Package leaflet: Information for the patient

Enrylaze® 10 mg/0.5 mL solution for infusion or injection
recombinant crisantaspase

▼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 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 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.

What is in this leaflet

1. What Enrylaze® is and what it is used for

Enrylaze® contains the active substance recombinant crisantaspase. It is a medicine used alongside other medicines to treat acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL). Enrylaze® can be given to patients aged 1 month of age or older.
Enrylaze® contains a protein made in the laboratory by recombinant DNA technology. This protein works by decreasing the amount of a protein called asparagine. This protein is needed by the ALL and LBL cancer cells to survive.

2. What you need to know before you are given Enrylaze®

You should not receive Enrylaze®
- if you have a severe allergic reaction to Enrylaze®.
- if you have an allergic reaction to any of the other ingredients of this medicine (listed in section 6).
- if you are currently experiencing severe pancreatitis (inflammation of the pancreas).
- if you have experienced severe pancreatitis after being treated with asparaginase therapies.
- if you have experienced serious blood clots after being treated with asparaginase therapies.
- if you have experienced serious bleeding events after being treated with asparaginase therapies.

Warnings and precautions
Talk to your doctor or pharmacist before you receive Enrylaze®.

The following problems may occur during treatment with Enrylaze®:
- serious allergic reactions that may be life threatening. The hospital will ensure they are prepared

to address any allergic reactions that may occur during treatment.
- inflammation of your pancreas. Discomfort or pain in your stomach or back area may be a sign of pancreatitis and should be reported to your doctor straight away.
- changes in your body's ability to manage blood sugar levels. Your doctor should monitor your glucose levels whilst on treatment and provide insulin if necessary.
- unusual bleeding events or blood clots. If either of these events occur treatment will be paused by your doctor until they are resolved.
- issues with your liver. Your doctor will monitor you to identify if you are experiencing any issues with your liver and treat you as necessary.
- central nervous system toxicity, such as seizures and impaired neurological function. Also, instances of posterior reversible encephalopathy syndrome (characterised by headache, confusion, seizures and loss of vision) may require blood-pressure lowering medicines and in case of seizure, treatment with anti-epileptic medicines.

Monitoring during treatment with Enrylaze®
You will be monitored during and after treatment with Enrylaze® for:
- allergic reactions
- functioning of your pancreas and liver
- blood sugar levels

Other medicines and Enrylaze®
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular inform your doctor or pharmacist if you have or are receiving:
- methotrexate or cytarabine, used in cancer treatment. Use of these medicines immediately before Enrylaze® may increase their effect.
- vincristine, used in cancer treatment. Use of vincristine with Enrylaze® may increase the toxicity of vincristine.
- glucocorticoids, used as anti-inflammation medicines. Use of these medicines immediately before Enrylaze® may increase the formation of blood clots.

Pregnancy
Enrylaze® should not be used during pregnancy, and women should check they are not pregnant prior to starting therapy. If you are pregnant or think you may be pregnant, ask your doctor or pharmacist for advice before receiving this medicine.

Breast-feeding
You should not breast-feed during treatment and for two weeks following treatment with Enrylaze®, as there may be a risk to the breast-feeding child.

Family planning
Both men and women should use a form of contraception and avoid conceiving a child during treatment with Enrylaze® and for 3 months after you last receive Enrylaze®. Hormonal contraceptives are not recommended for use in women when being treated with Enrylaze®.

Women should undergo pregnancy testing before starting treatment.

Driving and using machines
Enrylaze® can cause you to feel sick and have a headache. This may impact your ability to drive and operate machines.

Enrylaze® contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose unit, that is to say essentially 'sodium free'.

3. How Enrylaze® is given

Your doctor will determine what dose you are given and whether it will be given to you by an infusion into your veins or an injection into your muscle. You may also be given some other medicines before you start receiving Enrylaze®, such as paracetamol H1 and H2 blocker.

The dose and how it is given may vary depending on your specific condition, body surface area and response to therapy.

If you are given Enrylaze® into your veins, this will be given over a 2-hour period. If you are given Enrylaze® into a muscle, several injection sites may be used.

If you think you have been given more Enrylaze® than you should
If you have any concerns, contact your doctor or any healthcare professional immediately.

If you think you have missed a dose of Enrylaze®
If you have any concerns, contact your doctor or any healthcare professional immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. For patients treated with Enrylaze® the following side effects were reported.

Serious side effects
Tell your doctor immediately if you experience:
Symptoms of a serious allergic reaction, including swelling of the face, shortness of breath, hay fever like symptoms, rash, chills, wheezing, flushing, vomiting, high or low blood pressure. In severe cases anaphylaxis (a sudden, severe allergic reaction with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating and loss of consciousness) can also occur.

Symptoms of blood clots, including in the blood vessels of the lung which could present as sudden shortness of breath, chest pain, or coughing up blood and the blood vessels of the brain which could present with symptoms such as weakness/numbness, seizure, trouble speaking, or severe headache.

Symptoms of pancreatitis, including abdominal pain, nausea, vomiting, back pain, or loss of appetite.

Other side effects
Talk to your doctor if you get any of the following:

Very common side effects (may affect more than 1 in 10 people):
- allergic reaction, including rash, itching, and hives
- infections
- low levels of red blood cells (anaemia)
- low levels of blood platelets (thrombocytopenia)
- low levels of white blood cells (white blood cell count decreased)
- low levels of neutrophils, a type of white blood cell that fights off infection (neutropenia)
- low levels of white blood cells (neutrophils) with fever due to infection (febrile neutropenia)
- low levels of lymphocytes, a type of white blood cell that fights off infection (lymphocyte count decreased)
- pain in your stomach (abdominal pain)
- diarrhoea
- feeling sick (nausea)
- vomiting
- tiredness (fatigue)
- fever (pyrexia)

- high blood sugar levels (hyperglycaemia)
- pain in limbs (pain in extremity)
- weight loss (weight decreased)
- headache
- decreased appetite
- abnormal liver function test (transaminases increased, blood bilirubin increased)
- decreased albumin (a blood protein) level (hypoalbuminaemia)
- anxiety
- bruising (contusion)

Common side effects (may affect up to 1 in 10 people):
- blood poisoning (sepsis)
- sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness (anaphylactic reaction)
- skin rash characterized with flat, discolored patches (macules) and raised, reddened bumps (papules) (rash maculo-papular)
- skin rash with redness and inflamation (rash erythematous)
- hives (urticaria)
- itchy skin (pruritus)
- inflammation of the pancreas (pancreatitis)
- injection site pain
- injection site reaction
- infusion related reactions
- abnormal blood clotting factor levels (prolonged activated partial thromboplastin time, decreased antithrombin III, decreased blood fibrinogen)
- abnormal kidney function (increased blood creatinine)
- low blood sugar levels (hypoglycaemia)
- low blood pressure (hypotension)
- blood clots, including in the blood vessels of the lung and brain
- irritability
- dizziness

Uncommon side effects (may affect up to 1 in 100 people)
- blood clot in a major brain vein (superior sagittal sinus thrombosis)
- blood clot in the neck vein (jugular vein thrombosis)
- blood clot in extremity veins (deep vein thrombosis)

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

• **Saudi Arabia:**

The National Pharmacovigilance Centre (NPC):
- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa

• **Kuwait:**

Drug & Food Control, Ministry of Health, Kuwait
• Tel. No.: +965-24811532
• Fax No.: +965-24811507
• E-mail: Adr_reporting@moh.gov.kw

5. How Enrylaze® will be stored

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.

Store the unopened vials in a refrigerator (2 °C–8 °C) in an upright position. Do not freeze. Keep the vial in the outer carton in order to protect from light.

After preparing a dose in a syringe, Enrylaze® can be stored for up to 8 hours at room temperature (15°C–25 °C) or 24 hours when refrigerated (2 °C–8 °C).

After dilution in an intravenous bag, Enrylaze® can be stored for up to 12 hours at room temperature (15 °C–25 °C) or 24 hours when refrigerated (2 °C–8 °C). Storage time starts once the solution has been withdrawn from the unopened vials.

Do not use this medicine if you notice any particles in the solution.

Do not throw away any medicines via wastewater. 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 Enrylaze® contains

- The active substance is recombinant crisantaspase. Each vial contains 10 mg of recombinant crisantaspase in 0.5 mL solution.
- The other ingredients are trehalose dihydrate, sodium chloride (see section 2 “Enrylaze® contains sodium”), sodium hydroxide (for pH adjustment), disodium phosphate, sodium dihydrogen phosphate monohydrate, polysorbate 80 and water for injections.

What Enrylaze® looks like and contents of the pack

Enrylaze® is a clear to slightly yellow solution for infusion or injectionn, free from particulate matter.

One carton contains 3 glass vials, each with 0.5 mL of solution for infusion or injection.

Marketing Authorisation Holder and Batch release site:

Jazz Pharmaceuticals Ireland Ltd
5th Floor
Waterloo Exchange
Waterloo Road
Dublin 4
D04 E5W7
Ireland
Tel: +353 1 968 1631
Email: medinfo-int@jazzpharma.com

Bulk Manufacturer:
Patheon Manufacturing Services,
LLC 5900 Martin Luther King Jr. Highway,
Greenville,
NC 27834-8628
United States

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder in KSA and Kuwait:

KSA
Biologix, FZ Co, Hibatullah Al Ghaffari Street-Suliemaniah Kingdom of
Saudi Arabia P.O.Box 991, Riyadh 11421.
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Council of Arab Health Ministers

This is a Medicament
− Medicament 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 medicament.
− The doctor and the pharmacist are experts in medicine, its 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

This patient information leaflet is approved by the Saudi Food and Drug Authority