נובמבר 2023

Blincyto (Blinatumomab)
Powder for concentrate for solution for infusion

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,
אמג'ן אירופה בי וי, בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא לתכשיר בלינסייטו.
בהודעה זו מצוינים העדכונים המהותיים וההחמרות בלבד.
השינויים מפורטים להלן (קו תחתי – הוספת טקסט, ~~קו חוצה~~ – מחיקת טקסט).

ההתוויות הרשומות לתכשיר:

- BLINCYTO is indicated as monotherapy for the treatment of adults with CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukemia (ALL). Patients with Philadelphia chromosome positive B-precursor ALL should have failed treatment with at least 2 tyrosine kinase inhibitors (TKIs) and have no alternative treatment options.
- BLINCYTO is indicated as monotherapy for the treatment of adults with Philadelphia chromosome negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.
- BLINCYTO is indicated as monotherapy for the treatment of pediatric patients aged 1 year or older with Philadelphia chromosome negative CD19 positive B-precursor ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.
- BLINCYTO is indicated as monotherapy for the treatment of paediatric patients aged 1 year or older with high-risk first relapsed Philadelphia chromosome negative CD19 positive B-precursor ALL as part of the consolidation therapy.

Limitations of use:
After failure of two previous treatments and with no CNS involvement.

עדכונים בעלון לרופא:

4.8 Undesirable effects

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Immunogenicity

In clinical studies of adult ALL patients treated with BLINCYTO, less than ~~3%~~2% tested positive for anti-blinatumomab antibodies. ~~Six of those patients had anti-blinatumomab antibodies with *in vitro* neutralising activity.~~ Of patients who developed anti-blinatumomab antibodies, the majority had *in vitro* neutralizing activity. No anti-blinatumomab antibodies were detected in clinical studies of pediatric patients with relapsed or refractory ALL treated with blinatumomab.

Anti-blinatumomab antibody formation may affect the pharmacokinetics of BLINCYTO.

Overall, the totality of clinical evidence supports the finding that anti-blinatumomab antibodies are not suggestive of any clinical impact on the safety or effectiveness of BLINCYTO.

~~If formation of anti-blinatumomab antibodies with a clinically significant effect is suspected, the Marketing Authorisation Holder should be contacted to discuss antibody testing. Contact details are provided in section 6 of the package leaflet.~~

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בברכה,
מאיה ליפסון
רוקחת ממונה