

QARZIBA®▼ (dinutuximab beta)  
PATIENT BROCHURE

# INFORMATION BROCHURE FOR PARENTS AND CAREGIVERS



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Please talk to your attending physician if you have questions in addition to the information in this brochure.

Dear Parent/Caregiver,

Your attending physician has advised the use of an antibody therapy called QARZIBA® (dinutuximab beta) as a part of the treatment for high-risk neuroblastoma in your child.

Antibodies are proteins in the body which bind to foreign invaders (like bacteria, viruses, cancer cells) and activate a series of reactions within the immune system which leads to destruction of the foreign invaders. QARZIBA® is a specially developed antibody which helps your child's immune system fight the neuroblastoma cells in the body.

Treatment with QARZIBA® is complex and will likely last several months. The more you know about the individual treatment phases, the better you can support your child.

In order for you to understand what your child and family will be faced with, the most important information regarding therapy with QARZIBA® is summarised in this brochure, particularly:

- What is high-risk neuroblastoma?
- What is immunotherapy?
- How does QARZIBA® work?
- How is QARZIBA® administered?
- Which potential side effects could occur during the treatment?
- How can you and your child cope with the illness?



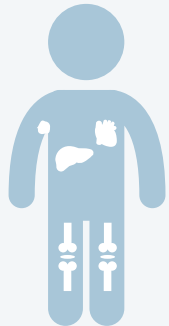
## HIGH-RISK NEUROBLASTOMA

A neuroblastoma is a tumour that develops from certain nerve cells during the early stages of pregnancy.

The word “neuro” means “nerve” and “blastoma” indicates a tumour. It usually affects nerve cells that are not yet mature or are still developing. A neuroblastoma occurs mostly in babies or young children. Children above the age of 10 are rarely affected.

Neuroblastoma is considered high-risk when the disease has certain characteristics. In high-risk neuroblastoma the tumour has already spread to other organs and/or there are certain peculiar genetic changes present in the tumour cells.

A high-risk neuroblastoma is fundamentally different to a low-risk neuroblastoma and should therefore be treated differently. The aforementioned characteristics do not exist in low-risk neuroblastoma.



**In most cases of high-risk neuroblastoma, the primary tumour has spread to other organs (metastasis) in the child's body and secondary tumours are already present at the time of diagnosis.**



# TREATMENT WITH QARZIBA®

## What is immunotherapy?

Immunotherapies are treatment options for some cancers. Immunotherapies boost the body's own immune system to fight cancer cells. Immunotherapies consist of antibodies produced in the laboratory.

The antibodies identify and bind to the tumour cells and help the body's own immune system to destroy these in a targeted manner.

## Why immunotherapy?

A high-risk neuroblastoma is a complex cancer, for which the usual treatment methods - removal of the tumour by surgery, chemotherapy and radiotherapy - are often not enough.

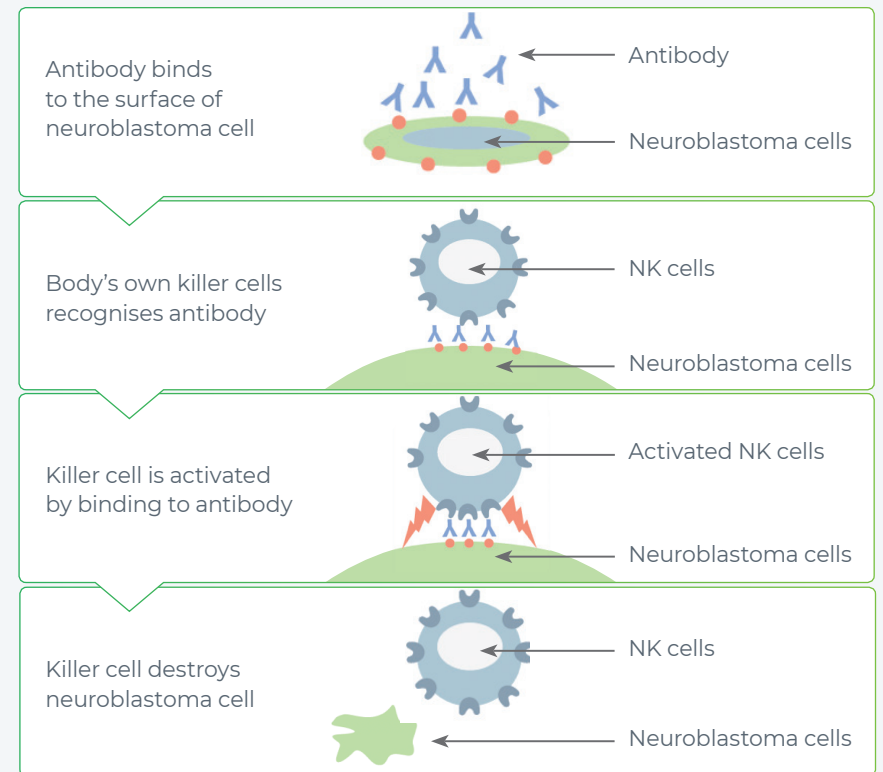
In such cases, immunotherapies can offer an additional method to fight the tumour cells in a targeted manner and hopefully prevent a relapse or recurrence of cancer.



## What is QARZIBA®?

QARZIBA® contains an active substance called dinutuximab beta, which is a specially developed antibody produced in the laboratory used as immunotherapy for high-risk neuroblastoma.

This antibody can specifically recognise and bind to neuroblastoma cells. As a result, the neuroblastoma cells are marked and can be destroyed by natural killer (NK) cells, which are part of the body's own immune system.



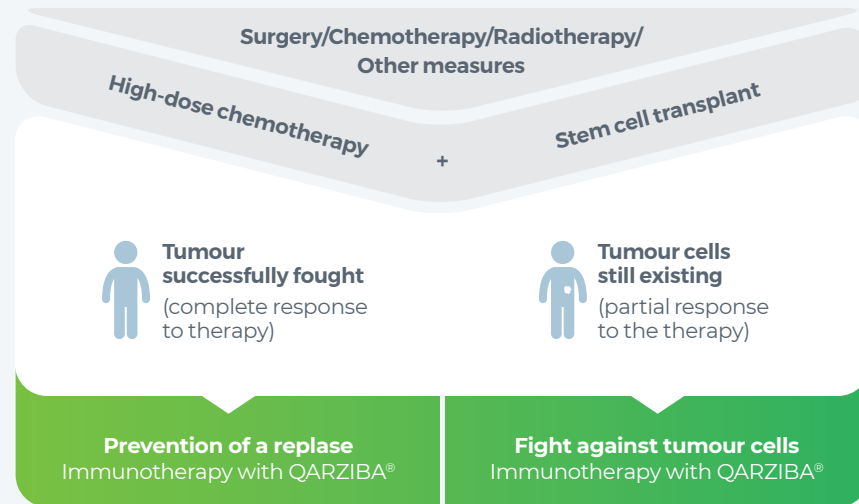
## When is QARZIBA® used?

Your child is likely to have already completed several treatment steps, including high-dose chemotherapy followed by stem cell transplantation, surgery or other measures to combat neuroblastoma. It is at this point that immunotherapy with QARZIBA® is used.

If previous treatments were successful in fighting the tumour cells, immunotherapy with QARZIBA® is used to prevent relapse or recurrence of the cancer.

If previous therapies have only partly worked, QARZIBA® is used to destroy remaining cancer cells.

## Course of treatment up to immunotherapy



# HOW DOES THE THERAPY WORK WITH QARZIBA®?

## In-patient treatment in hospital

Treatment with QARZIBA® is administered over 5 consecutive therapy cycles, with each cycle comprising 35 days (a total of approximately 6 months). Each cycle requires a hospital stay of several days, during which QARZIBA® is administered to your child as an infusion together with other medications.

The duration of the hospital stay per treatment cycle depends on the treatment regime of QARZIBA® your child is given. This may be between 8 - 17 days (approximately 1- 2 weeks).



## QARZIBA® administration

QARZIBA® can be administered in two different ways, either as a continuous infusion over a period of 10 days or as a daily infusion administered over 8 hours on 5 consecutive days.

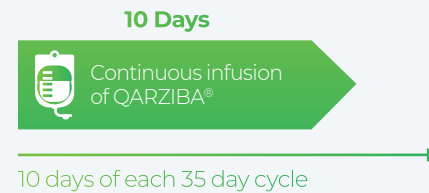
The only difference between both methods is that QARZIBA® is administered at different rates.

Your healthcare team will calculate the necessary amount of QARZIBA® based on the body surface area or weight of your child (measured in m<sup>2</sup> and kg respectively). Your child will receive the same total dose of QARZIBA® on either the continuous infusion or the daily infusion treatment schedule. The only difference is how much they will receive on each day of treatment. The doses are explained in the next section.

Your healthcare team will advise the most suitable method of administration of QARZIBA® for your child.

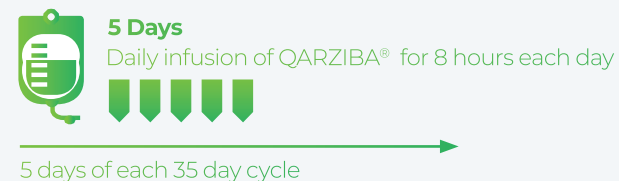
## Continuous infusion over 10 days

If your healthcare team advise the continuous infusion, QARZIBA® is administered as a continuous infusion (without interruption) for the first 10 days of a treatment cycle, each comprising of a total of 35 days. The daily dosage is 10 mg per m<sup>2</sup> of body surface area if your child weighs more than 12kg and 0.33mg per kg if they weigh between 5kg and 12kg.



## Daily infusion over 5 days

If your healthcare team advise the daily infusion, QARZIBA® is administered for 8 hours/day for the first 5 consecutive days of a treatment cycle, each comprising of a total of 35 days. The daily dosage is 20 mg per m<sup>2</sup> of body surface area if your child weighs more than 12kg and 0.66mg per kg if they weigh between 5kg and 12kg.



For both continuous infusion and daily infusion, the administration of other medications is necessary to reduce the risk of a possible allergic reaction and help to minimise the risk of pain and fever during the infusion of QARZIBA®.

## Accompanying medication during treatment with QARZIBA®

In addition to the immunotherapy, your child will receive other medications before as well as during the infusion of QARZIBA® to ease possible side effects associated with the administration of QARZIBA®.




## Why is pain management necessary?

Pain management is an important part of therapy with QARZIBA® because severe pain can occur during the infusion. Pain is caused by the antibody in QARZIBA® binding to nerves – which is an expected effect of the treatment.

To ensure your child does not suffer from pain, he/she is treated with a combination of the three painkillers: morphine, gabapentin and paracetamol or ibuprofen. The sensation of pain is different for every child; accordingly, the dose of each painkiller is individually adjusted to the pain sensation of your child during treatment.

Triple therapy, including classic over-the-counter pain medication (e.g. paracetamol), gabapentin and opioids, is often used to manage pain in patients receiving QARZIBA®.

Please consult your doctor for more information.

<b>Pain management</b>	 <b>Gabapentin</b> As liquid medicine or tablets
	 <b>Morphine</b> As injection or infusion
	 <b>Ibuprofen/paracetamol</b> As liquid medicine or tablets*

\*In some cases, ibuprofen/paracetamol may be infused.

## How are allergic reactions managed?

In addition to pain medication, your child will also receive preventative treatment with an antihistamine. Antihistamines are administered to prevent a possible allergic reaction to QARZIBA®. The antihistamine is usually administered as an injection about 20 minutes before the start of the QARZIBA® infusion, it is repeated every 4-6 hours as required.

<b>Allergic reactions</b>	 <b>Antihistamine</b> As injection
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## WHAT ARE THE SIDE EFFECTS THAT CAN OCCUR?

Immunotherapy with QARZIBA® is a very intensive treatment, which, like every cancer therapy is also associated with certain side effects.

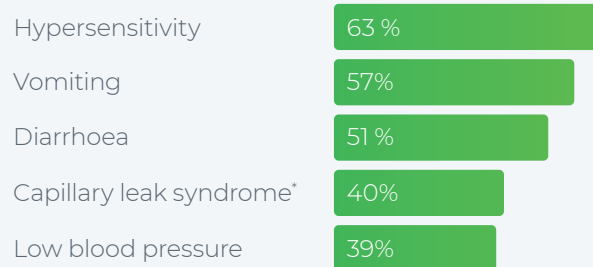
When and to what extent these side effects may occur during administration of QARZIBA® is different for each child and cannot be accurately predicted.

The most common side effects of treatment with QARZIBA® are fever and pain. To ensure that your child suffers as little as possible, the doctor will use various pain and fever reducing medications during the infusion of QARZIBA®. This will make the therapy easier for your child.

### Most common side effects despite treatment with painkillers:



### Further common side effects:



Other side effects not listed here may also occur. If you have any concerns about any side effects please speak to your treating doctor or nurse.

**\*Capillary leak syndrome:** A condition in which the blood vessels become permeable (porous) and fluid from the blood leaks into the surrounding tissue. This causes water retention, so-called oedema or swelling.

## WHAT HAPPENS AFTER THERAPY WITH QARZIBA®?

### Follow-up examinations

After the intensive medical treatment of the tumour is completed, a period known as 'aftercare' begins.

Tumour aftercare has the following purposes:

- To detect any recurrence of the cancer early and treat it promptly
- To determine the consequences of the treatment and/or accompanying illnesses, to treat and, if necessary, alleviate them
- To provide support to the patient/parent/caregiver in case of emotional and social problems

Your attending doctor will discuss the necessary follow-up examinations with you in detail.

This brochure was produced by EUSA to assist caregivers with general information on the use of QARZIBA®. This material does not contain all of the available information or replace advice received from your treating physician.

### Further information

For further information, please refer to the Consumer Medicine Information, available from your doctor or pharmacist.

IN AUSTRALIA QARZIBA® IS DISTRIBUTED BY:  
Link Medical Products Pty Ltd. Warriewood.  
ABN 73010971516.

**Date of preparation:** March 2021.  
LHCAU\_QAR03\_Jan21  
AU-DNB-2100001

