Prescribing Information

▼Zynlonta 10 mg powder for concentrate for solution for infusion **- Abbreviated Prescribing Information**

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Each vial of powder for concentrate for solution for infusion contains 10 mg of loncastuximab tesirine.

Indication: Monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy.

Dosage and administration: Zynlonta must only be administered under the supervision of a healthcare professional experienced in the diagnosis and treatment of cancer patients. Posology*:* 0.15 mg/kg every 21 days for 2 cycles, followed by 0.075 mg/kg every 21 days for subsequent cycles until disease progression or unacceptable toxicity. Unless contraindicated, administer dexamethasone 4 mg orally or intravenously twice daily for 3 days, beginning the day before administering Zynlonta to mitigate pyrrolobenzodiazepine (PBD)-related toxicities. If dexamethasone administration does not begin the day before Zynlonta, oral or intravenous dexamethasone should begin at least 2 hours prior to administration of Zynlonta. The administration schedule should be adjusted to maintain a 21-day interval between doses*.* Dose modification required for haematologic and non-haematologic adverse reactions (see SmPC for dosing modification information). Elderly: No dose adjustment of Zynlonta is required in patients ≥65 years of age. Renal Impairment: No dose adjustment of Zynlonta is required for patients with mild to moderate renal impairment. Zynlonta has not been studied in patients with severe renal impairment (CLcr 15 to 29 mL/min). The effect of severe renal impairment, and end-stage renal disease, with or without haemodialysis, on loncastuximab tesirine pharmacokinetics is unknown. Additional monitoring for adverse reactions may be warranted in these patients when loncastuximab tesirine is administered. Hepatic impairment: No dose adjustment is recommended for patients with mild hepatic impairment (total bilirubin ≤ upper limit of normal [ULN] and aspartate aminotransferase [AST] > ULN or total bilirubin >1 to 1.5 × ULN and any AST). Zynlonta has not been studied in patients with moderate or severe hepatic impairment (total bilirubin >1.5 × ULN and any AST). Monitoring for adverse reactions is recommended. Paediatric population: The safety and efficacy in children and adolescents below 18 years are not yet established. Method of administration: For intravenous use. The infusion is administered over 30 minutes through an intravenous line. Extravasation has been associated with irritation, swelling, pain, and/or tissue damage, which may be severe. Infusion site should be monitored for subcutaneous infiltration during administration. Zynlonta must be reconstituted and diluted using aseptic technique under the supervision of a healthcare professional. It must be administered using a dedicated infusion line equipped with a sterile, non-pyrogenic, low-protein binding in-line or add-on filter (0.2 or 0.22 micrometre pore size) and catheter. Precautions should be taken before handling or administering Zynlonta.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and precautions: Traceability: To improve traceability of biological medicinal products, the name and the batch number should be clearly recorded. Effusion and oedema: Serious effusion and oedema have been reported and patients should be monitored. Myelosuppression: Zynlonta can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anaemia. Complete blood counts should be monitored prior to each dose. Infections: Fatal and serious infections, including opportunistic infections have been reported. Patients should be monitored for new or worsening signs/symptoms of infection. Photosensitivity and cutaneous reactions, including photosensitivity reactions: Serious cutaneous reactions have been reported. Patients should be monitored for new or worsening cutaneous or photosensitivity reactions. Zynlonta should be withheld for severe (Grade 3) cutaneous reactions until resolution. Patients should be advised to minimise or avoid exposure to direct natural or artificial sunlight including exposure through glass windows. Patients should be instructed to protect skin from exposure to sunlight by wearing sun-protective clothing and/or the use of sunscreen products. Interactions: No interaction studies have been performed in humans for loncastuximab tesirine, free tesirine, SG3199 and related metabolites.

Fertility, pregnancy, and breastfeeding: Women of childbearing potential should use effective contraception during treatment and for at least 10 months after the last dose. Men with partners of childbearing potential should use effective contraception during treatment and for at least 7 months after the last dose. There are no data on the use in pregnant women. Zynlonta may cause embryo-foetal toxicity when administered to a pregnant woman. Zynlonta is not recommended during pregnancy unless the potential benefit for the woman outweighs the potential risk to the foetus. Zynlonta is not recommended in women of childbearing potential not using contraception. Pregnancy testing is advised prior to initiating Zynlonta. Breast-feeding should be discontinued during treatment and for at least 3 months after the last dose. Loncastuximab tesirine may impair male fertility. Men being treated should be advised to consider having sperm samples preserved and stored before initiating treatment.

Undesirable effects: *Serious very common side effects:* Anaemia, neutropenia, thrombocytopenia, pleural effusion, dyspnoea*; Serious common side effects:* Pneumonia (includes lung infection), upper respiratory tract infection, lower respiratory tract infection, febrile neutropenia, pericardial effusion, ascites; *Other serious side effects:* Oedema, pericarditis; *Other very common side effects:* Decreased appetite, abdominal pain, diarrhoea, nausea, vomiting, constipation, rash, pruritus, erythema, oedema peripheral, fatigue, γ-glutamyl transferase increased, aspartate aminotransferase increased, alanine aminotransferase increased, blood alkaline phosphatase increased; *Other common side effects:* Fluid retention, lethargy, photosensitivity reaction, maculopapular rash, skin hyperpigmentation, pruritic rash, swelling face, bullous dermatitis, neck pain, pain in extremity, back pain, musculoskeletal pain, myalgia, musculoskeletal chest pain, face oedema, asthenia, peripheral swelling, swelling, non-cardiac chest pain. For full list of side effects, consult section 4.8 of the SmPC.

Legal Category: Prescription only medication (POM). **Pack size:** Pack size of one vial. **Price:** NHS List Price: £15,200, Eire List Price: Available on request. **MA numbers:** PLGB 30941/0023, EU/1/22/1695/001. **MA Holder:** Swedish Orphan Biovitrum AB, SE-112 76 Stockholm, Sweden. **Date of Preparation:** June 2023. **Unique ID number:** PP-19138

▼ 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. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard (for United Kingdom) and www.hpra.ie (for Republic of Ireland). Adverse events should also be reported to Swedish Orphan Biovitrum Ltd at medical.info.uk@sobi.com or Telephone +44 (0) 800 111 4754.