

- ▼ 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.

BESPONSA®

Inotuzumab ozogamicin (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Besponsa.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving Besponsa against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Besponsa is used for

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Use in children

The safety and effectiveness of this medicine in children and adolescents under the age of 18 years have not been established.

Before you are given Besponsa

When you must not be given it

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]).

Do not receive Besponsa if you have an allergy to:

- any medicine containing inotuzumab ozogamicin
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

- rash, itching or hives.

Do not receive this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start receiving this medicine, talk to your doctor.

Before you start to receive it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- heart problems
- an infection or fever or bruising easily or getting nose bleeds on a regular basis.

Tell your doctor 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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.

You should not breast-feed during treatment with Besponsa and for at least 2 months after your last dose.

If you have not told your doctor about any of the above, tell him/her before you start taking Besponsa.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath 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.

How Besponsa is 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 an overdose is suspected, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital.

You may need urgent medical attention.

While you are being given 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.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Besponsa.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- rapid weight gain, pain in the upper right side of your abdomen (stomach), swelling of your abdomen
- These could be symptoms of a very serious and potentially fatal condition called venoocclusive liver disease.
- 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.
- fever, sweating and chills
- 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)
- 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)

- 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.
- dizziness, feeling lightheaded, or fainting
- These could be signs of a heart rhythm disorder that can cause serious irregular heart rhythms.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

- bleeding
- fatigue and shortness of breath
- fever
- pain in the abdomen.

The above list includes signs of serious side effects that may require urgent medical attention.

Tell your doctor or nurse if you notice any of the following:

- nausea (feeling sick)

- vomiting
- diarrhoea
- constipation
- headache
- general weakness
- a yellowish colour of the skin, eyes, and other tissues
- mouth ulcer, redness or pain
- decreased appetite.

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.

Tell your doctor or nurse if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After receiving Besponsa

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.

Product description

What it looks like

Besponsa is a white or off-white powder or cake supplied in a glass vial.

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.

Ingredients

Besponsa contains 1 mg of inotuzumab ozogamicin as the active ingredient.

It also contains:

- sucrose
- trometamol
- polysorbate 80
- sodium chloride.

Supplier

Besponsa is supplied in Australia by:

Pfizer Australia Pty Ltd

38-42 Wharf Road

West Ryde NSW 2114

Australia

Toll Free number: 1800 675 229

Australian registration

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