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SCHEDULING STATUS

4

ENTYVIO 300 mg Lyophilised powder for concentrate for solution for infusion

Read all of this leaflet carefully before you start taking

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ENTYVIO has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side-effects, talk to your doctor or pharmacist. This includes any possible side-effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Entyvio is and what it is used for
2. What you need to know before you take Entyvio
3. How to take Entyvio
4. Possible side effects
5. How to store Entyvio
6. Contents of the pack and other information

1. What ENTYVIO is and what it is used for

The active substance is 300 mg of vedolizumab in each vial.

After reconstitution, each ml contains 60 mg of vedolizumab.

The other ingredients are:
L-arginine hydrochloride, L-histidine, L-histidine monohydrochloride, L-arginine hydrochloride, polysorbate 80, sucrose

Contains sugar: sucrose

ENTYVIO is a medicine used for induction and maintenance treatment in adults:
• with moderate to severe active ulcerative colitis (UC) when certain other UC medicines have not worked well enough or cannot be tolerated.
• with moderate to severe active Crohn's disease when certain other Crohn's disease medicines have not worked well enough or cannot be tolerated

2. What you need to know before you take

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You should not be given ENTYVIO if you:

- have had an allergic reaction to ENTYVIO or any of the ingredients in ENTYVIO.
- are pregnant or breast-feeding
- have tuberculosis or any active infection.

Tell your doctor or healthcare professional before being given ENTYVIO if you:

• have an infection, 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. Talk to your healthcare provider about bringing your vaccines up-to-date before starting treatment with ENTYVIO

• you think you are pregnant

Pregnancy, breast-feeding and fertility

If you are a woman of childbearing potential, you should avoid becoming pregnant while using Entyvio.

You should use effective contraception during treatment for at least 18 weeks after the last treatment.

If you are pregnant or plan to become pregnant. Tell your healthcare provider right away while receiving ENTYVIO.

Breast-feeding

Tell your doctor if you are breast-feeding or planning to breast-feed. Entyvio passes into breast milk. There is not enough information on what effect this may have on your baby and on milk production. A decision must be made whether to stop breast-feeding or to stop using Entyvio therapy taking into account the benefit of breast-feeding for your child and the benefit of therapy for you.

Important information about some of the ingredients of ENTYVIO

ENTYVIO contains a sugar called sucrose. Patients with rare hereditary problems of sucrose intolerance or malabsorption should consult their doctor before using ENTYVIO.

ENTYVIO contains L-arginine and should not be given to patients with an inherited disorder that increases the levels of a substance called phenylalanine in the blood. (phenylketonuria)

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Driving and using machines

ENTYVIO may impair your ability to drive or operate machines, as dizziness and altered sensation have been reported.

3. HOW TO RECEIVE ENTYVIO

You will not be expected to give yourself ENTYVIO. It will be given to you by a person who is qualified to do so.

ENTYVIO will be given through a needle placed in a vein (intravenous infusion) in your arm.

ENTYVIO will be given to you over a period of about 30 minutes.

Your healthcare professional will monitor you during and after the ENTYVIO infusion for side effects to see if you have a reaction to the treatment.

4. Possible side effects

ENTYVIO can have side effects.

Not all side effects reported for ENTYVIO are included in this leaflet. Should your general health or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

ENTYVIO may cause serious side effects, including:

Infusion 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 professional 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 professional 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)**. Although it has not been reported with ENTYVIO, it may be possible for a person to get progressive multifocal leukoencephalopathy (PML) (a rare, serious brain infection caused by a virus). People with weakened immune systems can get PML. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML. Tell your healthcare professional 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 professional right away if you have any of the following symptoms: tiredness, loss of

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appetite, pain on the right side of your stomach (abdomen), dark urine, or yellowing of the skin and eyes (jaundice).

Other side effects

Tell your doctor **as soon as possible** if you notice any of the following:

Very common side effects (may affect more than 1 in 10 people):

- common cold
- joint pain
- headache

Common side effects (may affect up to 1 in 10 people):

- pneumonia
- infection of the large intestine due to Clostridium difficile bacteria
- fever
- chest infection
- tiredness
- cough
- flu (influenza)
- back pain
- throat pain
- sinus infection
- itching / itchiness
- rash and redness
- pain in the limb
- muscle cramps
- muscle weakness
- throat infection
- stomach flu
- anal infection
- anal sore
- hard faeces
- bloated stomach
- passing gas
- high blood pressure
- prickling or tingling
- heart burn
- haemorrhoids
- blocked nose
- eczema

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• night sweats
• acne (pimples)
• rectal bleeding
• shingles (herpes zoster)

Uncommon side effects (may affect up to 1 in 100 people):
• redness and tenderness of hair follicle
• throat and mouth yeast infection
• vaginal infection
• blurred vision (loss of sharpness of eyesight)

Very rare side effects (may affect up to 1 in 10,000 people):
• sudden, severe allergic reaction which can cause breathing difficulty, swelling, fast heartbeat, sweating, drop in blood pressure, light-headedness, loss of consciousness and collapse (anaphylactic reaction and anaphylactic shock)

Not known (frequency cannot be estimated from the available data):
• lung disease causing shortness of breath (interstitial lung disease)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or health care provider. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Additionally, suspected adverse reactions can be reported to AE.southafricassa@takeda.com or on the 24 hours contact number: 082 525 3040. By reporting side effects, you can help provide more information on the safety of this.

5. How to store ENTYVIO
Store all medicine out of reach of children.

Do not use this medicine after the expiry date which is stated on the carton, and on the label

Store at 2 °C – 8 °C (in a refrigerator)
ENTYVIO does not contain preservatives. Once reconstituted, the infusion solution should be used as soon as possible. However, if necessary, the infusion solution may be stored for up to 24 hours: this 24 hour hold may include up to 12 hours at 20 °C – 25 °C; any additional hold time must be at 2 °C – 8 °C. Do not freeze. Do not store any unused portion of the infusion solution for reuse.

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Each vial is for single-use only.

6. Contents of the pack and other information

ENTYVIO is a lyophilized powder for concentrate for solution for infusion.

White to off-white lyophilised cake or powder.

Entyvio contains 300 mg lyophilized powder for concentrate for solution in a clear 20 ml glass vial fitted with grey rubber stopper and aluminium crimp protected by a plastic cap.

Each pack contains 1 vial.

Holder of Certificate of Registration

TAKEDA (Pty) Ltd
Building A, Montecircle
64 Montecasino Boulevard
Fourways
2191
Tel: 011 514 3000

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