מאי 2025

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:

4.4 Special warnings and precautions for use

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It is recommended that a neurological examination be performed in patients prior to starting BLINCYTO therapy and that patients be clinically monitored for signs and symptoms of neurologic events including ICANS (e.g. writing test which could be part of a comprehensive neurological assessment). Management of these signs and symptoms to resolution may require either temporary interruption or permanent discontinuation of BLINCYTO and/or treatment with corticosteroids (see section 4.2). In the event of a seizure, secondary prophylaxis with appropriate anticonvulsant medicinal products (e.g. levetiracetam) is recommended.

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4.8 Undesirable effects

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MedDRA system organ class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)
Nervous system disorders[a]	Headache[18] Tremor[18]	Encephalopathy[18] Aphasia[18] Paresthesia[18] Seizure[18] Cognitive disorder[18] Memory impairment Dizziness[18] Somnolence[18] Hypoesthesia[18] Cranial nerve disorder[b] Ataxia[18] Immune effector cell-associated neurotoxicity syndrome (ICANS)	Speech disorder[18]

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Description of selected adverse reactions

Neurologic events including ICANS

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ICANS, including Grade 3 and higher ICANS, were reported in clinical trials and with post-marketing experience. The most frequent clinical manifestations of ICANS were confusional state, aphasia, disorientation, altered state of consciousness, dysarthria, encephalopathy, seizure, mental status changes, somnolence and dysgraphia.

The observed time to onset of ICANS ranged from 0 to 299 days with the majority of ICANS occurring within the first three weeks.

את השינויים המפורטים ניתן לראות בעלון לרופא והעלון לצרכן המצורפים למכתב זה.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות של אתר משרד הבריאות, וניתן לקבלם גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה.
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בברכה,
אמג'ן יורופ בי. וי