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Important Safety Information for ENTYVIO® (vedolizumab)

- Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients.
- ENTYVIO may cause serious side effects, including:
- o Infusion-related and serious allergic reactions can happen while you are receiving ENTYVIO or several hours after treatment. You may need treatment if you have an allergic reaction. Tell your healthcare provider or get immediate medical help if you get any of these symptoms during or after an infusion of ENTYVIO: rash, itching, swelling of your lips, tongue, throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing).
- ENTYVIO may increase your risk of getting a serious infection. Before receiving and during treatment with ENTYVIO, tell your healthcare provider if you think you have an infection or symptoms of an infection, such as fever, chills,

- muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, tiredness, or pain during urination.
- People with weakened immune systems can get progressive multifocal leukoencephalopathy (PML) (a rare, serious brain infection caused by a virus). Although unlikely while receiving ENTYVIO, a risk of PML cannot be ruled out. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML. Tell your healthcare provider right away if you have any of the following symptoms: confusion or problems thinking, loss of balance, change in the way you walk or talk, decreased strength or weakness on one side of the body, blurred vision, or loss of vision.
- Liver problems can happen in people who receive ENTYVIO. Tell your healthcare provider right away if you have any of the following symptoms: tiredness, loss of appetite, pain on the right side of your abdomen, dark urine, or yellowing of the skin and eyes (jaundice).

- The most common side effects of ENTYVIO include common cold, headache, joint pain, nausea, fever, infections of the nose and throat, tiredness, cough, bronchitis, flu, back pain, rash, itching, sinus infection, throat pain, and pain in extremities. These are not all the possible side effects of ENTYVIO. Call your healthcare provider for medical advice about side effects.
- Before receiving ENTYVIO, tell your healthcare provider about all of your medical conditions, including if you: have or think you may have an infection or have infections that keep coming back; have liver problems; have tuberculosis (TB) or have been in close contact with someone with TB; have recently received or are scheduled to receive a vaccine; or if you are pregnant, breastfeeding, plan to become pregnant, or plan to breastfeed.

Please see the Important Facts for ENTYVIO on the following page and talk with your healthcare provider.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Uses of ENTYVIO® (vedolizumab)

ENTYVIO is a prescription medicine used in adults for the treatment of:

- moderately to severely active ulcerative colitis
- moderately to severely active Crohn's disease



ENTYVIO is a trademark of Millennium Pharmaceuticals, Inc., registered with the U.S. Patent and Trademark Office and is used under license by Takeda Pharmaceuticals U.S.A., Inc.

IMPORTANT FACTS

ENTYVIO (en ti' vee oh) (vedolizumab) for injection, for intravenous use

What is the most important information I should know about ENTYVIO?

ENTYVIO may cause serious side effects, including:

- Infusion-related and serious allergic reactions. These reactions can happen while you are receiving ENTYVIO or several hours after treatment. You may need treatment if you have an allergic reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an infusion of ENTYVIO: rash, itching, swelling of your lips, tongue, throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing).
- Infections. ENTYVIO may increase your risk of getting a serious infection. Before receiving ENTYVIO and during treatment with ENTYVIO, tell your healthcare provider if you think you have an infection or have symptoms of an infection such as fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, tiredness, or pain during urination.
- Progressive Multifocal Leukoencephalopathy (PML). People with weakened immune systems can get progressive multifocal leukoencephalopathy (PML) (a rare, serious brain infection caused by a virus). Although unlikely while receiving ENTYVIO, a risk of PML cannot be ruled out. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML. Tell your healthcare provider right away if you have any of the following symptoms: confusion or problems thinking, loss of balance, change in the way you walk or talk, decreased strength or weakness on one side of the body, blurred vision, or loss of vision.
- Liver Problems. Liver problems can happen in people who
 receive ENTYVIO. Tell your healthcare provider right away if
 you have any of the following symptoms: tiredness, loss of
 appetite, pain on the right side of your stomach (abdomen),
 dark urine, or yellowing of the skin and eyes (jaundice).

See "What are the possible side effects of ENTYVIO?" for more information about side effects.

What is ENTYVIO?

ENTYVIO is a prescription medicine used in adults for the treatment of:

- moderately to severely active ulcerative colitis.
- moderately to severely active Crohn's disease.

It is not known if ENTYVIO is safe and effective in children under 18 years of age.

Who should not receive ENTYVIO?

Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of the ingredients in ENTYVIO. See the end of this Medication Guide for a complete list of ingredients in ENTYVIO.

Before receiving ENTYVIO, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection, think you may have an infection or have infections that keep coming back (see "What is the most important information I should know about ENTYVIO?").
- have liver problems.

- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or are scheduled to receive a vaccine.
 Talk to your healthcare provider about bringing your vaccines up-to-date before starting treatment with ENTYVIO.
- are pregnant or plan to become pregnant. It is not known if ENTYVIO will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving ENTYVIO.
 - Pregnancy Registry: There is a pregnancy registry for women who use ENTYVIO during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry or you may contact the registry at 1-877-825-3327 to enroll.
- are breastfeeding or plan to breastfeed. ENTYVIO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ENTYVIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Especially tell your healthcare provider if you take or have recently taken Tysabri (natalizumab), a Tumor Necrosis Factor (TNF) blocker medicine, a medicine that weakens your immune system (immunosuppressant), or corticosteroid medicine.

How will I receive ENTYVIO?

- ENTYVIO is given through a needle placed in a vein (intravenous infusion) in your arm.
- ENTYVIO is given to you over a period of about 30 minutes.
- Your healthcare provider will monitor you during and after the ENTYVIO infusion for side effects to see if you have a reaction to the treatment.

What are the possible side effects of ENTYVIO?

ENTYVIO may cause serious side effects, see "What is the most important information I should know about ENTYVIO?".

The most common side effects of ENTYVIO include: common cold, headache, joint pain, nausea, fever, infections of the nose and throat, tiredness, cough, bronchitis, flu, back pain, rash, itching, sinus infection, throat pain, and pain in extremities.

These are not all of the possible side effects of ENTYVIO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about ENTYVIO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about ENTYVIO that is written for health professionals.

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For more information, go to www.ENTYVIO.com or call 1-877-TAKEDA-7 (1-877-825-3327).

THE LATEST ON_

PROTECTIVE PROTEIN POTENTIAL

About half of Americans have a gene mutation that raises the risk for Crohn's, but only 500,000 get it. In some people, norovirus may be the trigger. A new study helps explain how. Researchers found that in healthy people, the gut emits a protein called API5 that prevents the Crohn's-risk gene from wreaking havoc. This protects most people from the condition. But if you get norovirus, the germ prevents cells from producing protective API5 and opens the door to Crohn's disease. In tissue from people with Crohn's, tests show that API5 levels are five times below normal. The discovery could lead to medicines that boost API5 to stop the disease.

SOURCE: Nature

>200

Number of genes known to be linked with IRD risk

SOURCE: Frontiers in Pediatrics



How much the risk for ulcerative colitis increases when you have a next-of-kin that has it.

SOURCE: National Library of Medicine

NEW SUSPECT GENES

Experts believe that certain genes in combination with triggers in the world around you likely ignite the development of IBD. Researchers recently discovered 10 more risk-related genes. They analyzed the genetic makeup of 30,000 people with Crohn's and 80,000 people without it. Six genes common in folks with Crohn's may interfere with certain cells in the gut and trigger inflammation. Drugs that block that interaction could one day be treatments for Crohn's. Other newly discovered genes, when they are less active, protect against Crohn's. Drug developers could explore whether deactivating this gene in people with Crohn's could stop the disease.

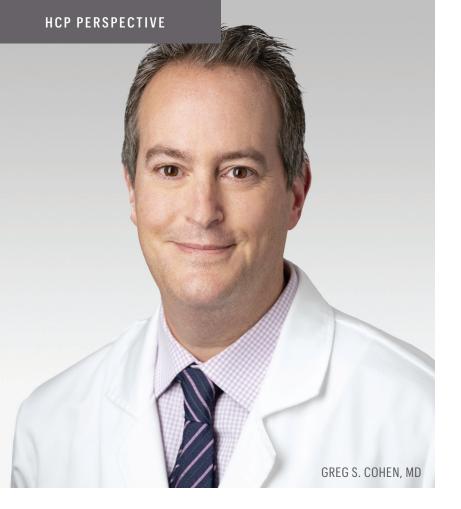
SOURCE: Nature Genetics

ANTI-INFLAMMATORY FIBER

Fiber-rich foods are good for the gut, but the specific benefit depends on the type of fiber and how it interacts with your insides. New research finds that psyllium husk—a common ingredient in fiber supplements—blocks the kind of inflammation you have in ulcerative colitis. Lab experiments showed that this form of semi-soluble fiber raises levels of an acid in the gut, which then activates an anti-inflammatory receptor cell. The findings suggest it's possible psyllium husk could help prevent flares. But before you try any new supplement, get your doctor's advice.

SOURCE: Cellular and Molecular Gastroenterology and Hepatology





ASK YOUR DOCTOR

GASTROENTEROLOGIST GREG S. COHEN ANSWERS COMMON QUESTIONS ABOUT IBD

By Rachel Reiff Ellis

Reviewed by Melinda Ratini, DO, MS, WebMD Medical Reviewer

Before your visit with your doctor, it's good to think through what you need to know to best manage your disease. These questions will help you start a dialogue.

Q. What's causing my inflammatory bowel disease (IBD) symptoms?

In IBD, the immune system mounts an inappropriately high level of inflammation in your gastrointestinal [GI] tract. This inflammation can cause diarrhea, nausea, abdominal pain, and fatigue.

"This is very similar to rashes like eczema and psoriasis," says Greg S. Cohen, MD, a gastroenterologist and clinical associate professor of medicine at Northwestern University in Chicago. "In some ways it is fair to say that having IBD is like having a rash inside your GI tract."

Q. Why is it important to get my inflammation under control?

Although doctors have made great strides in treating IBD and developing new highly targeted medications, there still is no cure. But even though it's a lifelong condition, you can effectively manage it with ongoing treatment.

Cohen says finding an IBD treatment that works is key, both for symptom control and for prevention of long-term complications.

"Controlling the inflammation will control the symptoms of IBD and allow you to return to a normal life," he says. In addition, chronic inflammation can increase your risk of GI tract cancer. When your inflammation is in check, this risk goes down.

Q. Do I need to make changes to my diet?

No specific diet has been shown to prevent or treat IBD. However, Cohen says the evidence shows that a healthy diet low in animal fats such as the Mediterranean diet is the best dietary strategy to reduce inflammation. But it's not a replacement for medication.

"[A low-inflammation diet] does not come close to the effect that medications produce on controlling the inflammation," he says. "In general, I find that when patients are on heavily restricted diets in an effort to control their symptoms, it is an indication that they are using their diet as a crutch and that there are unresolved issues with their IBD that need to be addressed more effectively with medications."

Talk to your doctor about how your diet can—and can't—support IBD management.

Q. What symptoms do you need to know about right away?

Fevers, nausea, vomiting, abdominal pain, or worsening diarrhea with blood in the stool should all be brought to your doctor's attention, Cohen says. Be sure you know the best ways to get in touch with your doctor should you experience any of these.

"The most important thing for a new IBD patient to have is a doctor they feel comfortable with," Cohen says. "The key to effectively managing this condition and learning about it is to have a doctor that is easy to communicate with and able to answer questions in a timely manner."

MY LIFE WITH CROHN'S DISFASE

HERE'S WHY I REFUSE TO SETTLE FOR TREATMENT FAILURE

By Kita Hardy

Reviewed by Melinda Ratini, DO, MS, WebMD Medical Reviewer

My journey to diagnosis and treatment with Crohn's disease has not been easy. I was an adult with four children before I ever heard the word Crohn's. These days, I try to share my story to help others.

A LONG ROAD

Growing up, I had so many digestive issues. I couldn't eat a lot of food and had a few embarrassing moments in public. Over time, I had rectal bleeding and vomiting. My mom was told, "Your daughter just has a stomach virus or she's constipated." So we treated those things, and nothing worked.

I didn't have insurance for most of my life, so I spent a lot of time in the ER. I became depressed. I avoided social things for fear of an urgent bathroom need. All of this, plus life as a single mom started to weigh heavy on me.

TWISTS AND TURNS

Finally, I got a diagnosis in 2016 after getting insurance. Those days were a blur. My first gastro doctor didn't explain what Crohn's was or how to treat it. The second one started by apologizing for how long it took me to get diagnosed. This went a long way to build trust. She started me on a biologic in 2017. I was doing well on that along with prednisone and medication for constipation. I had energy and was able to come out of my bubble. I started doing social things.

My biologic worked well for years. I thought I was at a turning point. Unfortunately, after 3 years, my insurance denied this biologic and I had to go to a drug called a biosimilar.



Right away, it was clear it wasn't working for me. With the biologic, it would take a day to recover from the injection and then I'd have lots of energy. The biosimilar takes about a week or more. I don't like to say I failed a drug. I like to say, 'The drug failed me.'

MOVING FORWARD

I'm not giving up! My doctor is now trying to help me work through insurance to get back to the original biologic. I'm on the biosimilar until we can figure out a better treatment for me. She says I'm a good candidate for some of the newer drugs also. It is tough to be on a drug that works and then have to change. I have dealt with depression and have gone to a low place as I try to navigate my health. As I continue to climb, my kids and helping others with Crohn's keep me going.



KITA'S TIPS

- + Give yourself grace and patience.
- + Ask questions if you don't understand something.
- + Find a community. For me it's Color of Crohn's & Chronic Illness.

MY JOURNEY WITH ULCERATIVE COLITIS

HOW SWITCHING TO A BIOLOGIC HELPED ME REACH REMISSION

By April Michelle Harris Reviewed by Melinda Ratini, DO, MS, WebMD Medical Reviewer



Three months from those first symptoms, I got my diagnosis. It was like a bomb dropped. One day, I didn't know anything about ulcerative colitis, and then, suddenly, I had it.

I took 16 pills a day, but I was still losing a lot of blood. I was jaundiced and so fatigued that I couldn't work. My boss asked me why I was so lazy and avoiding work by disappearing to the bathroom 15 times a day.

I wasn't getting better. I called my doctor, in my small town in southeast Finally, when some friends saw how I looked, they encouraged me to go to

At the ER in St. Louis, they admitted me right away. I was losing so much blood and my colon was so diseased that they said they had to remove it.

But there was one last thing they could try: a biologic.

They would prep me for surgery but give me the biologic first. If it was going to work, it would work right away, and then they wouldn't have to operate.

The blood loss stopped almost immediately. I wasn't going to the bathroom as much. I started eating again-first liquids, then soft solids, then regular foods. I had one more

flare that put me back in the hospital, but after that, I got better. I came off my other medications. I was in remission. I didn't even have to think about having ulcerative colitis.

After 8 years on that medication, I started reading about how some people treated their ulcerative colitis with diet alone. I was forced to make the decision to go on a biologic so fast that I wished I had had the chance to see if I could manage my disease with just diet.

My doctor was supportive. I went on what's called the specific carbohydrate diet, which was developed by a doctor for IBD. I stayed on the biologic for the first year of that diet. Then I went off the medication while my doctor continued to monitor me.





Within 4 to 5 months, I was having symptoms and flares again. It was so disappointing. So I went back on pills, but it wasn't enough to control the flares and put me in remission. I was still flaring several times a year.

I went back on a biologic. I wish I had never gone off it the first time. But now, it has helped put me back in remission.

I've written a book about my journey, selfpublished on Amazon, called I Pooped My Pants: Removing the Stigma of IBD One Pair of Trashed Underwear at a Time.

And I now run my own business: Virtually April Michelle. I'm a virtual assistant and teach others how to launch virtual assistant businesses and work from home. I work with clients of all types, but I like to work with people with health challenges who are looking for a flexible and profitable way to support themselves from home.



APRIL'S TIPS

- + It's OK to get a second opinion about your treatment options.
- + Find a health care provider who listens to you.
- + IBD is a lifelong condition, so you want the best possible team in your corner.

EXPLORING AT-HOME STRATEGIES

WHAT YOU CAN DO TO KEEP YOUR GUT AND OTHER SYMPTOMS UNDER CONTROL

By Kendall K. Morgan Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs

When you have IBD, you'll want to do all you can to feel well. The good news is you'll have plenty of choices.

"One benefit of having IBD now is that there are a lot more options than there were before," says Ayanna Lewis, MD, a gastroenterologist at Mount Sinai in New York City. "Twenty years ago, the options were steroids and a couple immunomodulators. Now we have a host of different things that can be used to treat IBD."

TREAT YOURSELF

Some IBD medicines you'll take as pills by mouth. But there are also a growing number of injectable medicines you can give yourself in the comfort of your own home. While you're not alone, if you feel unsure about giving yourself shots, it's surprisingly easy, Lewis says.

"With new ways to give these medicines, you can take them outside the infusion center," she says. "They can be safely given at home. With some training, most people are comfortable doing injections after one or two attempts."

Tiny needles in today's devices mean that you can take your medicine with little pain, she explains. With some pen-like devices, you can give yourself a shot without ever seeing a needle.

DIETARY TIPS

Your diet doesn't cause IBD. But watching what you eat can help you with symptoms.

"We're finding diet may play a role in disease progression to a certain extent and symptom control," Lewis says.

While diet isn't enough to control your moderate to severe IBD, an anti-inflammatory or Mediterranean diet high in vegetables, fruits, lean meats, and olive oil may help. Choose whole foods over those that are heavily processed, Lewis advises.

If you're curious about supplements, Lewis suggests turmeric and curcumin. Certain probiotics may help, too. Remember that supplements aren't regulated the same way medicines are. It's always a good idea to check with your doctor before trying anything new.

COPE WITH STRESS

When focusing on your gut, don't forget your mental health. "Stress plays a role in symptoms," Lewis says.

Look for online resources that can help you develop skills to cope with or lower your stress. Try activities to help you relax, including exercise, yoga, meditation, or reading a book. Many organizations also offer support groups you can attend online without leaving home.

KEEP TRACK

As you try different ways to manage your IBD, keep track of how you feel and any symptoms so you know what works and can follow up with your doctor about it later. By tracking symptoms and seeing how they relate to stress, travel, diet, or other factors, Lewis says, you'll have a better understanding of how day-to-day choices you make at home affect your IBD and its symptoms.



THE RISKS OF **NOT** TREATING YOUR IBD

WHAT HAPPENS WHEN YOUR CONDITION **GOES UNCHECKED**

By Rachel Reiff Ellis

Reviewed by Melinda Ratini, DO, MS, WebMD Medical Reviewer

The goal of treatment for inflammatory bowel disease is to reduce or even eliminate inflammation in your GI (gastrointestinal) tract, so you experience fewer symptoms and—ideally—reach remission. Fewer flare-ups mean improved quality of life and a healthier gut.

UNTREATED IBD

Without treatment, your IBD can cause severe symptoms that have a big impact on your daily life.

"If inadequately treated or not treated at all, the symptoms can be quite disabling, leading to missing work as well as social and family functions," says gastroenterologist Rajeev Jain, MD, partner at Texas Digestive Disease Consultants in Dallas.

When you don't treat ulcerative colitis (UC), you'll have diarrhea that progressively gets worse, bleeding, fatigue, and anemia (low red blood cell

"In its most severe form, the inflammation in the colon can lead to perforation, which is life-threatening," Jain says. A perforation is a hole in your GI tract that requires emergency medical care.

Crohn's disease that progresses to severe stages causes similar symptoms to untreated UC, but with some additional complications.

"More unique to Crohn's disease is the development of a collection of pus, which is called an abscess, abnormal connections between the inflamed intestine and other parts of the body, called fistulae, and narrowing of the intestines—stenoses—where inflammation occurs," Jain says.

COMPLICATIONS OVER TIME

The longer your IBD goes untreated, the higher your risk climbs for colon cancer. Long-term inflammation to the tissue in your small intestine may keep you from getting proper nutrition from your food.

"In some cases where chronic small intestinal inflammation and damage has occurred, the patients can suffer from malabsorption where they do not absorb adequate amounts of calories and essential nutrients," Jain says.

In addition to physical effects, IBD can also impact your mental state.



Jain says research shows that when IBD decreases quality of life, other pieces are affected too, such as education, employment, and social life.

"IBD can be a progressive and unpredictable chronic disease with a substantial psychosocial burden with increased rates of anxiety and depression," he says.

PERMANENT DAMAGE

Your colon and small intestine can also narrow over time, causing bowel obstruction. In some cases, this blocks you from having a bowel movement—or passing gas—completely.

"Scarring does not allow the gut to function properly," Jain says. "Narrowing or stenosis in the small intestine or colon can cause obstructive or blockage-type symptoms, which can be painful and require surgical remedy."

SYMPTOM SPREAD

develop outside the GI tract.

- + MOUTH SORES
- + KIDNEY STONES
- + SKIN RASHES
- + JOINT PAINS
- + RARE IMMUNE **DISORDER OF** THE BILE DUCTS IN THE LIVER
- + OSTEOPOROSIS

STATS & FACTS

By Sonya Collins

Reviewed by Melinda Ratini, DO, MS, WebMD Medical Reviewer

Estimated number of people in the U.S. who have Crohn's disease or ulcerative colitis.



Number of people with inflammatory bowel disease (IBD),

including Crohn's disease and ulcerative colitis, who have a family history of the condition.



the most bothersome symptoms of IBD.



How many more white adults have IBD than Black or Hispanic adults.

Rank of urgency to go to the bathroom among the most bothersome symptoms of IBD.

Estimated number of people in the U.S. who have Crohn's disease.



SOURCES: Preventive Medicine Reports, National Library of Medicine, Inflammatory Bowel Diseases, Alimentary Pharmacology & Therapeutics

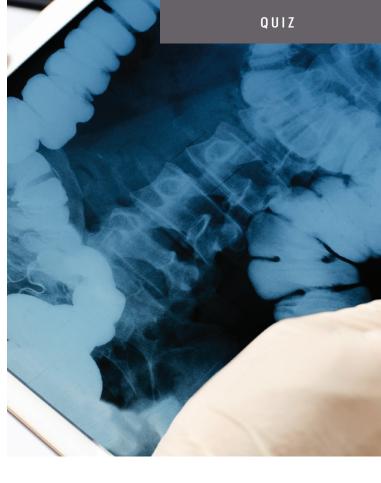
WHAT'S YOUR IBD IQ?

TAKE OUR TEST TO SEE **HOW MUCH YOU KNOW**

By Kendall K. Morgan Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs

	when you have inflammatory bowel disease (IBD), it normal to see blood in your stool.					
○ True	○ False					

- 2. Your doctor can tell if your IBD is getting worse even before you do. True False
- 3. Ulcerative colitis (UC) and Crohn's disease can give you a fever.
 - O True O False



4.	When yo	ur UC isn't well	controlled,	it can	affect you	ır
	blood cel	l counts.				

○ True	○ False
--------	---------

5. You should try biologic medicines for your IBD only if your symptoms are severe.

might help you feel better. treating your IBD with other medicines, ask if a biologic your symptoms are moderate or severe. If you've been standard treatments for both UC and Crohn's disease when 5. FALSE. Doctors now consider biologics safe and effective

Active Crohn's disease often causes anemia, too. including a drop in your red blood cell counts (anemia). 4. TRUE. Over time, active UC can lead to complications,

sign your disease is getting worse. bug. But when you have UC or Crohn's, it may be a warning 3. TRUE. A fever usually means you've got a virus or other

before you start feeling worse. inflammation. Seeing your doctor can help you treat a flare 2. TRUE. Your doctor can order tests that pick up signs of

your doctor about other medicines you might try. isn't under good control or something else may be wrong. Ask when you use the toilet. If you're seeing blood, your disease I. FALSE. Even when you have IBD, you shouldn't see blood



Over 66,000 veterans in the United States live with inflammatory bowel disease (IBD).

Are you one of them? The Crohn's & Colitis Foundation is here for you.

Whether you were diagnosed while in service or after you were discharged, you may have questions about your disease, need resources to navigate your healthcare options, or want to connect with others who understand what you are experiencing.

Visit www.crohnscolitisfoundation.org/veterans to find resources just for you or contact our IBD Help Center at info@crohnscolitisfoundation.org or 888-MY-GUT-PAIN to get answers to your questions.

