

# elaprased 2 mg/ml

(idursulfase)

Concentrate for solution for infusion

**Read all of this leaflet carefully before you start having this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Elaprased is and what it is used for
2. Before you are given Elaprased
3. How Elaprased is given
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## 1. WHAT ELAPRASE IS AND WHAT IT IS USED FOR

Elaprased is used as enzyme replacement therapy to treat children and adults with Hunter syndrome (Mucopolysaccharidosis II) when the level of the enzyme iduronate-2-sulfatase in the body is lower than normal. If you suffer from Hunter syndrome, a carbohydrate called glycosaminoglycan which is normally broken down by your body is not broken down and slowly accumulates in various organs in your body. This causes cells to function abnormally, thereby causing problems for various organs in your body which can lead to tissue destruction and organ failure. Elaprased contains an active substance called idursulfase which works by acting as a replacement for the enzyme that is at a low level, thereby breaking down this carbohydrate in affected cells.

Enzyme replacement therapy is usually administered as a long-term treatment.

## 2. BEFORE YOU ARE GIVEN ELAPRASE

**You should not be given Elaprased**

If you are allergic (hypersensitive) to idursulfase or any of the other ingredients of Elaprased.

**Take special care with Elaprased**

If you are treated with Elaprased you may experience side effects during or following an infusion (see section 4 Possible side effects). The most common symptoms are itching, rash, hives, fever, headache, increased blood pressure, and flushing (redness). Most of the time you can still be given Elaprased even if these symptoms occur. If you experience an allergic side effect following administration of Elaprased, you should contact your doctor immediately. You may be given additional medicines such as antihistamines and corticosteroids to treat or help prevent allergic-type reactions.

If severe allergic (anaphylactic-type) reactions occur, your doctor will stop the infusion immediately, and start giving you suitable treatment. You may need to stay in hospital.

**Using other medicines**

There is no known interaction of Elaprased with other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Pregnancy and breast-feeding**

Use of Elaprased during pregnancy is not recommended. Elaprased may get into breast milk therefore you should talk to your doctor or pharmacist before using this medicine if you are breast-feeding.

**Driving and using machines**

It is not known if Elaprased will affect the ability to drive or use machines.

## 3. HOW ELAPRASE IS GIVEN

Elaprased will be given to you under the supervision of a doctor or nurse who is knowledgeable in the treatment of Hunter syndrome or other inherited metabolic disorders.

Elaprased has to be diluted in 9 mg/ml (0.9%) sodium chloride solution for infusion before use. The usual dose is an infusion of 0.5 mg (half a milligram) for every kg you weigh. After dilution Elaprased is given through a vein (drip feed). The infusion will normally last for 1 to 3 hours and will be given every week.

**Use in children and adolescents**

The recommended dosage in children and adolescents is the same as in adults.

**If you are given more Elaprased than you should**

There is no experience with overdoses of Elaprased.

**If you forget to have Elaprased**

If you have missed an Elaprased infusion, please contact your doctor.

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

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Elaprased can cause side effects, although not everybody gets them. Most side effects are mild to moderate and associated with the infusion, however some side effects may be serious. Over time the number of these infusion-associated reactions decreases.

**If you have problems breathing, with or without bluish skin, tell your doctor straight away and seek immediate medical assistance.**

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

- Headache
- Increased blood pressure, flushing (redness)
- Shortness of breath, wheezing
- Abdominal pain, nausea, indigestion, frequent and/or loose stools
- Chest pain
- Hives, rash, itching
- Fever
- Infusion site swelling
- Infusion related reaction (see section entitled "Take special care with Elaprased")

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

- Dizziness, tremor
- Rapid heart beat, irregular heart beat, bluish skin
- Decreased blood pressure
- Difficulty breathing, cough, quickened breathing, low oxygen levels in your blood
- Swollen tongue
- Redness of the skin
- Pain in the joints
- Swelling of the extremities, facial swelling

Side effects for which the frequency cannot be estimated from available data are:

- Serious allergic reactions

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

## 5. HOW ELAPRASE IS STORED

Keep out of the reach and sight of children.

Do not use Elaprased after the expiry date which is stated on the label after EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Do not use Elaprased if you notice that there is discolouration or presence of foreign particles. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

**What Elaprased contains**

The active substance is idursulfase, which is a form of the human enzyme iduronate-2-sulfatase. Idursulfase is produced in a human cell line by genetic engineering technology (it involves the introduction of genetic information into human cells in the lab, which will then produce the desired product).

Each vial of Elaprased contains 6 mg of idursulfase. Each ml contains 2 mg of idursulfase.

The other ingredients are Polysorbate 20, sodium chloride, sodium phosphate dibasic, heptahydrate, sodium phosphate monobasic, monohydrate and water for injection.

**What Elaprased looks like and contents of the pack**

Elaprased is a concentrate for solution for infusion. It is supplied in a glass vial as a clear to slightly opalescent, colourless solution.

Each vial contains 3 ml of concentrate for solution for infusion.

Elaprased is supplied in pack sizes of 1, 4 and 10 vials per carton

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Shire Human Genetic Therapies Inc, 300 Shire Way, Lexington, 02421, MA, USA

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Biologix FZ Co

Dubai Free Zone, Road WB 21, Warehouse, C17 PO Box 54405,

Al Tawar Dubai, United Arab Emirates

Telephone no.: 00971 4 299 7171

**This leaflet was last approved in 11/2011, version number 6.**

**To report any side effects**

- **Saudi Arabia**
  - National Pharmacovigilance and Drug Safety Center (NPC)  
Call NPC at +966-11-2038222,  
Exts: 2317-2356-2353-2354-2334-2340
    - Fax: +966-11-205-7662
    - Toll-free: 8002490000
    - Email: npc.drug@sfd.gov.sa
    - Website: www.sfd.gov.sa/npc
- **Other GCC States:**

– Please contact the relevant competent authority.

**This is a medicinal product**

- A medicinal product is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicinal product.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers  
Union of Arab Pharmacists