

QARZIBA

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.

1. Why am I using QARZIBA?

QARZIBA contains the active ingredient dinutuximab beta. 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.

For more information, see Section [1. Why am I using QARZIBA?](#) in the full CMI.

2. What should I know before I use QARZIBA?

Do not use if you have ever had an allergic reaction to dinutuximab beta or any of the ingredients listed at the end of the CMI. Do not take Qarziba if you have acute grade 3 or 4, or extensive long-lasting graft-versus-host 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 I use QARZIBA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with QARZIBA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use QARZIBA?

- The administration of the medicine will be started by a doctor or nurse while you are in hospital.
- 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.

More instructions can be found in Section [4. How do I take QARZIBA?](#) in the full CMI.

5. What should I know while using QARZIBA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using QARZIBA.• Keep all of your doctor appointments so that your progress can be checked.• If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• 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.• Avoid vaccinations during treatment with QARZIBA and for 10 weeks afterwards.
Driving or using machines	<ul style="list-style-type: none">• 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.
Looking after your medicine	<ul style="list-style-type: none">• 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.

For more information, see Section [5. What should I know while using QARZIBA?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects. You might notice the following when you first receive QARZIBA and during the course of treatment: pain, allergic reactions or other infusion-related reactions, leakage from small blood vessels (capillary leak syndrome), eye problems, problems with your nerves and spinal cord and brain problems (central nervous system, CNS).

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.

QARZIBA

Active ingredient(s): *dinutuximab beta*

Consumer Medicine Information (CMI)

This leaflet provides important information about using QARZIBA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using QARZIBA.**

Where to find information in this leaflet:

- [1. Why am I using QARZIBA?](#)
- [2. What should I know before I use QARZIBA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use QARZIBA?](#)
- [5. What should I know while using QARZIBA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using QARZIBA?

QARZIBA contains the active ingredient **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.

2. What should I know before I use QARZIBA?

Warnings

Do not use QARZIBA if:

- you are allergic to dinutuximab beta or any of the ingredients listed at the end of this leaflet.
- 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.

- Always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- 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

Symptoms of kidney failure:

Tell your doctor or nurse if you notice an altered frequency or absence of urination.

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.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

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

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect QARZIBA.

4. How do I use QARZIBA?

How much QARZIBA is given

- A doctor experienced in the use of medicines to treat cancer will direct your treatment.
- 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.

How QARZIBA is given

- 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.

If you are given too much QARZIBA

As this medicine will be given to you by your doctor or nurse, it is unlikely that you will be given too much. If you think you or anybody else has been given too much QARZIBA, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using QARZIBA?

Things you should do

- 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.
- Remind any doctor, dentist or pharmacist you visit that you are using QARZIBA.

Things you should not do

- 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.
- 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.

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

Driving or using machines

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

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.

Looking after your medicine

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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

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 or pharmacist if you have any further questions about side effects.

Less serious side effects

Very common side effects	What to do
Pain <ul style="list-style-type: none"> • pain in the stomach, throat, chest, face, hands, feet, legs, arms, back, neck, joint, or muscles 	Speak to your doctor if you have any of these side effects and they worry you.
Nervous system related <ul style="list-style-type: none"> • headache 	
Respiratory related <ul style="list-style-type: none"> • cough 	
Skin related <ul style="list-style-type: none"> • itching, rash 	
General disorders and administration site related	

<ul style="list-style-type: none"> • infection, in particular infection associated with the catheter that delivers the medicine • fever, chills • injection-site reactions, skin problems such as reddening, dry skin, eczema, excessive sweating, reaction to light • tissue swelling (in the face, lip, around the eye, in the lower limbs) 	
Gastrointestinal related <ul style="list-style-type: none"> • vomiting, diarrhoea, constipation • inflammation of the mouth and lips (stomatitis) • decreased appetite, nausea • abdominal distension, accumulation of fluid in the abdominal cavity • inflammation of the intestine 	
Body as whole <ul style="list-style-type: none"> • increased weight • decreased weight, loss of fluids (dehydration) • abnormal blood or urine tests (blood cells and other components, liver function, renal function) 	
Heart related <ul style="list-style-type: none"> • low blood pressure, increased heartbeat • high blood pressure 	

Serious side effects

Common side effects	What to do
Allergic reactions <ul style="list-style-type: none"> • 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 	Speak to your doctor if you have any of these side effects and they worry you.
General disorders <ul style="list-style-type: none"> • shock due to decreased body fluid volume 	
Heart related: <ul style="list-style-type: none"> • oxygen deficiency • cardiac failure, fluid around the heart 	
Capillary leak syndrome <ul style="list-style-type: none"> • rapid swelling of arms, legs and other body parts, rapid drop in blood pressure, light- 	

headedness and breathing difficulties (capillary leak syndrome)

Nervous system related

- fits
- agitation, anxiety
- nerve disorder in the arms and/or legs (with abnormal sensations or weakness), light-headedness, trembling, muscle spasms
- a brain disorder characterised by headache, confusion, seizures and loss of vision

Eye related

- paralysis of eye muscles, blurred vision, light sensitivity, swelling in the retina
- dilated pupils or abnormal pupil reactions

Respiratory related

- respiratory failure, fluid in the lungs
- sudden constriction of the airways (bronchospasm, laryngospasm), rapid breathing

Urinary related

- unable to pass urine or passing reduced urine volume

Blood vessel related

- formation of blood clots in the small blood vessels
- Extreme tiredness and shortness of breath (which may be due to a low number of red blood cells)
- Bleeding and bruising (which may be due to a low number of blood platelets)

Infection related

- a type of allergy (serum sickness) with fever, rash, joint inflammation
- life-threatening infection (sepsis)

Kidney related

- kidney failure
- kidney disease where you pass little or no urine (atypical haemolytic uraemic syndrome)

Liver related

- a condition in which some of the small veins in the liver are obstructed
- injury to the liver

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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 QARZIBA contains

Active ingredient (main ingredient)	dinutuximab beta <ul style="list-style-type: none">• 1 mL concentrate contains 4.5 mg dinutuximab beta.• Each vial contains 20 mg dinutuximab beta in 4.5 mL.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• histidine• sucrose• polysorbate 20• water for injections• hydrochloric acid (for pH adjustment)

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

What QARZIBA 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. AUST R 321016.

Who distributes QARZIBA

QARZIBA is distributed/supplied in Australia by:

Recordati Rare Diseases Australia Pty Ltd

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North Sydney, NSW, 2060, Australia

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