

**PACKAGE LEAFLET**

## Package leaflet: Information for the patient

### ERWINASE®

10,000 Units, Powder for solution for injection

(Asparaginase from *Erwinia chrysanthemi*; *Erwinia* L-asparaginase)

**Read all of this leaflet carefully before you start receiving 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 your pharmacist.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What ERWINASE is and what it is used for

##### How does Erwinase work

Erwinase is an anti-blood-cell-cancer treatment. It works by lowering the levels of asparagine in your body, a substance the cancer cells need to survive.

##### What this medicine is used for

Erwinase is used for the treatment of a cancer of the white blood cells called Acute Lymphoblastic Leukaemia. It may also be used to treat other cancers where lower levels of asparagine might have a useful effect.

Erwinase may be used alone or with other treatments.

#### 2. What you need to know before you receive ERWINASE

##### You should not receive Erwinase if :

- you are allergic (hypersensitive) to the active substance (*Erwinia* L-asparaginase) or any of the other ingredients of Erwinase (see section 6).
- you have had a bad reaction to treatment with Erwinase on a previous occasion.
- you have history of pancreas problems (acute pancreatitis).
- you are pregnant or trying to get pregnant.
- you are breast-feeding.

##### Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Erwinase.

Your body may become sensitive to the active substance after repeated treatments. It could be the cause of allergic reactions (see section 4. Possible side effects).

##### Blood and urine tests

Treatment with Erwinase can sometimes affect the results of certain blood or urine tests. Your doctor will be aware of this and may carry out routine blood tests before and during your treatment to check for any changes.

Posterior reversible encephalopathy syndrome (characterised by headache, confusion, seizures and visual loss) may require blood-pressure lowering medicines and in case of seizure, anti-epileptic treatment.

### **Other medicines and Erwinase**

**Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.**

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

Your doctor or your nurse will not mix Erwinase with other medicines in the same infusion.

However you will probably be given other medicines before, during or after Erwinase treatment as part of your course of therapy.

### **Pregnancy and breast feeding**

- You must not use this medicine if you are pregnant. Tell your doctor straightaway if you are pregnant, become pregnant during treatment with this medicine, or plan to become pregnant in the near future.
- You must not breast-feed your baby during your treatment with Erwinase.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Erwinase is not known to affect your ability to drive or operate machines. However, as in all cases, you should not drive if you feel unwell or if your doctor has advised you not to drive.

### **Erwinase contains sodium and glucose**

Erwinase contains the following ingredients :

- **sodium** (less than 23 mg per dose). You can consider this medicine as essentially sodium free if you are on a salt-free or low-salt diet.
- **glucose**. If you are diabetic, please note that each bottle of Erwinase contains 5 mg glucose

## **3. How to receive Erwinase**

### **Dosage**

Your doctor will decide what dose to administer, how often you will be given Erwinase and for how long. It varies according to your body weight, your specific condition being treated, and your response to therapy.

### **Method of administration**

Erwinase can be given to you in one of the following ways:

- a) Into a vein (intravenous use).
- b) Into a muscle (intramuscular use).
- c) Just under the skin (subcutaneous use).

Erwinase should be injected by your doctor or your nurse. Your treatment will normally be given without interruption. If your dose is large, it may be given at two different sites.

### **If you receive more Erwinase than you should**

If you are concerned that you have been given too much Erwinase, contact your doctor or another healthcare professional immediately.

### **If you don't receive Erwinase**

If you are concerned that you have missed a dose, contact your doctor or another healthcare professional immediately.

If you have any further questions on this product, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, Erwinase can cause side effects, although not everybody gets them. Erwinase will be given under strict medical supervision and your doctor may give you other medicines to treat these side effects. Most of the side effects will stop once you stop taking Erwinase.

The most common side effects experienced by patients treated with Erwinase are:

Allergic reactions: You may develop the following symptoms: redness or inflammation of the skin, decrease in blood pressure, swelling of the face and/or the throat and difficulty breathing. You may require emergency treatment and should seek medical advice immediately. Erwinase treatment should be discontinued.

Coagulation disorders: Asparaginase can increase the risk of your blood clotting, which may block major blood vessels in the brain or heart, or may cause bleeding.

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

- Fits (convulsions), drowsiness, confusion, dizziness, tiredness or headache.
- Pancreas disorders with increase of the blood glucose level or other changes in blood tests.
- Diarrhoea.
- Pale skin.
- Unusual blood test results in liver enzymes.
- High temperature, chills, generalised pain, swelling of legs and injection site reactions (pain, redness, bruising, swelling)

Uncommon (may affect up to 1 in 100 people) side effects include:

- Difficulty breathing or stopping breathing.
- Increase in blood levels of sugars and lipids (fats).
- Runny nose.

Rare (may affect up to 1 in 1,000 people) side effects include:

- Liver failure.
- Complication of diabetes.
- Depressed level of consciousness or coma.
- Difficulty speaking, difficulty swallowing, impaired movement.
- Heart attack, usually secondary to other adverse effects.
- Posterior reversible encephalopathy syndrome (a condition characterised by headache, confusion, seizures and visual loss).

Very rare (may affect up to 1 in 10,000 people) side effects include:

- Severe inflammation of the pancreas.
- Muscle pain, joint pain.
- Low white blood cells as manifested by increased susceptibility to infection.

Other side effects with unknown frequency include:

- High blood levels of ammonia.
- High or low blood pressure, flushing.
- Nausea, vomiting, abdominal pain.
- Liver disorders.
- Pain in arms and legs.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed [\(see the details below\)](#).

By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**5. How to store ERWINASE**

Keep out of the reach and sight of children. Erwinase will be stored in a refrigerator (2°C to 8°C) by the hospital and must not be used after the expiry date which is stated on the label. The expiry date refers to the last day of the month.

**6. Contents of the pack and other information****What ERWINASE contains**

The active substance is *Erwinia* L-asparaginase. Each vial contains 10,000 Units *Erwinia* L-asparaginase. The other ingredients are sodium chloride and glucose monohydrate.

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

Erwinase comes as a white powder in a glass bottle. Each pack contains 5 glass bottles of powder.

**Marketing Authorisation Holder**

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**This leaflet was last revised in September 2016**

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