

הריני להודיעכם כי העלון לרופא של התכשיר עודכן:

Qarziba®

קארזיבה

Concentrate for Solution for Infusion**Active ingredient and its quantity:**

Dinutuximab Beta 4.5 mg/mL

החומר הפעיל וכמותו:**התוויה מאושרת :**

Qarziba is indicated for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures.

In patients with a history of relapsed/refractory disease and in patients who have not achieved a complete response after first line therapy, Qarziba should be combined with interleukin-2 (IL-2).

להלן העדכונים בעלון לרופא המהווים החמרות (מסומנים בצהוב):

4.8 Undesirable effectsSummary of the safety profile

The most common adverse reactions were pyrexia (88%) and pain (77%) that occurred despite analgesic treatment. Other frequent adverse reactions were hypersensitivity (63.7%), vomiting (57%), diarrhoea (51%), capillary leak syndrome (40%), **Anaemia (72.3%), neutropenia (52%), thrombocytopenia (49.6%)** and hypotension (39.4%).

Tabulated list of adverse reactions

* includes abdominal pain, pain in extremity, **oropharyngeal pain, and Back pain reported in >10% of patients. In addition, other common pain types reported were arthralgia, injection site pain,** musculoskeletal pain, **bone pain,** chest pain, **arthralgia and neck pain.**

Description of selected adverse reactionsEye problems

These included impaired visual accommodation that is correctable with eye glasses, as well as mydriasis (43.7%), **periorbital oedema and eyelid oedema (7.1%),** blurred vision (3%) or photophobia (3%), which were usually reversible after treatment discontinuation.

העלון לרופא המעודכן מצורף להודעתנו להלן ונשלח למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות. ניתן לקבל עלון זה מודפס על ידי פניה לבעל הרישום: מדיסון פארמה בע"מ, רח' השילוח 10, פתח תקווה.

בברכה,

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