BESPONSA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I being given Besponsa?

Besponsa contains the active ingredient inotuzumab ozogamicin. Besponsa is used to treat adults with acute lymphoblastic leukaemia (ALL). ALL is a cancer of the blood where the cells that help protect your body from infection and foreign materials (white blood cells) grow uncontrollably. For more information, see Section 1. Why am I being given Besponsa? in the full CMI.

2. What should I know before receiving Besponsa?

Do not receive Besponsa if you have ever had an allergic reaction to Besponsa or any of the ingredients listed at the end of the CMI, or have had severe confirmed venoocclusive disease, or have serious ongoing liver disease. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding**. For more information, see Section 2. What should I know before receiving Besponsa? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Besponsa and affect how it works. Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy with or without a prescription from your pharmacy, supermarket or health food shop. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is Besponsa given?

Besponsa is given in "cycles". One Besponsa treatment cycle is made up of a single Besponsa dose given each week for 3 weeks. A doctor or nurse will give you your Besponsa dose gradually over 1 hour through a drip in your vein. More instructions can be found in Section 4. How is Besponsa given? in the full CMI.

5. What should I know while receiving Besponsa?

Things you should do	• Remind any doctor, surgeon, dentist and pharmacist you visit that you are receiving Besponsa. • Keep all of your doctor's appointments so that your progress can be checked. • Use a proven method of birth control during treatment with Besponsa if you can become pregnant or if you can father a child. You must continue to use effective birth control for at least 8 months (women) or at least 5 months (men) after the last dose of Besponsa.
Things you should not do	• You must avoid becoming pregnant or fathering a child whilst receiving Besponsa
Driving or using machines	• This medicine may cause fatigue in some people. If you feel tired, do not drive, operate machinery or do anything else that could be dangerous.
Looking after your medicine	• Besponsa must be kept in the original packaging in a refrigerator, protected from light, before it is time to use it. Your doctor, nurse or pharmacist will prepare the infusion for you before you are given it.

For more information, see Section 5. What should I know while receiving Besponsa? in the full CMI.

6. Are there any side effects?

Common side effects may include: nausea, vomiting, diarrhoea, constipation, decreased appetite, headache, general weakness, mouth ulcer, redness or pain.

Serious side effects may include: rapid weight gain, pain in the upper right side of stomach, a yellowish colour of the eyes and skin, changes in heart rhythm, decreased urine, blood in urine, muscle spasms, weakness, cramps, fever, sweating, chills, bruising easily or getting regular nose bleeds, lightheadedness, rash or trouble breathing shortly after receiving the injection. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING:

Hepatotoxicity, including fatal and life‐threatening hepatic venoocclusive disease has occurred in patients treated with BESPONSA.

An increased risk of post‐haematopoietic stem cell transplant (HSCT) non-relapse mortality has been observed in patients treated with BESPONSA.

Besponsa®

Active ingredient: *Inotuzumab ozogamicin (rch)*

Consumer Medicine Information (CMI)

This leaflet provides important information about Besponsa.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about Besponsa.

Where to find information in this leaflet:

1. Why am I being given Besponsa?

The active ingredient in Besponsa is inotuzumab ozogamicin. It belongs to a group of medicines called antineoplastic agents that target cancer cells.

Besponsa is used to treat adults with acute lymphoblastic leukaemia (ALL). ALL is a cancer of the blood where the cells that help protect your body from infection and foreign materials (white blood cells) grow uncontrollably.

This medicine works by stopping the abnormal growth of these cells and destroying them.

2. What should I know before receiving Besponsa?

Warnings

Do not receive Besponsa if you:

- have had severe confirmed venoocclusive disease (a condition in which the blood vessels in the liver become damaged and blocked by blood clots) or you currently have this disease
- have serious ongoing liver disease (e.g., 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 can be caused by chronic use of medicines], active hepatitis [a disease characterised by inflammation of the liver])
- are allergic to inotuzumab ozogamicin, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can receive this medicine. See Section 7. Product details for a list of ingredients

Check with your doctor if you:

- have any other medical conditions such as:
  - liver problems
  - heart problems
  - an infection or fever or bruising easily or getting nose bleeds on a regular basis.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant, are breastfeeding or intend to breastfeed.

It is unlikely that you will be given this medicine if you are pregnant or trying to become pregnant, as it may harm your unborn baby. Your doctor can discuss with you the risks involved.

You must avoid becoming pregnant or fathering a child if you are being treated with Besponsa.

It is not known whether this medicine passes into breast milk.

A risk to the newborn/infant cannot be excluded therefore you should not breastfeed during treatment with Besponsa and for at least 2 months after your last dose.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, vitamins or supplements that you buy with or without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Besponsa or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

There are certain periods before, during and after Besponsa treatment where live vaccines are not recommended. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure if the medicine(s), vitamin(s) or supplement(s) you are taking are affected by Besponsa or may affect how Besponsa works.

4. How is Besponsa given?

Besponsa is given in "cycles". One Besponsa treatment cycle is made up of a single Besponsa dose given each week for 3 weeks.

A doctor or nurse will give you your Besponsa dose gradually over 1 hour through a drip in your vein (intravenous infusion).

How much is given

Your doctor will calculate how much you need to be given.

This will depend on your height and weight and may also depend on your condition and how you have responded to previous treatment.

Medicines given before each cycle

Before each treatment with Besponsa, you will be given other medicines (premedication) to help reduce symptoms such as fever, chills or hot flush, known as infusion reactions, and other possible side effects.

How long it is given

If the medicine works well and you are going to receive a stem cell transplant, you may receive 2 cycles or a maximum of 3 cycles of treatment.

If the medicine works well, but you are not going to receive a stem cell transplant, you may receive up to a maximum of 6 cycles of treatment.

If you do not respond to the medicine within 3 cycles, your treatment will be stopped.

Your doctor will discuss with you how long your treatment will last.

If you forget a treatment

If you miss a treatment, contact your doctor or nurse as soon as possible to make a new appointment.

If you are given too much (overdose)

It is unlikely that you will be given too much Besponsa, as your dose will be calculated and given to you in a specialised setting under the supervision of a doctor.

If you think that you have been given too much Besponsa, you may need urgent medical attention.

If there are no signs of discomfort or poisoning but you still think that you have been given too much Besponsa, and you are in contact with a doctor, you should follow your doctor's advice.

If you are unable to reach your treating doctor, then go to the emergency department at your nearest hospital.

5. What should I know while receiving Besponsa?

Things you must do

If you (or your partner) become pregnant while you are being given this medicine, tell your doctor immediately.

You must avoid becoming pregnant or fathering a child.

Use a proven method of birth control (contraception) during treatment with Besponsa if you can become pregnant or if you can father a child.

You must continue to use effective birth control for at least 8 months (women) or at least 5 months (men) after the last dose of Besponsa.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being treated with Besponsa.

Tell all doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will take regular blood tests to make sure Besponsa is working and to check for side effects.

In particular, your blood counts and liver function will need to be checked before each treatment.

Your doctor will also monitor your heart rhythm, the levels of certain electrolytes (such as calcium, magnesium, potassium) in your blood, and the level of enzymes (known as amylase and lipase) in your blood.

Your doctor may change your dose, interrupt, or completely stop treatment with this medicine if you have certain side effects.

Your doctor may also lower your dose based on your response to treatment.

Tell your doctor immediately if you have had any of the following symptoms during or shortly after being given Besponsa:

- fever, chills, hot flush, dizziness or lightheadedness, rash or trouble breathing
- nausea, vomiting, diarrhoea, changes in heartbeat, decreased urine or blood in urine, muscle weakness or cramps.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Besponsa affects you.

This medicine may cause fatigue in some people. If you feel tired, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

No information available.

Tell your doctor if you drink alcohol.

Storage

Besponsa must be kept in the original packaging in a refrigerator, protected from light, before it is time to use it.

Your doctor, nurse or pharmacist will prepare the infusion for you before you are given it. They may give it to you straight away or within 8 hours after the start of preparation.

Your doctor, nurse and pharmacist have more information on how to store Besponsa.

Disposal

Your doctor, nurse or pharmacist will dispose of any left-over medicine.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor if you have any further questions about side effects.

Common side effects

Common side effects	What to do
Gastrointestinal (stomach)-related • nausea (feeling sick) • vomiting • diarrhoea • constipation **Metabolism-related** • decreased appetite **General** • headache • general weakness • mouth ulcer, redness or pain	**Speak to your doctor if you have any of these side effects.**

The above list includes the more common side effects of your medicine.

Some side effects (for example, changes in your liver function) can only be found when your doctor does tests from time to time to check your progress.

Serious side effects

Serious side effects	What to do
• rapid weight gain, pain in the upper right side of your abdomen (stomach), a yellowish colour of the skin, eyes, and other tissues o These could be symptoms of a very serious and potentially fatal condition called venoocclusive liver disease. o If you are over 65 years of age, have a prior history of liver disease and/or hepatitis, have previously received a stem cell transplant (a process that involves replacing blood-forming cells called stem cells that are diseased or have been damaged by anti-cancer medicines), and/or have received several prior treatments, you have an increased chance of getting this side effect. • symptoms in the stomach and intestines (for example, nausea, vomiting, diarrhoea), heart (for example, changes in the rhythm), kidney (for example, decreased urine, blood in urine), and nerves and muscles (for example, muscle spasms, weakness, cramps) o These could be signs of a serious condition known as tumour lysis syndrome, which is caused by chemical disturbances in the blood due to the breakdown of dying cancer cells. • fever, sweating and chills o These could be signs of an infection which may be serious and potentially fatal. • bruising easily or getting nose bleeds on a regular basis • fever, chills, hot flush, dizziness or lightheadedness, rash or trouble breathing during or shortly after the Besponsa infusion (infusion-related reactions) • dizziness, feeling lightheaded, or fainting o These could be signs of a heart rhythm disorder that can cause serious irregular heart rhythms.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• Symptoms of an allergic reaction such as: o shortness of breath o wheezing or difficulty breathing o swelling of the face, lips, tongue or other parts of the body o rash, itching or hives.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Besponsa contains

Active ingredient (main ingredient)	inotuzumab ozogamicin
Other ingredients (inactive ingredients)	Sucrose Trometamol Polysorbate 80 Sodium chloride

Do not take this medicine if you are allergic to any of these ingredients.

What Besponsa looks like

Besponsa is a white or off-white powder or cake supplied in a glass vial (AUST R 288135).

Before Besponsa is given, the powder is mixed with sterile water and diluted with a solution of sodium chloride.

Each Besponsa carton contains 1 vial.

Who distributes Besponsa

Pfizer Australia Pty Ltd

Sydney, NSW

Toll Free Number: 1800 675 229.

www.pfizermedicalinformation.com.au

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