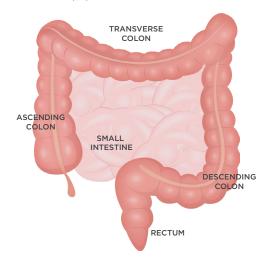
SEE HOW THE CONDITION AFFECTS YOU

Ask your doctor how Crohn's disease is different from other types of inflammatory bowel disease, and where it affects your gastrointestinal (GI) tract.



NOTES		

ENTYVIO is for adult patients with moderate to severe Crohn's disease when certain other medicines have not worked well enough or cannot be tolerated.

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).
 - 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 <u>full Prescribing Information</u>, including the <u>Medication Guide</u>, for ENTYVIO 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.





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ADVANCED THERAPY* OPTIONS FOR CROHN'S DISEASE



*Advanced therapies are used after conventional therapies, which include corticosteroids and immunomodulators.

This overview is not intended to compare the safety, efficacy, or uses of these treatments.

	CLASSES OF TREATMENTS FOR CROHN'S DISEASE						
	Anti-	integrin	Anti-interleukin	Anti-TNFa			
HOW THE DRUG WORKS	Anti-α4β7 integrins block gut-directed white blood cells involved in the inflammatory response from moving out of the blood vessels and into the gut tissue by blocking a protein on the surface of these cells	Anti-alpha 4 integrins block white blood cells involved in the inflammatory response from moving out of the blood vessels and into the tissues by blocking a protein on the surface of these cells	Blocks interleukin proteins, which are associated with the inflammation process	Blocks a protein called tumor necrosis factor α (TNF-α), which promotes inflammation in the intestine			
WHERE IT WORKS							

		APPROVED TREATMENTS FOR CROHN'S DISEASE				
	Entyvio * (vedolizumab)	Tysabri® (natalizumab)	Stelara * (ustekinumab)	Humira* (adalimumab)	Remicade® (infliximab)	Cimzia® (certolizumab pegol)
WHO IT'S FOR	For adults with moderately to severely active Crohn's disease	For adults with moderate to severe Crohn's disease who have not been helped enough by, or cannot use the usual medicines and medicines called TNF inhibitors	For adults with moderately to severely active Crohn's disease	For children 6 years and older and adults with moderate to severe Crohn's disease when other treatments have not worked well enough	For children 6 years and older and adults with moderate to severe Crohn's disease who have not responded well to other medicines	For adults with moderately to severely active Crohn's disease who have not been helped enough by usual treatments
FOR ADULTS: DOSING SCHEDULE AND ROUTE OF ADMINISTRATION	Start IV infusion dose at Weeks 0, 2, and 6	Start P IV infusion dose at Weeks 0, 4, and 8	Start P IV infusion dose at Week 0	Start SC dose ^s at Days 1 and 15	Start IV infusion dose at Weeks 0, 2, and 6	Start SC dose [§] at Weeks 0, 2, and 4
=intravenous (IV) infusion†	Continue IV infusion dose every 8 weeks	Continue IV infusion dose every 4 weeks	Continue ↓ SC dose every 8 weeks	Continue ↓ SC dose every 2 weeks	Continue IV infusion dose every 8 weeks	Continue ↓ SC dose ^s every 4 weeks
=subcutaneous (SC) injection [‡]		2.2. .		2.13, 2.113.0	Please refer to the Prescribing Information for recommendations on dosage adjustment based on certain circumstances	
DOSES FOR THE 1ST YEAR	8	13	7	26	8	15

Please refer to each product's Prescribing Information for additional information.

Safety Considerations

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 while receiving ENTYVIO or several hours after treatment. ENTYVIO may increase your risk of serious infections. Although unlikely, progressive multifocal leukoencephalopathy (PML), a rare, serious brain infection caused by a virus, cannot be ruled out. Liver problems can occur with ENTYVIO.

Please see Important Safety Information on page 1.

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.

There are additional considerations for selecting a treatment. Please talk to your doctor about treatment options and what might be right for you.

[†]A needle placed in a vein in your arm.

[§]Dose may include more than one injection.



[‡]Injection takes place under the skin.