PACKAGE LEAFLET

Package leaflet: Information for the patient

Voraxaze 1000 units powder for solution for injection
glucarpidase

▼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 are given 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Voraxaze is and what it is used for

The active substance in this medicine is glucarpidase, an enzyme that breaks down the cancer medicine methotrexate.

Voraxaze is used in adults and children older than 28 days if they are being given methotrexate for cancer treatment but their body is not able to get rid of the methotrexate fast enough and they are at risk of severe side effects. The medicine breaks down the methotrexate in the bloodstream, reducing methotrexate levels and so helping to control side effects and stop them worsening. It works very quickly and can reduce the amount of methotrexate in the bloodstream by more than 90% in 15 minutes. The medicine does not enter cells, so it does not prevent any methotrexate that has already entered the cancer cells from working to treat the cancer.

2. What you or your child need to know before you are given Voraxaze

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

Warnings and precautions
Talk to your doctor before you are given Voraxaze.
You will be given this medicine as soon as possible after your doctor decides you need it in order to prevent serious side effects from methotrexate.

This medicine alone cannot prevent or stop all of the side effects of high-dose methotrexate, and you will also be given other treatments and supportive care as required.

It is important that your doctor knows how much methotrexate is in your blood and how well your kidneys are working. You will have tests to check this before and after treatment with this medicine.

Children and adolescents

This medicine can be given to children from 28 days of age. The safety and efficacy of this medicine in children aged less than 28 days has not been established.

Other medicines and Voraxaze

This medicine can affect the amount of folinic acid in your body, another product that you may be given by your doctor to reduce methotrexate toxicity. As a precaution, your doctor will adjust the timing of your folinic acid and doses of Voraxaze to ensure that there is at least 2 hours between the two medicines. Your doctor will restart folinic acid administration no earlier than 2 hours after glucarpidase administration.

No other interactions between this and other medicines have been reported during clinical studies.

Pregnancy and breast-feeding
Talk to your doctor if you are pregnant or breastfeeding or you are planning to have a baby.

As this medicine is only used in people who have already been given methotrexate, which is known to cause harmful effects to a developing baby, no studies have been done to determine whether this medicine alone can cause harmful effects to a developing baby during pregnancy or whether it is excreted in breast milk.

Driving and using machines

This medicine has no or negligible effect on the ability to drive or use machines.

3. How this medicine will be given

This medicine is given as an injection into a vein, over a 5-minute period. Your doctor will work out the right dose for you, based on your weight. The recommended dose is 50 Units per kilogram of body weight.

As the medicine is given under medical supervision, it is unlikely that you will be given too much. If you think you have been given more than you should, talk to your doctor or nurse.

You will be monitored for changes in the amount of methotrexate in your blood after treatment with this medicine.

4. Possible side effects

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

Tell your doctor or one of the medical staff immediately if you experience any of the following:

- Swelling of the throat, tightness in the chest, difficulty breathing
- Swelling of the hands, feet, face, lips or mouth
- Rash, with or without flushing and swelling of the face
- Shaking or chills without fever

If you have any of the symptoms listed above, you may be having a serious allergic reaction and may need urgent medical attention. These side effects (allergic reactions) are very rare and if they do occur, usually occur on the day of treatment.

You should tell your doctor or one of the medical staff as soon as possible if you experience any of the following side effects which are also rare but have been reported during treatment with this medicine:

- Fever

- Headache
- A tingling or pricking sensation on the skin ("pins and needles")
- A burning sensation on the skin

If you experience any other side effects not mentioned in this leaflet, inform your doctor or one of the medical staff.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via theYellow 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 Voraxaze

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 vial after EXP. The expiry date refers to the last day of that month.

You will be given this medicine under medical supervision. It is stored between 2 and 8°C and should not be stored in a freezer.

Use by Date**:** This medicine will not be used after the expiry date stated on the vial and outer carton. The pharmacist will check this before it is dispensed.

6. Contents of the pack and other information

What Voraxaze contains

The active substance is glucarpidase.

Voraxaze contains Lactose, Trometamol, and Zinc acetate dihydrate

What Voraxaze looks like and contents of the pack
Each pack contains one vial which is a white or off-white lyophilised powder, to be reconstituted with 1 mL of sterile 0.9% sodium chloride solution (not included).

Marketing Authorisation Holder and Manufacturer
Name and address of the marketing authorisation holder
Protherics Medicines Development Limited
Blaenwaun
Ffostrasol
Llandysul
Ceredigion, SA44 5JT

Name and address of the manufacturer(s) responsible for batch release
Almac Pharma Services Limited
Seagoe Industrial Estate,
Portadown,
Craigavon,
BT63 5UA, UK (Northern Ireland)

This leaflet was last revised in June 2023

The following information is intended for healthcare professionals only:
Each vial of Voraxaze should be reconstituted with 1 mL of sterile 0.9% sodium chloride solution. Reconstitution should take place immediately prior to use (do not further dilute). It should be administered intravenously by bolus intravenous injection over 5 minutes.

After reconstitution with 1 mL of sterile 0.9% sodium chloride solution each 1 mL will contain 1,000 Units of glucarpidase. A syringe suitable for withdrawing small volumes should be used to remove the solution from the vials. It may not always be possible to withdraw a full 1 mL from the vial but removal of at least 0.90 mL from the vial will provide an adequate amount of glucarpidase for dosing purposes.

Any unused product or waste material should be disposed of in accordance with local requirements.