KIDROLASE 10,000 IU, powder and solvent for solution for injection

L-asparaginase

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What KIDROLASE 10,000 IU, powder and solvent for solution for injection is and what it is used for
2. What you need to know before you use KIDROLASE 10,000 IU, powder and solvent for solution for injection
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1. WHAT KIDROLASE 10,000 IU, powder and solvent for solution for injection IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: OTHER ANTINEOPLASTIC AGENT - ATC code: L01XX02.

Kidrolase is a treatment against cancer cells. It acts by reducing the level of asparagine in your body, a substance that cancer cells need to survive.

Kidrolase is used in the treatment of certain cancers of the white blood cells (acute lymphoblastic leukaemia and non - Hodgkin lymphoma) and their potential complications (leukaemic meningitis).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE KIDROLASE 10,000 IU, POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

Do not use KIDROLASE 10,000 IU, powder and solvent for solution for injection:
- if you are allergic to Escherichia coli L-asparaginase or any of the other ingredients of this medicine (listed in section 6).
- if you have an allergic reaction during treatment, this should be discontinued;
- if you have liver disease (severe liver failure) or a painful inflammation of the pancreas (pancreatitis);
- in combination with live attenuated vaccines (against yellow fever, chickenpox, shingles, measles, mumps, rubella, tuberculosis, rotavirus, flu) and for 6 months following the discontinuation of chemotherapy (see Interaction with other medicinal products and other forms of interactions).

Warnings and precautions
- Tell your doctor if you have (or have had) diabetes.
- Administration of Kidrolase must be performed in a healthcare facility, in the presence of trained personnel and the resources necessary to ensure treatment of an allergic reaction that may occur during administration.
- The treatment should only be administered under close medical monitoring. This usually includes:
  - full blood count;
  - level of blood sugar (glucose), uric acid and pancreatic enzymes;
  - liver and kidney function tests.
- 24-48 hours before each administration, a corticoid (medicine that reduces inflammation) could be administered in order to avoid the onset of allergic reactions.
- The onset of reversible posterior leukoencephalopathy (characterised by headache, confusion, seizures and loss of vision) could require the use of hypertensive agents and, in the event of seizures, of antiepileptic agents.

Talk to your doctor or pharmacist before using KIDROLASE 10,000 IU, powder and solvent for solution for injection.

Children

Not applicable.

Other medicines and KIDROLASE 10,000 IU, powder and solvent for solution for injection
- Kidrolase MUST NOT BE USED in combination with live attenuated vaccines (vaccines against yellow fever, chickenpox, shingles, measles, mumps, rubella, tuberculosis, rotavirus, flu) and for 6 months following the discontinuation of chemotherapy.
- Tell your doctor if you are taking or have been administered any of the following medicines:
  - a medicine to treat certain types of cancer or rheumatism (methotrexate);
  - a medicine used to treat epilepsy (phenytoin, fosphenytoin).

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

KIDROLASE 10,000 IU, powder and solvent for solution for injection with food, drink and alcohol

Not applicable.

Pregnancy and breast-feeding
- If you are pregnant or think you may be pregnant, do not use Kidrolase.
- Do not breastfeed during treatment.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Not applicable.

KIDROLASE 10,000 IU, powder and solvent for solution for injection contains

Not applicable.

3. HOW TO USE KIDROLASE 10,000 IU, powder and solvent for solution for injection

Posology

Your doctor will decide the dose to be administered, how many times and for how long.

Method of administration

Kidrolase may be administered to you:
Into a muscle (intramuscular use).
Into a vein (intravenous use).
Into the spinal canal (intrathecal use).

If you use more KIDROLASE 10,000 IU, powder and solvent for solution for injection than you should

Talk to your doctor or pharmacist immediately.

If you forget to use KIDROLASE 10,000 IU, powder and solvent for solution for injection

Not applicable.

If you stop using KIDROLASE 10,000 IU, powder and solvent for solution for injection

Not applicable.

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

4. POSSIBLE SIDE EFFECTS

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

The following side effects could occur:
- urticaria type allergic reactions (redness), itching, redness of the skin, inflammation of the face and throat, spasm of the airways, difficulty breathing, blood pressure decrease and more rarely allergic shock with difficulty breathing, which could be fatal;
- coagulation abnormalities, which could give rise to complications such as bleeding (haemorrhage) or the formation of blood clots, which could obstruct large blood vessels in the brain, heart, legs or lungs;
- rarely, decrease in the number of white blood cells (neutrophils), which could make you more sensitive to the risk of infection;
- decrease in the level of insulin in the blood, which in turn causes an increase in blood sugar (hyperglycaemia), which could develop into diabetes;
- increase in the level of lipids in the blood and in the body, and increase in the level of ammonium in the blood, causing somnolence, sedation and confusion, or seizures and even coma;
- mild redness or pain at the injection site;
- fatigue, nausea (feeling sick), vomiting (being sick);
- inflammation of a gland called pancreas (pancreatitis). This is a medical emergency that could rarely be fatal;
- liver disease with abnormal blood test results or jaundice (yellow colouring of the whites of the eyes) or swelling or impairment of the liver;
- kidney function impairment;
- lipid deposits in your liver and changes in protein metabolism;
- neurological impairment (rare): reversible posterior leukoencephalopathy (disease characterised by headache, confusional state, seizures and loss of vision).

In women, the menstrual cycle may be suppressed and in men, KIDROLASE may affect the production of sperm, and even lead to absence of sperm in the semen (azoospermia).

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 national reporting system: Agence nationale de sécurité du médicament et des produits de santé [French National Agency for Medicines and Health Products Safety] (ANSM) and the network of Regional Pharmacovigilance Centres – website: www.ansm.sante.fr.

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

5. HOW TO STORE KIDROLASE 10,000 IU, powder and solvent for solution for injection

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 bottle label.

Do not use after the deadline stated on the outer packaging. The expiry date refers to the last day of that month.

Store in a refrigerator (between 2°C and 8°C).

After reconstitution, this medicine should be used immediately. However, chemical and physical stability during use have been demonstrated for 24 hours at a temperature between +2°C and +8°C.

Do not freeze.

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What KIDROLASE 10,000 IU, powder and solvent for solution for injection contains
- The active substance is: L-asparaginase
- The other ingredients are: glycine, sodium hydroxide
- Solvent: water for injections

What KIDROLASE 10,000 IU, powder and solvent for solution for injection looks like and contents of the pack

This medicine is available in the following presentations:
- Powder and solvent for solution for injection, box of 1 bottle + 1 ampoule.
- Powder for solution for injection, box of 10 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

JAZZ PHARMACEUTICALS FRANCE SAS

CITY ONE, 84 QUAI CHARLES DE GAULLE, 69006 LYON, FRANCE

Distributor for the Marketing Authorisation Holder

JAZZ PHARMACEUTICALS FRANCE SAS

CITY ONE, 84 QUAI CHARLES DE GAULLE, 69006 LYON, FRANCE

Manufacturer

CENEXI LABORATOIRES THISSEN

2-6, RUE DE LA PAPYREE, 1420 BRAINE L'ALLEUD, BELGIUM

Names of the medicinal products in the Member States of the EEA

Not applicable.

The last date on which this information leaflet was approved is April 2017

Other

Detailed information on this medicine is available on the ANSM (France) website.

Jazz Pharmaceuticals®

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