▼ **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.**

QARZIBA

Dinutuximab beta

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about QARZIBA. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking QARZIBA against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.
You may need to read it again.

What QARZIBA is used for

QARZIBA contains dinutuximab beta, which belongs to a group of medicines called 'monoclonal antibodies'. These are proteins, which specifically recognise and bind to other unique proteins in the body.
Dinutuximab beta binds to the molecule known as disialoganglioside 2 (GD2), which is present on cancer cells, and this activates the body's immune system, causing it to attack the cancer cells.

QARZIBA is **used to treat neuroblastoma** that has a high risk of coming back after a series of treatments and who have achieved at least a partial response.

Neuroblastoma is a type of cancer that grows from abnormal nerve cells in the body, in particular in the glands above the kidneys. It is one of the most common cancers in infancy.

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.

Before you start QARZIBA

When you must not have it

Do not take QARZIBA:

- If you are allergic to dinutuximab beta or any of the other ingredients of this medicine (listed at the end of this leaflet)
- If you have acute grade 3 or 4, or extensive long-lasting graft-versus-host disease

This disease is a reaction in which cells of transplanted tissue attack cells of the recipient).

Do not have this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If the medicine has expired or is damaged, your doctor will return it to the hospital pharmacist for disposal.

Before you start treatment

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

Warnings and precautions

Before receiving QARZIBA, you will have blood tests to check your liver, lung, renal and bone marrow functions.

You might notice the following when you first receive QARZIBA and during the course of treatment:

- **Pain:**
  Pain is one of the most common side effects of QARZIBA. It usually occurs at the beginning of infusion. Therefore, your doctor will give you an appropriate pain treatment starting 3 days before and continuing during use of QARZIBA.
- **Allergic reactions or other infusion-related reactions:**
  Tell your doctor or nurse if you have any kind of reaction during or after the infusion, such as:
  - fever, shivering and/or low blood pressure
  - difficulties in breathing
  - skin rash, hives
  You will receive appropriate treatment to prevent these reactions and be closely monitored for these symptoms during infusion of QARZIBA.
- **Leakage from small blood vessels (capillary leak syndrome):**
  Leakage of blood components from small blood vessels may cause rapid swelling in arms, legs and other parts of the body. Rapid drop in blood pressure, light-headedness and breathing difficulties are further signs.
- **Eye problems:**
  You may notice changes to your vision.
- **Problems with your nerves:**
  You may notice numbness, tingling or burning in your hands, feet, legs or arms, reduced sensation or weakness with movement.
- **Spinal cord and brain problems (central nervous system, CNS)**
  Tell your doctor or nurse if you have any kind of CNS symptoms, such as: substantial prolonged neurological deficit without apparent reason such as muscle weakness or loss of muscle strength in the legs (or arms), or mobility problems or unusual sensations and numbness. Persistent or sudden onset of a headache, or progressive loss of memory and cognitive ability, subtle personality changes, inability to concentrate, lethargy, and progressive loss of consciousness

Tell your doctor immediately if you notice any of these problems.

Your doctor may decide to stop your treatment if you have any of the problems mentioned here. In some cases your treatment may be able to start again after a break or at a slower rate, but sometimes it may need to be stopped completely.

Your doctor will do blood tests and may do eye tests while you are taking this medicine.

Pregnancy, breast-feeding and fertility

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.

Talk to your doctor before you receive QARZIBA if you are of childbearing age. It is recommended to use contraception for 6 months after discontinuation of treatment with QARZIBA. You may only use QARZIBA if your doctor assesses that benefits outweigh risks for a foetus.

Tell your doctor if you are breast-feeding. Do not breast-feed during treatment with QARZIBA and for 6 months after the last dose. It is not known if the medicine can pass into breast-milk.

Taking other medicines

Tell your doctor if you are using, have recently used or might use any other medicines.

Do not use **medicines that suppress the immune system** from 2 weeks before the first dose of QARZIBA until 1 week after the last treatment course, unless prescribed by your doctor. Examples of medicines that suppress the immune system are corticosteroids used to reduce inflammation or prevent organ transplant rejection.

Avoid **vaccinations** during treatment with QARZIBA and for 10 weeks afterwards.

How to take QARZIBA

A doctor experienced in the use of medicines to treat cancer will direct your treatment. The administration of the medicine will be started by a doctor or nurse while you are in hospital. It is given into one of your veins (intravenous infusion) usually by using special tubes (catheters) and a pump. During and after the infusion, you will be checked regularly for infusion-related side effects.

QARZIBA will be given to you in five treatment courses of 35 days and the infusion will last 5 or 10 days in the beginning of each course. The recommended dose for patients weighing over 12 kg is 100 mg dinutuximab beta per square metre of body surface per treatment course. The recommended dose for patients weighing over 5 kg but below 12 kg is 3.3 mg/kg per course. The doctor will calculate your body surface area from your height and weight.

While you are using QARZIBA

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking QARZIBA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

QARZIBA has several side effects that may affect your ability to drive and use machines. Do not perform these activities if your ability to concentrate and react is affected.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking QARZIBA.

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

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

Very common (may affect more than 1 in 10 people):

- rapid swelling of arms, legs and other body parts, rapid drop in blood pressure, light-headedness and breathing difficulties (capillary leak syndrome)
- pain in the stomach, throat, chest, face, hands, feet, legs, arms, back, neck, joint, or muscles
- allergic reactions and cytokine release syndrome with symptoms such as face or throat swelling, breathing difficulties, dizziness, hives, rapid or noticeable heartbeat, low blood pressure, hives, rash, fever, or nausea

Other side effects and their frequencies include:

Very common (may affect more than 1 in 10 people):

- fever, chills
- vomiting, diarrhoea, constipation
- inflammation of the mouth and lips (stomatitis)
- cough
- itching, rash
- low blood pressure, increased heartbeat
- oxygen deficiency
- tissue swelling (in the face, lip, around the eye, in the lower limbs)
- increased weight
- infection, in particular infection associated with the catheter that delivers the medicine
- headache
- dilated pupils or abnormal pupil reactions
- abnormal blood or urine tests (blood cells and other components, liver function, renal function)

Common (may affect up to 1 in 10 people):

- life-threatening infection (sepsis)
- fits
- agitation, anxiety
- nerve disorder in the arms and/or legs (with abnormal sensations or weakness), light-headedness, trembling, muscle spasms
- paralysis of eye muscles, blurred vision, light sensitivity, swelling in the retina
- high blood pressure
- cardiac failure, fluid around the heart
- respiratory failure, fluid in the lungs
- sudden constriction of the airways (bronchospasm, laryngospasm), rapid breathing
- decreased appetite, nausea, abdominal distension, accumulation of fluid in the abdominal cavity
- injection-site reactions, skin problems such as reddening, dry skin, eczema, excessive sweating, reaction to light
- unable to pass urine or passing reduced urine volume
- decreased weight, loss of fluids (dehydration)

Uncommon (may affect up to 1 in 100 people):

- shock due to decreased body fluid volume
- formation of blood clots in the small blood vessels
- a type of allergy (serum sickness) with fever, rash, joint inflammation
- a brain disorder characterised by headache, confusion, seizures and loss of vision
- inflammation of the intestine, injury to the liver
- kidney failure
- a condition in which some of the small veins in the liver are obstructed

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

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

After using QARZIBA

Storage

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 label and the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C - 8 °C). Keep the vial in the outer carton in order to protect from light.

Once opened, QARZIBA is intended for immediate use. Opened vials not immediately used are to be discarded.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Product description

What it looks like

QARZIBA is a colourless to slightly yellow liquid provided in a clear glass vial with a rubber stopper and aluminium seal.

Each carton contains 1 single use vial.

Ingredients

The active substance is dinutuximab beta. 1 mL concentrate contains 4.5 mg dinutuximab beta. Each vial contains 20 mg dinutuximab beta in 4.5 mL.

The other ingredients are histidine, sucrose, polysorbate 20, water for injections, hydrochloric acid (for pH adjustment).

Distributor/Supplier

QARZIBA is distributed/supplied in Australia by:

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