This medicinal product is subject to additional monitoring. For further information, see professional information MINJUVI on www.swissmedicinfo.ch.

MINJUVI (tafasitamab), 200 mg powder for concentrate for solution for infusion.

I: 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) after at least one line of systemic CD20-targeted antibody therapy who are not eligible for autologous stem cell transplantation (ASCT). P: MINJUVI must be administered by a healthcare professional experienced in treatment of cancer patients. The recommended dose is 12 mg of MINJUVI per kg body weight administered as an intravenous infusion. On cycles 1-3: Administer on days 1, 8, 15 and 22 with an additional dose on day 4 of cycle 1. From cycle 4 onwards: Administer 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 28-day cycle for a maximum of 12 cycles. Dose adjustments due to adverse reactions are needed. CI: Hypersensitivity to tafasitamab or any of the excipients. W/P: Infusionrelated reactions may occur. Patients should be monitored closely throughout infusion. Treatment can cause serious and/or severe myelosuppression. Monitor complete blood counts throughout treatment and prior to administration of each treatment cycle. Withhold MINJUVI based on the severity of the adverse reaction. Fatal and serious infections occurred. Monitor patients for symptoms and signs of progressive multifocal leukoencephalopathy (PML); suspend treatment in case of suspected PML. Administer MINJUVI to patients with an active infection only if the infection is treated appropriately and well controlled. Monitor patients closely for tumor lysis syndrome. QTc prolongation and syncopes have been observed during treatment with MINJUVI. MINJUVI can cause fetal harm. Women of childbearing potential should be advised not to become pregnant during treatment. IA: No interaction studies have been performed for tafasitamab. UE: The most common adverse reactions (≥ 20%) were infections, asthenia, neutropenia, anaemia, thrombocytopenia and diarrhea. The most common serious adverse reactions (≥3%) were febrile neutropenia and pneumonia. For further information on UE, see www.swissmedicinfo.ch. Dispensing cat.: A. Revision date: May 2024. Marketing authorisation holder: Incyte Biosciences International Sarl, CH-1110 Morges. MINJUVI and the "triangle" design are (registered) trademarks of Incyte. Refer to <u>www.swissmedicinfo.ch</u> for detailed information.