral and intravenous (IV)

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

Medication indication: Off-label use for the management of active Crohn's disease and ulcerative colitis to reduce signs and symptoms.

Most common side effects: Headache, hypertension, diarrhea, constipation, nausea, vomiting, heartburn, stomach pain, loss of appetite, difficulty falling asleep or staying asleep, dizziness, weakness, back or joint pain, burning, numbness, pain or tingling in the hands or feet, rash, and itching.

Other: Avoid eating grapefruit or drinking grapefruit juice while taking tacrolimus. There is a small risk of infections, skin cancer, kidney dysfunction; close monitoring is needed.

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).

Adherence: Taking medication as prescribed.

Aminosalicylates: [See page 6.](#)

Antibody: An *immunoglobulin* (a specialized protein) produced by certain cells of the immune system in response to foreign substances (*antigens*) within the body.

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 7.](#)

Bowel: Another name for the intestine. The small bowel and the large bowel are the small intestine and large intestine, respectively.

Chronic: Long lasting or long term.

Colitis: Inflammation of the large intestine (the colon).

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 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 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.](#)

Immunosuppressive: The suppression of the immune system; an agent that reduces the function of the immune system.

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

Inflammatory bowel diseases (IBD): A term used to refer to a group of disorders—including Crohn's disease (inflammation in the gastrointestinal tract) and ulcerative colitis (inflammation in 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.

Teratogen: An agent or substance that may cause defects in the developing embryo.

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.

Ulceration: The process or fact of being eroded away, as by an ulcer.

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

About CCFA

Founded in 1967, the Crohn's & Colitis Foundation of America (CCFA) is a nonprofit, volunteer-driven organization dedicated to finding a cure for Crohn's disease and ulcerative colitis. Today, the organization has grown to 40 local chapters, with more than \$200 million invested in research for a cure and improved treatments. This funding has enabled many groundbreaking treatments, improved the quality of care for individuals with these conditions, and brought hope to countless lives. But there's still plenty of work left to do.

We can help! Contact us at:

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