

## Treatment Options in IBD

### Medicines for IBD

#### Aminosalicylates (5-ASAs)

##### What are 5-ASAs?

5-ASAs are a type of medicine used to treat ulcerative colitis. 5-ASAs work on the lining of the gut to reduce inflammation. 5-ASAs work better for ulcerative colitis than for Crohn's disease because ulcerative colitis affects only the inner lining of the colon. Crohn's disease can affect the deeper layers of the colon and/or small intestine.

##### What are the benefits of taking 5-ASA?

5-ASAs are the first choice to treat mild to moderate ulcerative colitis. It is used to bring you into remission and also keep you in remission. 5-ASAs can decrease your symptoms and prevent flares. When you take a 5-ASA regularly, it may help to protect you from developing colon cancer.

People with Crohn's disease in the colon are more likely to feel relief of symptoms with 5-ASAs than those who have Crohn's disease only in the small intestine. But 5-ASAs do not prevent flares in the long run in Crohn's disease.

5-ASAs do not work as well in treating severe forms of both Crohn's disease and ulcerative colitis.

##### What are the medicine names of 5-ASAs and how do I take a 5-ASA?

- Sulfasalazine (Azulfadine, Sulfazine)
- Mesalamine (Asacol HD, Delzicol, Pentasa, Apriso, Lialda ,Rowasa, and Canasa)
- Balsalazide (Colazal, Giazol)
- Olsalazine (Dipentum)

These medicines are all pills that should be taken with plenty of water. While these medicines work similarly, they can differ in how many pills you need to take and how often you need to take them.

There are two forms of mesalamine made to be given in the rectum: Canasa (suppository) and Rowasa (enema). These medicines treat distal inflammation (when the left side of the colon and/or the rectum is the only area affected). The enema works best if it can be held in the rectum as long as possible, ideally for up to 8 hours.

##### How quickly do 5-ASAs start to work and how long should I take a 5-ASA?

If you take the medicine regularly, your symptoms should start to improve in 2 to 4 weeks. If your inflammation is more severe, you may also need to take a 5-ASA as an enema or a suppository in addition to pills. Taking these along with the 5-ASA pills will help you get better more quickly.

5-ASAs work best if they are taken all of the time, not just when you have a flare. Always talk to your doctor before taking a smaller dose of your medicine or if you plan to stop taking it.

### **Is there anything I should avoid while taking a 5-ASA?**

You should not take cardiac glycosides like digoxin when you are taking 5-ASAs. Be sure to tell all of your health care providers about all the medicines you are taking, including over-the-counter vitamins and herbal products. Talk to your doctor if you are also taking aspirin, as their side effects can increase when used at the same time.

### **What are the side effects and risks of 5-ASAs?**

5-ASAs generally cause very few side effects. The most common and less serious side effects of 5-ASAs include headache, abdominal pain, belching, nausea, diarrhea, and pharyngitis (sore throat). The enema and suppository form of mesalamine cause even fewer side effects.

Signs that your body is not able to tolerate these medicines include cramping, severe abdominal pain, and bloody diarrhea, and sometimes fever, headache, or rash. If you have any of these symptoms after starting the medicine call your provider right away. You may need to stop taking the medicine. These medicines only very rarely cause kidney problems.

5-ASAs may also make the varicella (chickenpox) vaccine more toxic. This is called Reye's syndrome and occurs in children. Children should never be given aspirin and 5-ASAs while they are ill with chickenpox or have just received the chickenpox vaccine.

Sulfasalazine (Azulfadine) contains sulfa. A common side effect of this medicine is an allergy to the sulfa. Allergic reactions include hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, and wheezing. Anaphylaxis (shutdown of blood vessels) can occur but is rare. If you have an allergic reaction, stop taking this medicine and call your doctor, call the gastroenterologist on call, go to the emergency room, or call 911. If you know you are allergic or cannot take sulfa drugs, do not take sulfasalazine

Another common side effect of sulfasalazine is headache. To help prevent this you will start with a lower dose and then slowly increase to the needed dose. Most people who cannot tolerate this medicine can still take other forms of 5-ASAs.

Sulfasalazine can cause anemia and low white blood cell counts. It can reduce sperm counts, but they return to normal after stopping the medicine.

### **Will I need to have any specific tests while I am taking a 5-ASA?**

Your kidney function and blood counts will be tested periodically while on this medicine.

### **Will I have to take medicines in addition to a 5-ASA to treat my ulcerative colitis?**

People who suffer from moderate to severe forms of IBD may need to take other medicines in addition to a 5-ASA. If you develop a flare you may need a course of a steroid medicine such as prednisone or budesonide (Entocort, Uceris). Once the flare has settled down and you taper off of the steroid you may be able to take only a 5-ASA.

Immunosuppressive drugs are frequently needed to treat more severe ulcerative colitis and Crohn's disease. The more flares you have, the more likely you will need to take an immunosuppressive medicine.

***This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist. Take all medications as prescribed by your doctor. Tell your doctor about any side effects you experience. Always check with your doctor before changing or stopping your medications.***

## **Azathioprine/Mercaptopurine**

### **What is azathioprine and how does it work?**

Azathioprine (abbreviated AZA, brand names Imuran and Azasan) is used to treat moderate to severe Crohn's disease and ulcerative colitis. AZA prevents your body from making certain kinds of white blood cells that cause inflammation in the gut. It is an immunosuppressive medicine, which means it partially blocks the action of the immune system, but does not completely turn it off.

### **What is mercaptopurine?**

6-Mercaptopurine (or mercaptopurine) is also called Purinethol (brand name) and is abbreviated 6-MP. It works the same way as AZA to help your disease. But you cannot change one pill for the other because the dose of each medicine is different.

### **What are the benefits of taking AZA or 6-MP?**

If you have disease flares fairly often (uncontrolled inflammation in your gut), you may need several courses of prednisone. But prednisone does not work to keep you in remission, and it has many side effects. This is why it is only used for acute flares.

AZA or 6-MP can lessen the damage to the intestine in both ulcerative colitis and Crohn's disease, which can improve your health in the long-term. If you get better while taking AZA or 6-MP, you will avoid the side effects of prednisone, avoid the complications of untreated inflammation, and improve your quality of life.

It can be used alone or in combination with other medications to treat IBD. AZA and 6-MP may also reduce your risk of developing colon cancer.

### **How quickly does AZA or 6-MP work?**

AZA or 6-MP may take 2 to 4 months to work, so it is important to keep taking the medicine even though you may feel that it isn't helping. AZA or 6-MP can be slow to work and it can also be slow to wear off.

### **How should I take AZA or 6-MP?**

Take AZA or 6-MP with a full glass of water or with food to prevent stomach upset. If you experience fatigue while on this medicine, you can try splitting the dose (  $\frac{1}{2}$  in the morning and  $\frac{1}{2}$  at night) or you can take the medication before going to sleep.

If you improve while taking AZA, you will take it for as long as you can.

### **Is there anything I should avoid while taking AZA or 6-MP?**

Non-prescription products: Do not take any over-the-counter herbal products with Echinacea or cat's claw because these can reduce the effect of all immunosuppressive medicines, including AZA or 6-MP.

Prescription medicines: Allopurinol is a medicine used to treat gout. Some people find that AZA or 6-MP works better for treating IBD if it is taken with allopurinol. But you should not take allopurinol with AZA or 6-MP unless told to do so because this can suppress your immune system.

AZA or 6-MP used along with ACE inhibitors may cause low white blood cell counts. AZA or 6-MP is not used if you are taking an alkylating agent for cancer chemotherapy such as cyclophosphamide (Cytoxan). Do not take AZA or 6-MP with methotrexate or natalizumab. Other prescription medicines may interact with AZA or 6-MP.

### **Will I need to have any tests while I am taking AZA or 6-MP?**

Before you start taking AZA or 6-MP, you will have a blood test called TPMT. This test will measure how quickly your body breaks down AZA. The result of this test will show if AZA or 6-MP is safe for you and will help find the best starting dose of the drug.

While you are taking AZA or 6-MP, you will need to have your blood tested on a routine basis to check your blood cell counts and your liver function. For the first few months after starting the medicine, these monitoring blood tests will be done very frequently, every 1-4 weeks.

After you are stable on the medicine, these blood tests will be checked every 1-3 months for as long as you take it. Your dose of AZA or 6-MP may change based on the results of your blood tests. If your dose is changed, the time between your blood tests may also change.

Your doctor may also check metabolite tests, which are blood levels of the breakdown products of AZA or 6-MP, to see if you are on the correct dose.

### **What are the possible side effects and risks of AZA or 6-MP?**

Allergic reactions are rare and usually happen right away. Allergic reactions such as hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, wheezing, and anaphylaxis (vascular shutdown) may occur but are very rare.

If you have an allergic reaction, go to the emergency room or call 911. Fever and rash are also a sign of an allergic reaction to AZA or 6-MP. Stop taking AZA or 6-MP permanently if you have an allergic reaction to it.

You may have side effects such as nausea, vomiting, diarrhea, fatigue, and/or muscle pain. Taking the medicine at night, or dividing the dose can improve some of these side effects. A change from AZA to 6-MP may be another option to help decrease side effects.

Call your doctor if you develop severe upper abdominal or back pain, nausea, and vomiting. If this happens, you will have a blood test to rule out pancreatitis (inflammation of the pancreas). If you

develop pancreatitis while you are taking AZA or 6-MP, it will be stopped for good. Because AZA or 6-MP is an immunosuppressive medicine there is a small risk for getting lymphoma, a type of cancer. It is not clear whether this risk is due to the medicine or to the IBD. There is only a very small increase in your risk and you will be monitored closely.

The benefit of getting into remission and maintaining remission often outweighs this small increased risk for lymphoma. Tell your doctor right away if you notice any increase in pain, weight loss, or ongoing fevers you cannot explain. If any of these occur, blood tests or a CT scan may be needed. Be sure to tell your doctor if you have cancer now or if you have had it in the past.

AZA or 6-MP may also increase your risk for certain types of skin cancer. To protect yourself from getting skin cancer while taking AZA or 6-MP, avoid being in the sun and make sure to use sun block when you spend time outside. Do not use tanning beds. You may need to have a yearly skin exam by a dermatologist if you take AZA or 6-MP long-term.

AZA or 6-MP can increase your risk for infections. Call your doctor if you have a fever, cough, shortness of breath, or other symptoms concerning for infection.

## **Methotrexate**

### **What is methotrexate?**

Methotrexate (abbreviated MTX) is used to treat Crohn's disease. It has been studied less as a treatment for ulcerative colitis. Low-dose methotrexate (15–25 mg weekly) used to treat Crohn's disease reduces inflammation. MTX is an immunosuppressive medicine, which means it partially blocks the action of the immune system but does not completely turn it off.

### **What are the benefits of taking MTX?**

MTX may be used if you cannot stop taking prednisone without your symptoms getting worse. You may also take MTX if you cannot take AZA or 6-MP, two other medicines often used to treat Crohn's disease and ulcerative colitis. MTX can lessen the damage to the intestine, which can improve your health in the long-term.

### **How quickly does MTX work?**

Methotrexate may take 1 to 3 months to work. It can be slow to work and it can also be slow to wear off.

### **How do I take MTX?**

MTX is a teratogenic agent (causes birth defects). Therefore, there are safety measures to follow when handling it and when getting rid of it.

You may take MTX either as a subcutaneous injection (a shot given under the skin) or as tablets that you swallow. A common starting dose is 25 mg. If you have impaired kidney or liver function, your dose will be decreased.

If you improve while taking MTX, you will take it for as long as you can.

### **May I take MTX with other medicines used to treat Crohn's disease and ulcerative colitis?**

You will need to take 1 mg of folic acid daily (a folate supplement) while taking MTX.

### **Is there anything I should avoid while taking MTX?**

Non-prescription products: Do not drink more than 2-3 alcoholic beverages per month while taking MTX because the two together can cause permanent liver damage.

Do not take more than 2 grams per day (two 500 milligram tablets twice per day) of acetaminophen (Tylenol) including other acetaminophen containing products while taking MTX.

Do not take any over-the-counter herbal products with Echinacea or cat's claw because these can reduce the effect of all immunosuppressive medicines, including MTX.

Prescription medicines: Do not take nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen. Severe (sometimes fatal) bone marrow suppression (low blood cell counts), aplastic anemia (the bone marrow does not make enough blood cells), and gastrointestinal damage, have been reported when MTX (usually in high doses) is taken along with NSAIDs.

Do not take MTX with acitretin, cyclosporine, eltrombopag, natalizumab, salicylates, sulfonamide derivatives, trimethoprim, and uricosuric agents. Some prescription medicines may interact with methotrexate.

### **Will I need any tests while I am taking MTX?**

While you are taking MTX you will need to have your blood tested on a routine basis to check your blood cell counts and your liver and kidney function.

You will have a blood test when you start the medicine and then every 2 weeks for the first few months. If the results of these blood tests are normal, your blood will be drawn every 1-3 months from then on.

Your dose of MTX may change based on the results of your blood tests. If your dose is changed, the time between your blood tests may also change. Ask your doctor about the results of your blood tests and what they mean. Be sure to tell your doctor if you are taking any other medicines because they may affect the level of MTX in your body.

### **What are the side effects of methotrexate?**

Allergic reactions are rare and usually happen right away. Allergic reactions such as hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, wheezing, and anaphylaxis (shutdown of blood vessels) may occur but are very rare. If you have an allergic reaction, go to the emergency room or call 911. Stop MTX permanently if you have an allergic reaction.

You may have side effects such as nausea, vomiting, fatigue diarrhea, or loss of appetite, especially on the day of the injection. Lowering the dose, taking the medicine in the evening, or dividing the dose into three smaller doses (one on Monday, one on Wednesday, and one on Friday) may help to reduce the side effects. Higher doses of folic acid (2 mg daily or 2 mg on the day of injection) can reduce nausea, vomiting, and stomach upset. Some people take an anti-nausea medicine just before the injection.

### **What are the risks of taking MTX?**

If you get sores inside your mouth or on your lips, call your doctor right away. This may mean that the dose is too high.

Liver enzymes spill into the blood if liver cells are damaged. These levels increase in a small number of people who take MTX. You should not take this medicine if you have chronic liver disease. Alcoholism, obesity, advanced age, and diabetes may increase your risk for liver problems.

Kidney damage usually only occurs when high doses of MTX are taken. Your kidney function will be checked by routine blood tests

Bone marrow suppression occurs in a small number of people taking methotrexate. The result is a low blood cell count. This increases your risk for infections and bleeding.

There is a rare risk of developing potentially fatal skin conditions, including Steven's-Johnson syndrome and toxic epidermal necrolysis. Tell your doctor right away if you notice any new rash. Your skin may become more sensitive to light when you take MTX so remember to use sunblock outside. Do not use tanning beds.

If you have chest pain, cough, difficulty breathing, or fever, call your doctor right away. A chest X-ray and CT scan may be needed to check your lungs.

MTX can increase your risk for infections. The risk is higher if you also take another immunosuppressive medicine. Use a thermometer to check for a fever whenever you are sick. If your fever is higher than 100.4 degrees call your doctor's office **right away**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue, you need to be seen by your doctor right away.

### **Can I get pregnant while on MTX?**

**No, you must not get pregnant while on MTX.** It is a Category X medicine, which means it should **never** be used by women during pregnancy or by women or men the 6 months before trying to become pregnant. There is a very high risk of birth defects for women if you use MTX while you are pregnant.

If you think you are pregnant, stop taking the medicine right away. Call your doctor so that you can have a high-risk pregnancy visit.

Special safety measures are always needed when using methotrexate during childbearing years. Double contraception is required while taking this medicine and for 6 months after stopping. This means that both the man and the woman need to use birth control. For example, condoms are used by the man and birth control pills or an IUD are used by the woman.

Breast-feeding is also not safe while taking MTX.

## **Corticosteroids**

### **Prednisone**

#### **What is prednisone?**

Prednisone is a steroid that reduces inflammation. It is an immunosuppressive medicine, which means it partially blocks the action of the immune system, but does not completely turn it off.

Prednisone is used to treat many different disorders, such as allergies, asthma, rashes, arthritis, lupus, psoriasis, as well as Crohn's disease and ulcerative colitis.

#### **What are the benefits of taking prednisone?**

Every time you have a severe flare your risk for complications increases. In the short term, prednisone will quickly prevent your flare from getting so out of control that you will need to be in the hospital or have surgery. Prednisone reduces symptoms and brings on remission for most people. But prednisone will not keep you in remission.

Taking prednisone for a long time or taking many short courses for a long time increases your risk for serious side effects. Prednisone is only used as a quick treatment for disease flares while you start a maintenance medicine, with the goal of tapering off as soon as possible.

#### **How quickly does prednisone work?**

Prednisone works quickly. Many people notice improvement in their symptoms by the second day. It generally takes about 5 to 7 days to reach full effect. Higher doses may work more quickly. If you are not getting better, your doctor may need to consider further testing for other causes of your symptoms, or hospitalization for IV steroids and other treatments.

#### **How should I take prednisone?**

Take prednisone after meals or with food or milk. Most people take it in the morning because it tends to keep them awake at night if taken later in the day.

Prednisone is generally taken at the highest dose (40mg for adults) for 1 to 2 weeks. Then you will decrease the dose by 5-10 mg every 1 to 2 weeks for about 4 to 12 weeks. Do not change your dose without talking to your doctor first because it is hard to know how well the medicine is working if the dose changes.

#### **Is there anything I should avoid while taking prednisone?**

Non-prescription products: Limit alcohol and caffeine to less than 1 to 2 drinks of each daily. Do not take any over-the-counter herbal products with Echinacea, cat's claw, or alfalfa because these can reduce the effect of the medicine. You also need to avoid St. John's wort.

Prescription medicine: Many medicines interact with prednisone. Talk with your doctor about your current medicines and whether they are safe to take with prednisone.

### **Will I need to have any tests while I am taking prednisone?**

Prednisone may cause a decrease in bone density, which may lead to osteoporosis. This can occur even in very young people who take prednisone. If you have taken prednisone before, you should have a bone density scan to be sure your bones are healthy.

It is a good idea to take 1500 mg of calcium plus 1000 IU (25 mcg) of vitamin D while you are taking prednisone. If you get osteoporosis you may need to take medicines called bisphosphonates. Regular exercise such as jogging or lifting weights can also help protect against bone loss. Talk to your doctor about which type of exercise is right for you.

### **What are the possible side effects and risks of prednisone?**

It is unlikely you will have an allergic reaction to prednisone because steroids are the medicines that work best to treat allergies. If you do have allergy-like symptoms while taking prednisone you may be allergic to one of the other things in the medicine. Allergic reactions such as hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, wheezing, and anaphylaxis (shutdown of blood vessels) are rare. If you have an allergic reaction, go to the emergency room or call 911.

Common side effects include feeling hungry a lot of the time, weight gain, trouble falling or staying asleep (insomnia), mood changes (anxiety, bad temper, anger), blurry vision, increased body fat (especially in the abdomen and the face), swelling of legs and face, slow wound healing, acne (can be severe), dry or thinning skin, easy bruising, increased sweating, increased blood sugar (especially in people with diabetes), increased facial hair, menstrual problems, impotence, and loss of interest in sex.

Less common but more serious side effects include dangerously high blood pressure (which may cause severe headache, blurred vision, buzzing in the ears, anxiety, confusion, chest pain, shortness of breath, uneven heartbeats), extreme mood swings, depression, headache, trouble falling or staying asleep (insomnia), personality changes, dizziness, easy bruising, stretch marks, flushing, very slow wound healing, low level of potassium (symptoms include confusion, uneven heart rate, extreme thirst, increased urination, leg cramps, muscle weakness or limp feeling), very high blood sugar, osteoporosis, cataracts, and glaucoma. Steroids also increase your risk of serious infections. When used in combination with immune suppressants or biologics, the risks of infection are higher.

### **What are the risks of taking prednisone?**

Never stop taking prednisone all of a sudden without tapering. If you stop without tapering, you will have no cortisol in your body, which is called adrenal crisis. This is a very serious condition, which can cause symptoms of abdominal pain, nausea and vomiting, diarrhea, headaches, fever, fatigue, low blood pressure, low blood sugar, confusion, psychosis, slurred speech, and seizures.

You are also at increased risk for an adrenal crisis during physical stress such as infection, injuries, or after surgery even if you are on prednisone. Your doctor may ask that you take higher doses of prednisone during these time periods.

## **Budesonide**

### **What is budesonide (Entocort, Uceris)?**

Budesonide is a medicine in the same class as prednisone. Budesonide just works in the bowel, which is very different from prednisone, which can affect the whole body. Budesonide is mostly used to treat Crohn's disease, but a new formulation is now approved for ulcerative colitis.

### **What are the benefits of taking budesonide?**

Budesonide is used to treat mild to moderate flares of Crohn's disease and ulcerative colitis. Budesonide has fewer side effects than prednisone, because it becomes inactive once it is absorbed by the body. It works for some patients to reduce symptoms and cause a remission. It has not been proven to be effective after 6 months, so your doctor will likely need to start you on a maintenance medicine.

### **How quickly does budesonide work?**

It works pretty quickly and most people notice their symptoms are better within the first week.

### **How should I take budesonide?**

When you take it, take the pills in the morning and swallow the pills whole. Do not crush or chew them. You will usually start at 9 mg per day.

### **Is there anything I should avoid while taking budesonide?**

Non-prescription products: Do not eat grapefruit or drink grapefruit juice because it makes budesonide less effective. Do not drink more than 1 to 2 drinks of alcohol daily. Do not take any over-the-counter herbal products with Echinacea or cat's claw because these reduce the effect of the medicine.

Prescription medicine: There are many prescription medicines that interact with budesonide. Ask your doctor if your current medicines are safe to take with budesonide. More common medicines to avoid include antacids.

### **What are the possible side effects and risks of budesonide?**

It is unlikely you will have an allergic reaction because steroids are the medicines that work best to treat allergies. If you do have allergy-like symptoms while taking budesonide, you may be allergic to one of the other things in the medicine. Allergic reactions such as hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, wheezing, and anaphylaxis (shutdown of blood vessels) are rare. If you have an allergic reaction, go to the emergency room or call 911.

Side effects are not common with budesonide but may include headache, nausea, diarrhea, respiratory tract infection, sinus infection, and joint pain.

Rare side effects include weight gain, fatigue, muscle weakness, facial rounding, fragile or thin skin, dizziness, throat irritation, and cataracts. Budesonide can cause any side effect that prednisone does but the side effects are less likely and less severe.

Adrenal crisis is much higher with prednisone but it is still possible with budesonide.

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## **Anti-Tumor Necrosis Factor Antibodies (Anti-TNFs)**

### **What are anti-TNFs and how do they work?**

Anti-TNF medicines are antibodies, proteins made by our bodies to help get rid of foreign things that can harm us. When antibodies are bound to TNF, the TNF cannot cause inflammation in the intestine.

### **What are the names of anti-TNF medicines and how do I take them?**

Infliximab (Remicade) is used to treat Crohn's disease and ulcerative colitis. It is given through an intravenous (IV) line in the office or hospital. You first receive three treatments at 0, 2, and 6 weeks. Then, maintenance treatment is needed every 6-8 weeks. The dose and time between doses may be changed to get the best response. Each treatment takes 2-4 hours.

Adalimumab (Humira) is used to treat Crohn's disease and ulcerative colitis. It is given as a shot just under the skin. It comes as a single dose in a pre-filled syringe or pen. The makers of Humira provide at-home injection teaching. You will give yourself the first dose of 160 mg (4 shots, 40 mg each), and the second dose of 80 mg (2 shots, 40 mg each) at 2 weeks. You will then give yourself 40 mg (one shot) every 1-2 weeks. Like Remicade, the dose and times between doses may be changed to get the best response.

Certolizumab pegol (Cimzia) is only used to treat Crohn's disease. The first dose is given as a shot just under the skin of 400 mg (2 shots, 200 mg each) and repeated at weeks 2 and 4. Then the dose is 400 mg (2 shots, 200 mg each) every 4 weeks. Cimzia comes in two forms: 1. powder that needs to be mixed with saline (sterile salt water) and given by a health professional; 2. liquid in pre-filled syringes that you can give to yourself. If necessary, we will teach you how to give yourself the injections.

Golimumab (Simponi) is only used to treat ulcerative colitis. The first dose is given as a shot just under the skin of 200 mg, and 100 mg at week 2. Then the dose is 100 mg every 4 weeks.

### **What are the benefits of taking an anti-TNF?**

If you have moderate to severe disease, your doctor may start this medication, perhaps with azathioprine/6-MP or methotrexate. If you respond to anti-TNFs, you will have the benefit of not needing to take prednisone for a long period of time.

You will also avoid the complications of inflammation that can lead to surgery. Anti-TNFs can improve your quality of life by controlling your symptoms. Over half of patients who take these medicines notice that their symptoms decrease and their test results improve. Almost half of patients will be in remission (back to normal) by 6 months. If you do get better or reach remission there is a good chance that you will remain free of symptoms for 1 year or longer.

### **How quickly do anti-TNFs start to work?**

You may feel the benefit of anti-TNF agents within a week of starting them, but it can take weeks to months to measure the full effect. Anti-TNFs work best if taken for the long-term. If you are able to take the anti-TNF and it is helping to control your disease you will need to continue taking it.

### **May I take an anti-TNF with other medicines used to treat Crohn's disease and ulcerative colitis?**

People with early Crohn's disease may do better if they take Remicade and AZA, 6-MP, or methotrexate together. You may take these two medicines together if you have more severe disease.

Other immunosuppressive medicines such as corticosteroids can be taken along with an anti-TNF as well. But whenever you take more than one immunosuppressive medicine for a long time, your risk for infection or cancer increases. You and your doctor will consider the risks and the benefits to choose the best plan for you.

### **Is there anything I should avoid while taking an anti-TNF?**

Non-prescription products: Do not take any over-the-counter herbal supplement with Echinacea or cat's claw because these have the ability to diminish the effect of the medicine.

Prescription medicines: Do not take abatacept, anakinra, natalizumab, or riloncept with anti-TNF medicines. Other prescription medicines may interact with anti-TNFs.

### **Will I need to have any tests while I am taking an anti-TNF?**

You will be asked if you have any side effects while you are taking an anti-TNF. You will also have testing for tuberculosis and hepatitis B infection before starting an anti-TNF.

### **What are the possible side effects and of anti-TNFs?**

Most people who take anti-TNFs don't have any side effects.

An allergic reaction right away when you start taking an anti-TNF is rare. Allergic reactions such as shortness of breath, tightness of the chest or throat, wheezing, hives, and anaphylaxis (severe shock) are also rare. If you have these symptoms, go to the emergency room or call 911.

You will stop taking that medicine but you may switch to another anti-TNF. Let your doctor know if you are sensitive to latex because the needle cover of the pre-filled syringe contains latex.

You may have an intravenous (IV) infusion-related reaction, which is a side effect that occurs within 2 hours of the start of a Remicade treatment. Symptoms include headaches, shortness of breath, being lightheaded, joint and muscle aches, rash, flushing, and nausea. These reactions can often be managed with decreasing the amount of the drug and taking Benadryl®, Tylenol®, and/or prednisone.

In some patients, the reaction is too severe to continue the medication. Some people who take Humira or Cimzia have an injection site reaction. The skin can become swollen, red and painful where the shot is

given. This can be reduced by taking acetaminophen (like Tylenol) as well as cooling the area with an ice pack before the shot is given.

There is a risk that your immune system may make antibodies against the medicine. If this occurs, your doctor may need to increase the dose, change the frequency of dosing, or stop the anti-TNF.

Anti-TNFs can increase your risk for infections, and a small number of patients of patients can develop a serious infection. This risk is higher if you take another immunosuppressive medicine along with an anti-TNF.

If you have been exposed to tuberculosis or hepatitis B in the past, anti-TNF agents can cause these into very serious infections again. You will be tested for both of these infections with blood tests or a skin test. If you test positive, you may need to be on treatment for these infections before starting anti-TNF therapy.

Because anti-TNFs suppress your immune system there is a small risk for getting lymphoma, which is a type of cancer. It is not clear whether this risk is due to the medicine or to the IBD. You will be closely monitored while you are taking an anti-TNF. You should call your doctor right away if you notice any increase in pain, weight loss, or fevers that you cannot explain. If this occurs, blood testing or CT scanning may be done. Tell your doctor if you have cancer now or in the past.

If you have congestive heart failure (CHF), multiple sclerosis, or lupus you should not take anti-TNFs.

It is rare, but some people get elevated liver enzymes, low blood count, or serious skin conditions from these medicines. Drug-induced lupus-like syndrome is also rare. If you get joint and muscle pain along with fatigue and a skin rash, call your doctor right away. Reactions like rash, welts, joint pain, fever, malaise, enlarged lymph nodes should also be reported right away.

A small amount of patients can develop a rash on their scalp, hands, and feet that resembles psoriasis. If this occurs, most patients need to stop the anti-TNF.

In very rare cases, patients can have severe neurologic symptoms like blindness or weakness in your arms or legs that are similar to symptoms of multiple sclerosis. Call your doctor if you have these symptoms and you may be referred to a neurologist.

**You cannot take live vaccines while on anti-TNF medications.** These include MMR (measles, mumps, rubella), varicella (chickenpox), rotavirus, oral polio and yellow fever. If you are older than 50, you cannot get a live shingles vaccine unless you are off anti-TNF medication for at least one month before and after the vaccine. There is a new inactivated shingles vaccine (called Shingrix) that you may be able to get. Please contact us or your primary care doctor about this.



## **Vedolizumab (Entyvio)**

### **What is vedolizumab and how does it work?**

Vedolizumab is approved for treatment in ulcerative colitis and Crohn's disease. By blocking a certain protein, it prevents inflammation. It is an immunosuppressive medicine, which means it partially blocks but does not completely turn it off completely. While there are some side effects, most people do not get more infections when taking this medication.

### **What are the benefits of taking vedolizumab?**

Vedolizumab has been shown to ease symptoms, control inflammation, and cause remission of ulcerative colitis and Crohn's disease in many patients.

### **How quickly does vedolizumab work?**

Most patients see some improvement in their symptoms within 12 weeks. Vedolizumab is given as an IV (intravenously) over 1 hour during the first treatment and at weeks 2 and 6. Then it is given every 8 weeks after that. Your doctor may change the interval or give you a "booster dose" if you have had no response by 8-10 weeks on the medicine.

### **May I take other medications with vedolizumab?**

Your doctor may recommend you take other medicines while taking vedolizumab. Medicines such as azathioprine, 6-MP, or methotrexate may be recommended to help the vedolizumab work better. You may also take prednisone or entocort but your doctor will likely want you to be on these for only short periods.

### **What medicines should I avoid while taking vedolizumab?**

Non-prescription products: Do not take any over-the-counter herbal supplement with Echinacea or cat's claw because these have the ability to diminish the effect of all immunosuppressive medicines.

Prescription medications: You should avoid other biologic medicines while on vedolizumab.

Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors.

### **What are the possible side effects?**

Most patients do not experience any side effects to vedolizumab.

Allergic reactions can happen when getting vedolizumab. Allergic reactions such as shortness of breath, tightness of the chest or throat, wheezing, hives, and anaphylaxis (severe shock) are also rare. If you have these symptoms, go to the emergency room or call 911.

Vedolizumab can increase your risk of getting a serious infection, but this is very rare. Before you start vedolizumab, tell your healthcare provider if you have an infection or symptoms of an infection like fevers, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, or pain during urination.

Sore throat, cough, or infections of the nose and throat can occur after starting vedolizumab. Please let your doctor know if you experience this side effect.

Liver problems very rarely occur in patients who receive vedolizumab. Your doctor will check liver tests frequently. Patients who have this side effect sometimes need corticosteroids.

Patients with Crohn's disease have an increased risk of rectal abscess (collection of pus from infection). Tell your doctor if you experience fevers, chills, drainage around your anus, severe pain, swelling, or tenderness around your anus or on your bottom.

Tell your doctor right away if you have the following symptoms: confusion, loss of balance, change in the way you walk or talk, decreased strength or weakness on one side of your body, blurred vision or loss of vision. It could be the sign of a serious condition.

There is a risk that your immune system will make antibodies to vedolizumab, which can make it less effective. Your doctor may want to start you on another medicine such as azathioprine, 6-MP or methotrexate to try to prevent this.

**You cannot take live vaccines while on biologic medicines.** These include MMR (measles, mumps, rubella), varicella (chickenpox), rotavirus, oral polio and yellow fever. If you are older than 50, you cannot get a live shingles vaccine unless you are off this medicine for at least one month before and after the vaccine. . There is a new inactivated shingles vaccine (called Shingrix) that you may be able to get. Please contact us or your primary care doctor about this.

***This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist. Take all medications as prescribed by your doctor. Tell your doctor about any side effects you experience. Always check with your doctor before changing or stopping your medications.***

## **Ustekinumab (Stelara)**

### **What is Ustekinumab (Stelara) and how does it work?**

Ustekinumab is a biologic medicine approved for treatment of Crohn's disease. By blocking a certain protein, it prevents inflammation. It is an immunosuppressive medicine, which means it partially blocks but does not completely turn it off completely.

### **What are the benefits of taking ustekinumab?**

Ustekinumab has been shown to ease symptoms and control inflammation and cause response and remission of disease activity in many patients with Crohn's disease.

### **How quickly does Ustekinumab work?**

You may feel the benefit of ustekinumab within a few days of starting it, but it can take weeks to months to measure the full-effect. Ustekinumab works best if taken long term.

### **How do I take Ustekinumab?**

Ustekinumab is given first through an intravenous (IV) line in the office or hospital. After this, it is given as a shot just under the skin every eight (8) weeks. It comes as a single dose in a pre-filled syringe or pen. Your doctor may change the interval if you have had no response to the medicine.

### **What medicines should I avoid while taking ustekinumab?**

Non-prescription products: Do not take any over-the-counter herbal supplement with Echinacea or cat's claw because these have the ability to diminish the effect of all immunosuppressive medicines.

Prescription medications: You should avoid other biologic medicines while on ustekinumab.

Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors.

### **What are the possible side effects?**

In general, there are few side effects to ustekinumab.

Ustekinumab can increase your risk of getting a serious infection, but this is very rare. Before you start ustekinumab, tell your healthcare provider if you have an infection or symptoms of an infection like fevers, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, or pain during urination.

Because ustekinumab suppresses your immune system there is a small risk for getting certain cancers such as skin cancer.

A very rare syndrome affecting the brain called Reversible Posterior Leukoencephalopathy Syndrome (RPLS) is possible when taking ustekinumab. This condition causes symptoms such as headache, seizures, confusion, and vision problems. Tell your healthcare provider right away if you develop these symptoms.

**You cannot take live vaccines while on biologic medications.** These include MMR (measles, mumps, rubella), varicella (chickenpox), rotavirus, oral polio and yellow fever. If you are older than 50, you cannot get a shingles vaccine unless you are off this medicine for at least one month before and after the vaccine. There is a new inactivated shingles vaccine (called Shingrix) that you may be able to get. Please contact us or your primary care doctor about this.

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## **Tofacitinib (Xeljanz)**

### **What is Tofacitinib (Xeljanz) and how does it work?**

Tofacitinib is approved for treatment in ulcerative colitis. It is an oral Janus Kinase (JAK) inhibitor and blocks a process within cells that can cause inflammation. It is an immunosuppressive medication, which means it partially blocks the immune system but does not turn it off completely.

### **What are the benefits of taking tofacitinib?**

Tofacitinib has been shown to ease symptoms and control inflammation and cause response and remission of disease activity in many patients with ulcerative colitis.

### **How quickly does tofacitinib work?**

You may feel the benefit of tofacitinib within a few days of starting it, but it can take weeks to months to measure the full-effect.

### **How do I take tofacitinib?**

Tofacitinib is an oral pill that is taken twice every day.

### **What medicines should I avoid while taking tofacitinib?**

Non-prescription products: Do not take any over-the-counter herbal supplement with Echinacea or cat's claw because these have the ability to diminish the effect of all immunosuppressive medicines.

Prescription medications: You should avoid other biologic medicines while on tofacitinib.

Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors.

### **What are the possible side effects?**

Some patients will develop elevations in their cholesterol while on this medicine. You will have tests to check your cholesterol level frequently while you are on tofacitinib.

Tofacitinib can increase your risk of getting a serious infection including viral infections such as Shingles as well as tuberculosis, but this is very rare. Before you start tofacitinib, tell your healthcare provider if you have an infection or symptoms of an infection like fevers, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, or pain during urination. You will also be tested for tuberculosis before starting this medication.

Tofacitinib can lower your white blood cell count, your hemoglobin, and can cause liver test abnormalities. Your blood tests will be checked while you are on tofacitinib.

Because tofacitinib suppresses your immune system there is a small risk of lymphoma and other cancers, including skin cancers. You will be closely monitored while you are taking tofacitinib. You should call your doctor right away if you notice any increase in pain, weight loss, or fevers that you cannot explain. If this occurs, blood testing or CT scanning may be done. Tell your doctor if you have cancer now or in the past.

**You cannot take live vaccines while on biologic medications.** These include MMR (measles, mumps, rubella), varicella (chickenpox), rotavirus, oral polio and yellow fever. If you are older than 50, you cannot get a shingles vaccine unless you are off this medicine for at least one month before and after the vaccine. There is a new inactivated shingles vaccine (called Shingrix) that you may be able to get. Please contact us or your primary care doctor about this.

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