03/2026

# Minjuvi 200 mg

# מינג'ובי 200 מ''ג

TAFASITAMAB 200 MG/VIAL

POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION

**רופא /ה, רוקח/ת נכבד**
חברת ניאופרם (ישראל) 1996 בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנידון. העלון עודכן בתאריך 03/2026.

ההתוויה הרשומה לתכשיר בישראל:
MINJUVI is indicated in combination with lenalidomide followed by MINJUVI monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

**בהודעה זו מצויינים העדכונים המהותיים בעלון לרופא:**

מידע שהוסר -מסומן בקו אדום חוצה ~~XXX~~
תוספת -כתב כחול
עדכוני בטיחות על רקע צהוב

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**
(…)
Excipient with known effect
Each vial of MINJUVI 200 mg contains 7.4 mg of sodium **and 1.0 mg of polysorbate 20**. For the full list of excipients, see section 6.1.

**4.4 Special warnings and precautions for use**
(…)
Excipient
This medicinal product contains 37.0 mg sodium per 5 vials (the dose of a patient weighing 83 kg), equivalent to 1.85% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
**This medicinal product contains 5.0 mg of polysorbate 20 per 5 vials. Polysorbate 20 may cause allergic reactions.**

**4.8 Undesirable effects**
(…)
Summary of the safety profile
***Patients with relapsed or refractory DLBCL***
**The safety of tafasitamab in patients with DLBCL was evaluated in the open-label, multicentre, single-arm phase 2 study L-MIND in 81 patients with relapsed or refractory DLBCL. Patients received tafasitamab 12 mg/kg intravenously in combination with lenalidomide for a maximum of 12 cycles, followed by tafasitamab monotherapy until disease progression or unacceptable toxicity..**
**The median duration of exposure to tafasitamab was 7.7 months**
(…)

Tabulated list of adverse reactions
Adverse reactions reported **for tafasitamab** in clinical trials are listed by MedDRA System Organ Class and by frequency. ~~**The frequencies of adverse reactions is based on the pivotal phase 2 trial MOR208C203 (L-MIND) with 81 patients. Patients were exposed to tafasitamab for a median of 7.7**~~

~~months.~~ The adverse reaction frequencies from clinical trials are based on all-cause adverse event frequencies, where a proportion of the events for an adverse reaction may have other causes than the medicinal product, such as the disease, other medicines or unrelated causes.

**Table 2: Adverse reactions in patients with relapsed or refractory DLBCL who received tafasitamab in combination with lenalidomide in the clinical trial MOR208C203 (L-MIND)**
(…)

**5.2 Pharmacokinetic properties**
(…)
Absorption
~~**Based on an analysis of tafasitamab in combination with lenalidomide, t**~~Tafasitamab average serum trough concentrations (± standard deviation) were ~~**179 (± 53)**~~ **178.4 (± 66)** µg/mL during weekly ~~**(plus an additional dose on day 4 of cycle 1)**~~ intravenous administrations of 12 mg/kg **from cycle 1 to 3**. During administration every 14 days from cycle 4 ~~**onwards**~~ **to 6**, average trough serum concentrations were ~~**153 (± 68)**~~ **163 (± 74.3)** µg/mL. ~~**Overall**~~ **Mean** maximum tafasitamab serum concentrations were ~~**483 (± 109)**~~ **488.4 (± 126.6)** µg/mL.
Distribution
The total volume of distribution **at steady state** for tafasitamab was 9.3 L.
(…)
Elimination
The clearance of tafasitamab was ~~**0.41**~~ **0.44** L/day and terminal elimination half-life was ~~**16.9**~~ **13.4** days. Following long-term observations, tafasitamab clearance was found to decrease over time to ~~**0.19**~~ **0.29** L/day after two years.
(…)

*Renal impairment*
The effect of renal impairment was not formally tested in dedicated clinical trials; however, no clinically meaningful differences in the pharmacokinetics of tafasitamab were observed for mild to ~~**moderate**~~ **sever** renal impairment (creatinine clearance (CrCL) ≥ ~~**30**~~ **15** and < 90 mL/min estimated by the Cockcroft-Gault equation). The effect of ~~**severe renal impairment to**~~ end-stage renal disease (CrCL < ~~**30**~~ **15** mL/min) is unknown.
*Hepatic impairment*
The effect of hepatic impairment was not formally tested in dedicated clinical trials; however no clinically meaningful differences in the pharmacokinetics of tafasitamab were observed for mild **to moderate** hepatic impairment (total bilirubin ≤ upper limit of normal (ULN) and aspartate aminotransferase (AST) > ULN, or total bilirubin 1 to 1.5 times ULN and any AST). The effect of moderate to severe hepatic impairment (total bilirubin > 1.5 times ULN and any AST) is unknown.

למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום (ניאופרם (ישראל) 1996 בע"מ, בנין ניאופרם, רחוב השילוח 6 ת.ד 7063 פתח תקווה 4917001, טלפון: 03-9373737, פקס: 03-9373716)

בברכה,

עוז וולך הרוקח הממונה של בעל הרישום