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Qarziba® (active substance: dinutuximab beta)

Authorisation in Switzerland: 18 April 2024

Concentrate for solution for infusion for the treatment of neuroblastoma in children and adolescents between 12 months and 18 years of age

About the medicinal product

The medicinal product Qarziba, containing the active substance dinutuximab beta, is used to treat high-risk neuroblastoma.

A neuroblastoma (NB) is a tumour originating from tissue in the sympathetic nervous system and can therefore occur in various parts of the body such as the neck, chest, abdomen or pelvis. NB occurs primarily in children younger than 5 years of age at diagnosis.

Qarziba can be used as maintenance therapy after first-line treatment[1] or to treat relapsed (recurrent) / refractory[2] NB. Its use is restricted to paediatric high-risk NB patients from 12 months of age. High-risk means that there is a high probability of the NB reoccurring.

Qarziba is used in combination with the medicine isotretinoin as maintenance therapy to treat high-risk NB in patients who have shown at least a partial tumour response to induction chemotherapy[3] during first-line therapy.

Qarziba may also be used to treat relapsed or refractory NB. This means that Qarziba is used in combination with isotretinoin or as a sole therapy for patients in whom NB has occurred again after first-line therapy, or who have not responded to this therapy.

Since NB is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

[1] First-line therapy: Therapy following the initial diagnosis

[2] In relation to cancer, refractory means that the cancer is resistant to treatment and does not recede or may even progress, despite treatment.

[3] Induction chemotherapy: high-dose administration of chemotherapy at the start of cancer treatment.

Mode of action

The active substance in Qarziba, dinutuximab beta, is a monoclonal IgG1 antibody (an immunologically active protein) which binds to certain structures on neuroblastoma cells (GD2) and in this way can mark cancer cells. This activates the body's own immune defences and the cancer cells are destroyed.

Administration

Qarziba is available only on prescription.

Qarziba is a concentrate for solution for infusion available in vials containing 20.25 mg/4.5 ml. It is administered into a vein.

The treatment is administered only in hospital so that any undesirable, life-threatening effects can be treated immediately. Treatment with Qarziba consists of a sequence of 5 cycles each lasting 35 days.

Qarziba can be administered either from Day 1-10 of each cycle with a daily dosage of 10 mg/m^2 body surface area or from Day 1-5 once daily at a dosage of 20 mg/m^2.

Efficacy

The efficacy of Qarziba was studied in patients with NB who had either received only a first-line therapy or who had relapsed or refractory NB.

Since supportive therapy with an anti-GD2 antibody is already recommended as the standard therapy worldwide for paediatric NB, it was not possible to carry out comparative studies with a dummy medicine (placebo).

First-line maintenance therapy: In the decisive (pivotal) study, Qarziba was studied in combination with isotretinoin compared with treatment with Qarziba, isotretinoin and interleukin-2. No relevant difference between the two groups was found with respect to event-free survival and overall survival. Improved overall survival was found compared to historical data without Qarziba.

The efficacy of Qarziba in relapsed or refractory high-risk NB was investigated in several studies. The results show that patients who were additionally treated with Qarziba tended to have a longer survival time compared with historical controls.

Precautions, undesirable effects, & risks

Qarziba must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most frequent undesirable effects are fever (86%) and pain (57%). Disorders of the gastrointestinal tract with vomiting (55%), diarrhoea (52%), and constipation (41%) and hypersensitivity reactions are also very common.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Taking into account the existing medical need and the inability to perform a comparative study, the submitted studies of the efficacy of Qarziba in paediatric patients with high-risk NB are adequate overall. No comparative efficacy data can be expected in the future either since Qarziba is already established as the standard therapy in clinical practice.

The benefit-risk relationship is considered to be positive. The medicinal product Qarziba containing the active substance dinutuximab beta was authorised in Switzerland for paediatric patients at least 12 months of age with high-risk neuroblastoma, both as first-line maintenance therapy and in patients with relapsed or refractory disease.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Qarziba®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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