PRESCRIBING INFORMATION

MINJUVI® ▼ (tafasitamab) 200 mg powder for concentrate for solution for infusion

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See below for how to report adverse reactions. Refer to SmPC for further information

Indication: MINJUVI is indicated in combination with lenalidomide followed by MINJUVI monotherapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).
Active ingredient: One vial of powder contains 200 mg of tafasitamab. 1 ml of reconstituted solution contains 40 mg tafasitamab.
Dosage and administration: MINJUVI must be administered by a healthcare professional experienced in treatment of cancer patients. *Recommended pre-medication:* A pre-medication to reduce the risk of infusion-related reactions should be administered 30 minutes to 2 hours prior to tafasitamab infusion. *Treatment of infusion-related reactions:* If an infusion-related reaction occurs (Grade 2 and higher), the infusion should be interrupted and appropriate medical treatment of symptoms should be initiated. If a patient has experienced a Grade 1 to 3 infusion-related reaction, pre-medication should be administered before subsequent tafasitamab infusions.
The recommended dose is 12 mg per kg body weight administered as an intravenous infusion according to the following schedule (each cycle has 28 days):

- Cycle 1: infusion on day 1, 4, 8, 15 and 22 of the cycle.
- Cycles 2 and 3: infusion on day 1, 8, 15 and 22 of each cycle.
- Cycle 4 until disease progression: infusion on day 1 and 15 of each cycle.

In addition, patients should self-administer lenalidomide capsules at the recommended starting dose of 25 mg daily on Days 1 to 21 of each cycle. The starting dose and subsequent dosing may be adjusted according to the lenalidomide Summary of Product Characteristics (SmPC). Combination therapy is given for up to maximum of twelve cycles. Patients should continue to receive MINJUVI infusions as a single agent on Days 1 and 15 of each 28-day cycle, until disease progression or unacceptable toxicity. See the SmPC of MINJUVI and lenalidomide for dose modifications in case of adverse reactions.
No dose adjustment is required for patients ≥ 65 years; or with mild or moderate renal impairment or with mild hepatic impairment. There are no data for patients with severe renal impairment or moderate or severe hepatic impairment. Safety and efficacy of MINJUVI have not been established in patients < 18 years.
Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SmPC.
Warnings and precautions: *Infusion-related reactions:* Cases have been reported more frequently during the first infusion. *Myelosuppression:* Treatment with tafasitamab can cause serious and/or severe myelosuppression including neutropenia, thrombocytopenia and anaemia. Complete blood counts should be monitored. *Neutropenia:* Neutropenia, including febrile neutropenia, has been reported during treatment with tafasitamab. Administration of granulocyte colony-stimulating factors (G-CSF) should be considered. *Thrombocytopenia*: Cases have been reported during treatment with tafasitamab. Withholding of concomitant medicinal products that may increase bleeding risk should be considered. *Infections:* Fatal and serious infections occurred in patients during treatment with tafasitamab. Caution should be exercised when considering the use of MINJUVI in patients with a chronic infection or a history of recurrent infection. *Progressive Multifocal Leukoencephalopathy (PML):* PML has been reported during combination therapy with tafasitamab. The symptoms of PML are nonspecific and can vary and include altered mental status, memory loss, speech impairment, motor deficits (hemiparesis or monoparesis), limb ataxia, gait ataxia, and visual symptoms such as hemianopia and diplopia. If PML is suspected, further dosing of tafasitanab must be immediately suspended. Referral to a neurologist should be considered. If PML is confirmed, tafasitamab must be permanently discontinued. *Tumour lysis syndrome:* Patients with high tumour burden and rapidly proliferative tumour may be at increased risk of tumour lysis syndrome. Patients should be monitored closely for tumour lysis syndrome during treatment with tafasitamab. *Immunisations:* Vaccinations with live vaccines are not recommended concurrently with tafasitamab therapy.
Pregnancy and breast-feeding: Treatment should not be initiated in female patients unless pregnancy has been excluded. Consult the SmPC of lenalidomide for full details. *Women of childbearing potential:* Use an effective method of contraception during and for at least 3 months after end of treatment with tafasitamab. *Breast-feeding:* Women should be advised not to breast-feed during and for at least 3 months after the last dose of tafasitamab.
Adverse reactions: *Most common > 20%:* Infections, neutropenia, asthenia, anaemia, diarrhoea, thrombocytopenia, cough, oedema peripheral, pyrexia, decreased appetite. *Most common serious adverse reactions:* infection, pneumonia and febrile neutropenia. Consult the SmPC in relation to other adverse reactions.

Legal category: POM
Marketing authorisation number: EU/1/21/1570/001
Marketing authorisation holder: Incyte Biosciences Distribution B.V., Paasheuvelweg 25, 1105 BP Amsterdam, Netherlands. For further information phone 1800-456-748

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Adverse events should be reported.
Reporting forms and information can be found at HPRA Pharmacovigilance: www.hpra.ie
Adverse events should also be reported to Incyte immediately by phoning the Toll-free phone number 1800-456-748