Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user
Inotuzumab Ozogamicin
INONZA®

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Inonza (Inotuzumab ozogamicin) is and what it is used for

Inonza (Inotuzumab ozogamicin) contains the active substance inotuzumab ozogamicin, which is an antibody-drug conjugate (ADC) composed of a CD22-directed monoclonal antibody that is covalently linked to N-acetyl-gamma-calicheamicin dimethylhydrazide. Inotuzumab is a humanised immunoglobulin class G subtype 4 (IgG4) antibody that specifically recognises human CD22. The small molecule, N-acetyl-gamma-calicheamicin, is a cytotoxic product.

Inonza (Inotuzumab ozogamicin) is indicated as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL). Adult patients with Philadelphia chromosome positive (Ph^+) relapsed or refractory B cell precursor ALL should have failed treatment with at least 1 tyrosine kinase inhibitor (TKI).

If you have any questions about how Inonza (Inotuzumab ozogamicin) works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Inonza (Inotuzumab ozogamicin)

Do not take Inonza (Inotuzumab ozogamicin)

- If you are allergic to Inotuzumab ozogamicin or any of the other ingredients of Inonza (Inotuzumab ozogamicin) (listed in section 6).
- If you have experienced prior confirmed severe or ongoing venoocclusive liver disease/sinusoidal obstruction syndrome (VOD/SOS).
- If you have serious ongoing liver disease (e.g., cirrhosis, nodular regenerative hyperplasia, active hepatitis).

Warnings and precautions

Talk to your doctor before taking Inonza (Inotuzumab ozogamicin):

- **If you have liver toxicity**. Hepatotoxicity, including severe, life-threatening, and sometimes fatal hepatic VOD/SOS, was reported in patients with relapsed or refractory ALL receiving inotuzumab ozogamicin. Your doctor may monitor your elevations in total bilirubin, increase in the size of liver (which may be painful), rapid weight gain, ascites. In addition to Total Bilirubin, liver tests including, ALT, AST and alkaline phosphatase, prior to and following each dose of inotuzumab ozogamicin may be monitored by your doctor.

- **If you have a decreased production of blood cells.** Treatment with Inonza (Inotuzumab ozogamicin) may lead to a decrease in neutrophils, platelets, haemoglobin, white blood cells, fever with decreased absolute neutrophil count, lymphocytes, and decrease in all cell lines including white blood cells, red blood cells and platelets. Your doctor may monitor your complete blood count while on treatment with Inonza (Inotuzumab ozogamicin).

- **If you have infusion related reactions**. Infusion during the treatment of Inonza (Inotuzumab ozogamicin) can cause a sudden drop in blood pressure, hot flushes and breathing problems. Depending on the severity of the infusion related reaction, discontinuation of the infusion or administration of steroids and antihistamines would be considered by your doctor. For severe or life-threatening infusion reactions, treatment should be permanently discontinued.

- **If you have had Tumor Lysis Syndrome (TLS).** A condition that occurs when a large number of cancer cells die within a short period, releasing their contents into the blood; your doctor may consider some premedications along with hydration and treatment according to standard protocols.

- **If you have had a history of heart problems.** Inonza (Inotuzumab ozogamicin) should be administered with caution in patients who have a history of, or predisposition to QT interval prolongation, who are taking medicinal products that are known to prolong QT interval (see section 4.5) and in patients with electrolyte disturbances. ECG and electrolytes should be obtained prior to the start of treatment and periodically monitored during treatment.

- **If your amylase and lipase level increase.** Inonza (Inotuzumab ozogamicin) can raise amylase and lipase in patients and should be monitored for increase in their levels.

- **Immunization -**
  Vaccination with live viral vaccines is not recommended for at least 2 weeks prior to the start of inotuzumab ozogamicin treatment, during treatment, and until recovery of B lymphocytes following the last treatment cycle.

Other medicines and Inonza (Inotuzumab ozogamicin)

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription and even those not prescribed.

Concomitant use of inotuzumab ozogamicin with medicinal products known to prolong QT interval or to induce *Torsades de Pointes* should be carefully considered.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine. Women of childbearing potential should avoid becoming pregnant while receiving inotuzumab ozogamicin and should use effective contraception during treatment with inotuzumab ozogamicin and for at least 8 months after the final dose. Men with female partners of childbearing potential must use effective contraception during treatment and for at least 5 months after the final dose of treatment.

If you are breast-feeding, inform your doctor. Women must not breast-feed during treatment with inotuzumab ozogamicin and for at least 2 months after the final dose.

Fertility

Male and female fertility may be compromised by treatment with Inonza (Inotuzumab ozogamicin).

Driving and using machines

Patients may experience fatigue during treatment with inotuzumab ozogamicin. Therefore, caution is recommended when driving or operating machines.

Inonza (Inotuzumab ozogamicin) contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per 1 mg of Inotuzumab ozogamicin, that is to say that Inonza is essentially ‘sodium-free’.

3. How to take Inonza (Inotuzumab ozogamicin)

Inotuzumab ozogamicin should be administered under the supervision of a physician experienced in the use of cancer therapy and in an environment where full resuscitation facilities are immediately available.

For the first cycle, the recommended total dose of Inonza (Inotuzumab ozogamicin) for all patients is 1.8 mg/m^2 per cycle, given as 3 divided doses on Days 1 (0.8 mg/m^2), 8 (0.5 mg/m^2), and 15 (0.5 mg/m^2). Cycle 1 is 3 weeks in duration, but may be extended to 4 weeks if the patient achieves a CR or CRi, and/or to allow recovery from toxicity.

For subsequent cycles, the recommended total dose of Inonza (Inotuzumab ozogamicin) is 1.5 mg/m^2 per cycle given as 3 divided doses on Days 1 (0.5 mg/m^2), 8 (0.5 mg/m^2), and 15 (0.5 mg/m^2) for patients who achieve a CR/CRi or 1.8 mg/m^2 per cycle given as 3 divided doses on Days 1 (0.8 mg/m^2), 8 (0.5 mg/m^2), and 15 (0.5 mg/m^2) for patients who do not achieve a CR/CRi. Subsequent cycles are 4 weeks in duration.

Your doctor will determine the appropriate dose modification if you suffer from any condition, as well as if and when you need to stop treatment with Inonza (Inotuzumab ozogamicin).

If you take more Inonza (Inotuzumab ozogamicin) than you should

In the event of an overdose, the infusion should be temporarily interrupted and patients should be monitored for liver and blood toxicities.

4. Possible side effects

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

You must immediately contact your doctor if you experience any of those serious side effects (see also **What you need to know before you take Inonza (Inotuzumab ozogamicin)**):

- Liver toxicity.
- Decreased production of blood cells.
- Bleeding
- Infections.
- Hot flushes or breathing problems.
- Tumor Lysis Syndrome (TLS).
- Heart problems.
- Amylase and lipase level increase

Other side effects with Inonza (Inotuzumab ozogamicin) may include:

Very common: may affect more than 1 in 10 people

- Infections like fungal, lower and upper respiratory tract, viral, bacterial, gastrointestinal and skin infections.
- Decrease in neutrophils, platelets, haemoglobin, white blood cells, fever with decreased absolute neutrophil count, lymphocytes.

- Decreased appetite.
- Headache.
- Gastrointestinal bleeding, CNS or nose bleed.
- Mouth sores/inflammation/stomach pain, nausea, vomiting, diarrhoea, constipation, abdominal pain.
- Increase in liver enzymes.
- Fever, extreme tiredness, chills.
- Infusion related reactions.

Common: may affect up to 1 in 10 people

- Decrease in white blood cells, red blood cells and platelets.
- Hypersensitivity/Undesirable reactions produced by the immune system.
- Increased uric acid levels.
- Tumor Lysis Syndrome.
- Fluid retention in the abdomen, and increased size of abdomen.
- Veno occlusive liver disease.
- ECG QT prolonged.
- Increased amylase and lipase.

5. How to store Inonza (Inotuzumab ozogamicin)

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on vial and carton after "EXP". The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C). Do not freeze. Store in the original carton in order to protect from light.
  The reconstituted solution must be used immediately. If the reconstituted solution cannot be used immediately, it may be stored for up to 4 hours in a refrigerator (2°C-8°C). Protect from light and do not freeze.
  The diluted solution must be used immediately or stored at room temperature (20°C-25°C) or in a refrigerator (2°C-8°C). The maximum time from reconstitution through administration should be ≤8 hours, with ≤ 4 hours between reconstitution and dilution. Protect from light and do not freeze.

- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your doctor 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 Inonza (Inotuzumab ozogamicin) contains

Each vial contains 1 mg inotuzumab ozogamicin.

After reconstitution, 1 mL of solution contains 0.25 mg inotuzumab ozogamicin.

Other ingredients:

Sucrose
Polysorbate 80
Sodium chloride
Tromethamine

What Inonza (Inotuzumab ozogamicin) looks like and contents of the pack

Each carton contains one 20 mL Type I amber glass vial with chlorobutyl rubber stopper and crimp seal with flip off cap containing 1 mg of white to off-white, lyophilized cake or powder.

Inotuzumab ozogamicin is in the form of white to off-white, lyophilised cake or powder.

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