Additional safety information that requires special attention

The use of BESPONSA is linked to several additional side effects.

You should contact your physician immediately if you have signs and symptoms of any of the following serious side effects:

- Suppressed immune system: Signs and symptoms include infection, fever, tendency to bruise easily or regular nose bleeds. A suppressed immune system condition may be expressed by a low number of blood cells known as neutrophils (occasionally accompanied by a fever), red blood cells, white blood cells, lymphocytes or blood components known as platelets.
- Infusion-related reactions: Signs and symptoms include fever and chills or breathing difficulties during or shortly after the BESPONSA infusion.
- Tumor lysis syndrome: This effect may be related to a wide range of symptoms in the stomach and intestines (for example: nausea, vomiting, diarrhea), the heart (for example: changes in regularity of the heart rate), the kidneys (for example: decreased urine output, blood in urine), and nerves and muscles (for example: spasms, cramps or muscle weakness).
- QT interval prolongation: Signs and symptoms include dizziness or fainting.

Not all patients will respond to BESPONSA in the same way. Some people might experience more side effects than others and some not. Certain side effects may be mild and appear for a short time and others may be more severe and require medical care.

Please speak to your medical team if you suffer from any side effects during treatment with BESPONSA, including side effects not specified on this card.

For full information about the side effects appearing on this card and other possible side effects, please contact your physician.

Reporting side effects

Side effects can be reported to the Ministry of Health using the online side effect report form on the home page of the Ministry of Health website: www.health.gov.il or by clicking the following link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

Side effects can also be reported to Pfizer by email to: isr.aereporting@pfizer.com

This information card was reviewed and approved by the Ministry of Health in July 2018.

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PP-INO-ISR-0010

BESPONSA®
inotuzumab ozogamicin
POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION

Besponsa

Patient Information Card

This card contains select safety information that is important for you to know before and during treatment with BESPONSA.
This card does not contain information about all of the side effects that you could experience during treatment with BESPONSA.

Besponsa is medication given as the sole treatment for patients with leukemia known as CD22-positive B-cell precursor ALL.

The active ingredient in BESPONSA is inotuzumab ozogamicin, which belongs to a medication group whose activity is aimed at cancer cells.

BESPONSA is used in cases of relapsed ALL or when there was no response to treatment (refactory ALL).

Important information before you receive BESPONSA

Do not use BESPONSA if you:

- Are allergic to BESPONSA or any of the other ingredients in this medication (sucrose, polysorbate 80, sodium chloride, tromethamine).
- You had proven severe VOD (veno-occlusion disease) in the past or have existing VOD (a condition in which the blood vessels in the liver become damaged and obstructed by blood clots).
- Suffer from a significant liver disease, such as:
- Cirrhosis (a condition in which the liver does not function properly due to long-term damage).
- Nodular regenerative hyperplasia – a condition with signs and symptoms of portal hypertension that may be caused by chronic use of certain medications.
- Active hepatitis (disease characterized by a liver infection).

- If you are pregnant, planning to have children or breastfeeding, please consult your physician before taking this medication. Women must use effective contraceptives during the treatment and for at least 8 months after the last treatment.
  Men must use effective contraceptives during the treatment and for at least 5 months after the last treatment.
- If you feel unusually tired (this is a very common side effect of BESPONSA), it is advisable to take care when driving or operating machinery.
- If you are due to receive a bone marrow (stem cell) transplant after your treatment with BESPONSA, please discuss the risk factors of VOD with your medical team.
- Before starting your treatment with BESPONSA, please speak to your medical team if you have any questions, or if you are unsure of any issue.

Changes in your liver function

- The use of BESPONSA may cause liver damage, which may be expressed, among other things, in elevated levels of bilirubin and liver enzymes in your blood.
- Please speak to your medical team if you have a history of liver problems or diseases.

Veno-occlusive disease (VOD)

- Your medical team will monitor you closely during your treatment with BESPONSA for signs and symptoms of a serious condition called hepatic VOD.
- The attending team will conduct liver function tests before and during use of the product.
- The risk of developing VOD is significantly higher in patients who continue to a bone marrow (stem cell) transplant after treatment with BESPONSA.

When to contact your medical team

Please tell your medical team immediately if you notice one of the following signs and symptoms, which may belong to VOD:

- Rapid weight gain
- Pain in the upper-right part of your abdomen
- Accumulation of fluids that causes your abdomen to swell
- Yellowing (jaundice) of your skin or eyes

These are not all of the symptoms of VOD. Please speak to your medical team if you encounter any side effect during treatment with BESPONSA.