

## RELIEF. REMISSION. FOR REAL.

In clinical trials, ENTYVIO helped many people achieve long-term relief and remission.

Individual results may vary.



See the results from Crohn's disease clinical studies

RESCRIBED BIOLOGIC

and UC patients
combined. Data through

Patient portraval

**GO TO PAGE 4 FOR RESULTS** 



See the results from ulcerative colitis (UC) clinical studies

**GO TO PAGE 2 FOR RESULTS** 



ENTYVIO has two ways to administer: IV infusions and self-administered injections under the skin (subcutaneous)

GO TO PAGE 6 FOR ADMINISTRATION INFORMATION



**ENTYVIO** is gut focused

**GO TO PAGE 7 FOR HOW IT WORKS** 



How do I take ENTYVIO?

**GO TO PAGE 8 TO LEARN MORE** 



What ENTYVIO patients are saying

GO TO PAGE 9 TO HEAR FROM PATIENTS



Get support with EntyvioConnect

**GO TO PAGE 10 TO LEARN HOW** 

Ask your healthcare provider about ENTYVIO

#### What is ENTYVIO?

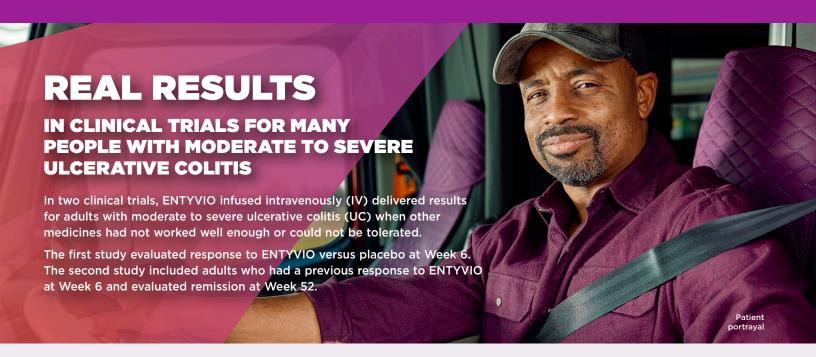
ENTYVIO is a prescription medicine used in adults for the treatment of:

- moderately to severely active ulcerative colitis (UC)
- moderately to severely active Crohn's disease (CD)

#### **Safety Considerations with ENTYVIO**

Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients. Infusion-related and serious allergic reactions can happen while you are receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of getting a serious infection.

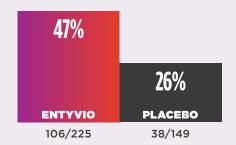




#### **Response at 6 weeks**

## ENTYVIO HELPED NEARLY TWICE

as many people achieve response at 6 weeks vs placebo

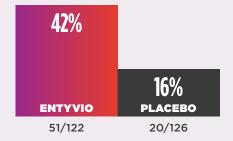


<sup>\*</sup>Response is a measure to determine improvement of the patient's UC symptoms and condition.

#### **Remission at 1 year**

## ENTYVIO HELPED MORE THAN TWICE

as many people achieve remission tat 1 year vs placebo



<sup>†</sup>Remission is a measure to determine when a patient with UC is experiencing a few to no symptoms and an improvement in their condition.

#### Ask your healthcare provider if ENTYVIO is right for you.

Individual results may vary.

In the ENTYVIO clinical studies, clinical response and remission were defined and measured by improvement in the Mayo Score, an assessment tool that measures stool frequency, rectal bleeding, appearance of the mucosal lining of the colon, and physician assessment.

#### Safety Considerations with ENTYVIO

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# EVEN MORE REAL RESULTS FROM CLINICAL TRIALS

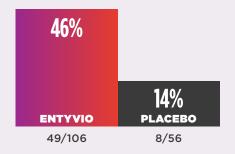


#### **Results with the ENTYVIO Pen**

## IN A SEPARATE STUDY, THE ENTYVIO PEN **HELPED MORE**

### THAN THREE TIMES

as many people achieve remission\* at 1 year vs placebo



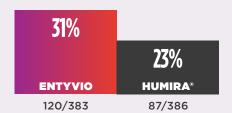
<sup>\*</sup>Remission is a measure to determine when a patient with UC is experiencing a few to no symptoms and an improvement in their condition.

### ENTYVIO vs HUMIRA®

IN A SEPARATE HEAD-TO-HEAD STUDY, ENTYVIO IV HELPED

#### SIGNIFICANTLY MORE

people than HUMIRA' achieve remission at 1 year



<sup>\*</sup>HUMIRA is a registered trademark of AbbVie Inc., North Chicago, IL. For more information related to adalimumab, please see AbbVie.com.

#### **Results your doctor can see**



For many people, ENTYVIO helped improve how their intestinal lining looked to their doctor.

As early as Week 6, 41% of patients experienced improvement compared to 25% of people on placebo.

At 1 year, 52% of patients experienced improvement compared to 20% on placebo.

Ask your healthcare provider if ENTYVIO is right for you.

#### **Safety Considerations with ENTYVIO**

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## **CROHN'S CLINICAL STUDIES**



## ENTYVIO MADE REMISSION REAL

FOR MANY PEOPLE WITH MODERATE
TO SEVERE CROHN'S DISEASE

In three clinical trials, ENTYVIO delivered results for adult patients with moderate to severe Crohn's disease when other medicines had not worked well enough or could not be tolerated.

The first and second studies evaluated the number of patients who achieved remission on ENTYVIO versus placebo at Week 6; additionally, the second study also evaluated remission at Week 10. The third study enrolled adults who had a previous response to ENTYVIO at Week 6 and evaluated remission at Week 52.



**Remission at 6 weeks** 

## ENTYVIO HELPED MORE THAN TWICE

as many people achieve remission at 6 weeks vs placebo

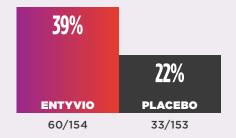


**Remission at 1 year** 

#### **ENTYVIO HELPED**

#### **ALMOST TWICE AS MANY**

people achieve remission at 1 year vs placebo



#### Ask your healthcare provider if ENTYVIO is right for you.

Individual results may vary.

\*Remission is a measure to determine when a patient with Crohn's is experiencing a few to no symptoms and an improvement in their condition.

In the ENTYVIO clinical studies, clinical remission was defined and measured by improvement in the CDAI score, a tool that assesses the number of liquid or very soft stools, abdominal pain, and other measures of disease activity.

#### Safety Considerations with ENTYVIO

Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients. Infusion-related and serious allergic reactions can happen while you are receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of getting a serious infection.



## **CROHN'S CLINICAL STUDIES**



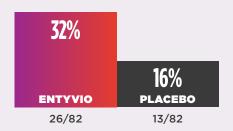
# EVEN MORE REAL RESULTS FROM CLINICAL TRIALS



#### **Remission without steroids**

## ENTYVIO HELPED TWICE AS MANY

people achieve remission without depending on steroids at 1 year vs placebo

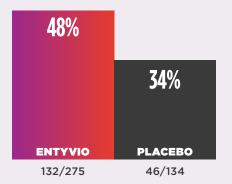


Some patients were on steroids at the beginning of the study. ENTYVIO helped some of these patients achieve remission without the use of steroids at Week 52.

#### **Results with the ENTYVIO Pen**

## IN A SEPARATE STUDY, THE ENTYVIO PEN HELPED MORE PEOPLE

achieve remission\* at 1 year vs placebo



#### Ask your healthcare provider if ENTYVIO is right for you.

Remission is a measure to determine when a patient with Crohn's is experiencing a few to no symptoms and an improvement in their condition.

#### **Safety Considerations with ENTYVIO**

Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients. Infusion-related and serious allergic reactions can happen while you are receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of getting a serious infection.



### ADMINISTRATION INFORMATION (



## ONE ENTYVIO. TWO ADMINISTRATION OPTIONS.

You and your healthcare provider can decide how ENTYVIO fits into your lifestyle, with two ways to administer therapy: intravenous (IV) infusions and self-administered injection under the skin (subcutaneous).



## ENTYVIO INTRAVENOUS (IV) TREATMENT is administered in an office, infusion center, or at home with medical support.

- A healthcare professional administers ENTYVIO by IV infusion and stays to monitor your treatments
- The ENTYVIO IV is delivered by a needle in the arm and takes about 30 minutes
- After your starting doses, the infusion is given every 8 weeks



### **THE ENTYVIO Pen** offers flexibility in your treatment schedule.

- The ENTYVIO Pen can be administered in several areas of the body
- After your starter IV doses, you or your caregiver inject ENTYVIO under the skin every 2 weeks
- Your healthcare provider will help train you on how to use this single-dose, prefilled pen. You can also receive virtual or in-home injection training before you start
- After you are prescribed the ENTYVIO Pen, a specialty pharmacy will reach out to you regarding coordination and delivery of your prescription



#### Find an infusion center

Use our infusion center finder to find a location that's convenient for you. Go to **infusionfinder.ENTYVIOhcp.com** 

#### **Safety Considerations with ENTYVIO**

Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients. Infusion-related and serious allergic reactions can happen while you are receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of getting a serious infection.





## HOW ENTYVIO TREATS ULCERATIVE COLITIS (UC) AND CROHN'S

#### What causes UC and Crohn's?

Your immune system uses white blood cells to protect you from infections and other diseases. In people who have UC or Crohn's, the immune system mistakenly identifies certain parts of your gut as invasive material and sends too many white blood cells to the area.

This causes increased inflammation, which can result in permanent damage to your gut.

#### In UC and Crohn's







Overactive immune system sends **too many** white blood cells into the gut

White blood cells can cause inflammation

#### **How Does ENTYVIO Work?**

ENTYVIO works by blocking a type of gut-directed, inflammation-causing white blood cell from entering the gut. This can help control inflammation seen in UC.



#### What are white blood cells?

White blood cells are part of your immune system. They help your body fight off infections and other diseases.

#### With ENTYVIO







Overactive immune system sends **too many** white blood cells into the gut

**ENTYVIO BLOCKS** certain white blood cells from entering the gut, helping to control inflammation

Learn more about the science of ENTYVIO at **ENTYVIO.com/how-entyvio-works**.

#### Safety Considerations with ENTYVIO

Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients. Infusion-related and serious allergic reactions can happen while you are receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of getting a serious infection.



## INTRAVENOUS INFUSION DOSING SCHEDULE

#### Starting treatment schedule

You will receive ENTYVIO by infusion at **Weeks 0, 2, and 6.** 







Week 2

Week

#### **Maintenance schedule**

After your initial doses, you will continue to receive **ENTYVIO by IV every 8 weeks.** 



#### **Every 8 Weeks**

- In the first year, you'll receive 8 doses of ENTYVIO
- After the first year, you'll receive 6 doses each year

### **SELF-INJECTION DOSING SCHEDULE**

#### Starting treatment schedule

You will receive ENTYVIO by infusion at **Weeks 0** and 2.\*





Week 0

Week 2

Go to **page 6** to learn more about infusions and where you can receive yours.

#### **Maintenance schedule**

With ENTYVIO self-administration, you will inject ENTYVIO **every 2 weeks** or up to 26 times per year.



**Every 2 Weeks** 

See the full Instructions For Use at ENTYVIO.com/IFU.

\*Your healthcare provider will determine if it's appropriate to transition to self-administration with the ENTYVIO Pen after at least 2 IV doses.

#### Safety Considerations with ENTYVIO

Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients. Infusion-related and serious allergic reactions can happen while you are receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of getting a serious infection.





### WHAT REAL PATIENTS ARE SAYING

Living with moderate to severe ulcerative colitis (UC) or Crohn's disease can bring its challenges. But for these patients, ENTYVIO has made a difference. Individual results may vary.



"Since starting treating with ENTYVIO, I've noticed a difference in my UC symptoms, and I feel that they are more manageable."

TARIKA: Living with moderate to severe UC



"After my doctor and I decided that ENTYVIO was right for me, I enrolled in *EntyvioConnect*, which offers insurance support, access to Nurse Educators, helpful resources, and useful tips that helped me manage my condition with my doctor."

JEN: Patient living with severe Crohn's

## REAL PEOPLE. REAL-LIFE EXPERIENCES.

Want to talk to someone who knows the experiences of living with UC or Crohn's firsthand? The Entyvio Connections program can connect you with our Patient Ambassadors for insight and encouragement.

Call <u>1-833-492-8847</u> or visit <u>UCCDmentorprogram.com</u> to register for Entyvio Connections.

**RON:** Living with moderate to severe UC



#### **Safety Considerations with ENTYVIO**

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## RESOURCES DESIGNED FOR YOU



## **Entyvio** CONNECT

## WHEN YOU NEED HELP, ENTYVIOCONNECT IS HERE FOR YOU

Living with moderate to severe ulcerative colitis or Crohn's disease can be difficult enough. Managing your treatment shouldn't be. Whether you and your healthcare provider have decided to treat with **IV infusions** or **self-administered injection** under the skin (subcutaneous), the caring team of experts at *EntyvioConnect* is available to guide you with resources designed to make your journey as stress-free as possible.

Once you're prescribed ENTYVIO, you're eligible for EntyvioConnect.



#### **One-on-one nurse support**

We can pair you with a Nurse Educator who can answer your questions about ENTYVIO resources and help you make the most out of every conversation with a healthcare provider. They cannot, however, provide medical advice.

If you are prescribed self-administered ENTYVIO, virtual and in-person nurse injection training is available through *EntyvioConnect*.



#### **Financial and insurance help**

A specialist can help you navigate the insurance and prior authorization process for both IV infusions and self-administered ENTYVIO. They can also help with co-pay assistance and out-of-pocket costs. With our Co-Pay Program, you may pay as little as \$5 per dose.\*

\*Must meet eligibility requirements.



#### **Ongoing support**

Get treatment reminders and useful information, including healthy recipes.



#### **Get connected**

Call 1-844-ENTYVIO (<u>1-844-368-9846</u>) or sign up at **ENTYVIO.com/Connect.** 

#### **Safety Considerations with ENTYVIO**

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## TALKING TO YOUR HEALTHCARE PROVIDER



The questions below can help get your conversation started as you and your healthcare provider explore potential treatment options for your condition. Fill out this page and bring it with you to your next appointment.

How many times have you had to refill your prescription of steroids in the last year?

Never Once Monthly More

How often do you currently take steroids to control flare-ups, as prescribed by your healthcare provider?

Daily Weekly Monthly Once every 2 months Once every 3 months

How many bowel movements do you have a day?

1 2 3 4 5 6 7 8 9 10+

Have you experienced any weight loss?

Yes No

#### How often do you experience any of the following symptoms?

#### **Abdominal pain or cramping**

Never Occasionally Sometimes
Often Always

#### **Diarrhea**

Never Occasionally Sometimes
Often Always

#### **Rectal bleeding**

Never Occasionally Sometimes Often Always

#### **Accidents**

Never Occasionally Sometimes
Often Always

#### **Constipation**

Never Occasionally Sometimes
Often Always

#### Straining during bowel movements

Never Occasionally Sometimes
Often Always

#### **Lack of energy**

Never Occasionally Sometimes
Often Always

### Please indicate how you feel using the following scale



### Are your current treatments working well enough?

Yes No



Your healthcare provider can help you find a treatment that works best for you.

This is a sample dialogue. It is not, nor is it intended to be, a medical evaluation, examination, advice, consultation, diagnosis, or treatment. Always consult your healthcare professional for all medical and health-related matters.

## QUESTIONS TO ASK YOUR DOCTOR



Here are some examples of questions you may want to ask your doctor as you work together to find the best treatment for your specific needs.

How is a biologic medication different from other medications?	
How does ENTYVIO work to help fight inflammation?	
How do you and I choose between IV infusion and self-administered injection?	
How will I know if the treatment is working for me?	
What goals should I set for my treatment?	
Could ENTYVIO be right for me?	



#### **Important Safety Information**

- 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:
  - 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).
  - Infections. 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.
  - 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 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, pain in extremities, and with injections under the skin: pain, swelling, itching, hives, bruising, rash, or redness at the injection site. 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.
- Tell your healthcare provider about all the medicines you take, especially if you take or have recently taken Tysabri (natalizumab), Tyruko (natalizumab-sztn), a Tumor Necrosis Factor (TNF) blocker medicine, a medicine that weakens your immune system (immunosuppressant), or corticosteroid medicine.

Please see accompanying <u>full Prescribing Information</u>, including the <u>Medication Guide</u>, for ENTYVIO and talk with your healthcare provider.

#### **ENTYVIO** is available for:

- intravenous (IV) infusion: 300 mg vedolizumab.
- subcutaneous (SC) injection: 108 mg vedolizumab.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call <a href="https://www.fda.gov/medwatch">1-800-FDA-1088</a>.

#### What is ENTYVIO (vedolizumab)?

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

- moderately to severely active ulcerative colitis (UC).
- moderately to severely active Crohn's disease (CD).

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

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