Package leaflet: Information for the patient

VYDURA® 75 mg oral lyophilisate

(rimegepant)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

This product is called Vydura 75 mg oral lyophilisate but will be referred to as Vydura throughout the leaflet.

What is in this leaflet

1. What VYDURA is and what it is used for

VYDURA contains the active ingredient rimegepant, that stops the activity of a substance in the body called calcitonin gene-related peptide (CGRP). People with migraine may have increased levels of CGRP. Rimegepant attaches to the receptor for CGRP, reducing the ability of CGRP to also attach to the receptor. This reduces the activity of CGRP and has two effects:

1) it can stop an active migraine attack, and

2) it can decrease the number of migraine attacks that occur when taken preventively.

VYDURA is used to treat and prevent migraine attacks in adults.

2. What you need to know before you take VYDURA

Do not take VYDURA
- if you are allergic to rimegepant or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking VYDURA, if any of the following applies to you:
- if you have severe liver problems
- if you have reduced kidney function or are on kidney dialysis

During treatment with VYDURA, stop taking this medicine and tell your doctor immediately:
- if you experience any symptoms of an allergic reaction, e.g., trouble breathing or severe rash. These symptoms can occur several days after administration.

Children and adolescents

VYDURA should not be given to children and adolescents under 18 years of age because it has not yet been studied in this age group.

Other medicines and VYDURA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some medicines may affect the way VYDURA works or VYDURA may affect how other medicines work.

The following is a list of examples of medicines that should be avoided when taking VYDURA:
- itraconazole and clarithromycin (medicines used to treat fungal or bacterial infections).
- ritonavir and efavirenz (medicines to treat HIV infections).
- bosentan (a medicine used to treat high blood pressure).
- St. John's wort (a herbal remedy used to treat depression).
- phenobarbital (a medicine used to treat epilepsy).
- rifampicin (a medicine used to treat tuberculosis).
- modafinil (a medicine used to treat narcolepsy).

Do not take VYDURA more than once every 48 hours with:
- fluconazole and erythromycin (medicines used to treat fungal or bacterial infections).
- diltiazem, quinidine, and verapamil (medicines used to treat an abnormal heart rhythm, chest pain (angina) or high blood pressure).
- cyclosporin (a medicine used to prevent organ rejection after an organ transplant).

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is preferable to avoid the use of VYDURA during pregnancy as the effects of this medicine in pregnant women are not known.

If you are breast-feeding or are planning to breast-feed, talk to your doctor or pharmacist before using this medicine. You and your doctor should decide if you will use VYDURA while breast-feeding.

Driving and using machines

VYDURA is not expected to affect your ability to drive or use machines.

3. How to take VYDURA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

For prevention of migraine, the recommended dose is one oral lyophilisate (75 mg rimegepant) every other day.

For treatment of a migraine attack once it has started, the recommended dose is one oral lyophilisate (75 mg rimegepant) as needed, not more than once daily.

The maximum daily dose is one oral lyophilisate (75 mg rimegepant) per day.

How to take this medicine

VYDURA is for oral use.

The oral lyophilisate can be taken with or without food or water.

Instructions:

Use dry hands when opening. Peel back the foil covering of one blister and gently remove the oral lyophilisate. Do **not** push the oral lyophilisate through the foil.

As soon as the blister is opened, remove the oral lyophilisate and place it on or under the tongue, where it will dissolve. No drink or water is needed.

Do not store the oral lyophilisate outside the blister for future use.

If you take more VYDURA than you should

Talk to your doctor or pharmacist or go to a hospital straight away. Take the medicine pack and this leaflet with you.

If you forget to take VYDURA

If you take VYDURA for the prevention of migraine and you miss a dose, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using VYDURA and contact your doctor straight away if you have signs of an allergic reaction such as severe rash or shortness of breath. Allergic reactions with VYDURA are uncommon (may affect up to 1 in 100 people).

A common side effect (may affect up to 1 in 10 people) is nausea.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VYDURA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C. Store in the original blister in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What VYDURA contains
- The active substance is rimegepant. Each oral lyophilisate contains 75 mg rimegepant (as sulfate).
- The other ingredients are: gelatin, mannitol, mint flavour, and sucralose.

What VYDURA looks like and contents of the pack

VYDURA 75 mg oral lyophilisates are white to off-white, circular, and debossed with the symbol .

Pack sizes:
- 2 x 1 oral lyophilisate perforated unit dose blisters.

Not all pack sizes may be marketed.

Manufacturer:
Millmount Healthcare Limited
Block-7, City North Business Campus
Stamullen
Co. Meath
K32 YD60
Ireland

Procured from within the EU and repackaged for the PL Holder: Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

PL: 45763/1455

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