SYLVANT®▽ (siltuximab) 100mg and 400mg powder for concentrate for solution for infusion prescribing information

This prescribing information is derived from EU approved labelling. Consult the Prescribing Information from your local country for more information.

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

PRESENTATION: Siltuximab, 100 mg or 400 mg freeze-dried white powder for concentrate. **INDICATION:** Treatment of adults with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus 8 (HHV8) negative. **POSOLOGY & ADMINISTRATION: This medicinal product should be administered by qualified healthcare professionals and under appropriate medical supervision. Adults & Elderly:** recommended 11 mg/ kg siltuximab intravenous infusion over 1 hour every 3 weeks until treatment failure. Perform haematology tests before each dose for first 12 months, then every third cycle. Consider delaying treatment if: absolute neutrophil count <1.0x10^9/L; platelet count <75x10^9/L for first administration or <50x10^9/L for subsequent administration; or haemoglobin >170g/L (10.6mmol/L). Withhold treatment if severe infection or any severe non-haematological toxicity until recovery. Discontinue if severe infusion-related reaction, anaphylaxis, severe allergic reaction or cytokine release syndrome. Consider discontinuation if more than 2 dose delays due to treatment-related toxicities during first 48 weeks. **Paediatric population:** Safety and efficacy not established. No data available. **Renal & Hepatic impairment:** No studies. **CONTRAINDICATIONS:** Severe hypersensitivity to active substance or any excipient. **SPECIAL WARNINGS & PRECAUTIONS: Concurrent active serious infections:** treat prior to administering SYLVANT. Total IgG, IgA, or IgM levels below normal in 4 to 11% of patients in clinical study. Two cases of reactivated hepatitis B reported with concomitant high dose dexamethasone, and bortezomib, melphalan and prednisone in multiple myeloma. Monitor for serious infections as SYLVANT may mask signs/ symptoms of acute inflammation, including suppression of fever and C-reactive protein. **Vaccinations:** do not administer live, attenuated vaccines concurrently or within 4 weeks prior to SYLVANT. **Hyperlipidaemia: triglyceride and cholesterol elevations** observed, manage as per current guidelines for hyperlipidaemia. **Infusion reactions: slow/stop infusion if mild/moderate;** upon resolution of reaction, restart at lower infusion rate and consider use of antihistamines, acetaminophen, and corticosteroids. Discontinue if severe infusion related hypersensitivity reactions occur. **Malignancy:** potential risk, present data do not suggest increased risk. **Gastrointestinal perforation: use with caution in patients with increased risk of perforation;** evaluate if symptoms present. **Hepatic impairment: transient/intermittent elevation of hepatic transaminase / liver function tests e.g. bilirubin reported;** monitor patients with known hepatic impairment or elevated transaminase/bilirubin levels. **SIDE EFFECTS: Very common (≥1/10):** upper respiratory tract infection, urinary tract infection, nasopharyngitis, neutropenia, thrombocytopenia, hypertriglyceridaemia, hyperuricaemia, dizziness, headache, nausea, vomiting, constipation, diarrhea, oropharyngeal pain, gastroesophageal reflux disease, mouth ulceration, hypertension, abdominal pain, maculopapular rash, pruritus, eczema, arthralgia, pain in extremity, renal impairment, localised oedema, weight increased. **Common (≥1/100 to <1/10):** Anaphylactic reaction, hypercholesterolaemia. **Refer to SmPC for other side effects. PREGNANCY:** not recommended. Women of childbearing potential must use effective contraception during and up to 3 months after treatment. **BREAST-FEEDING:** No data. Risk to newborn/infant cannot be excluded. FERTILITY: effects on fertility not been evaluated in humans. **INTERACTIONS: SYLVANT may increase metabolism of CYP450 substrates.** Concomitant use of CYP450 substrates with a narrow therapeutic index: monitor the effect (e.g., warfarin) or concentration (e.g., cyclosporine or theophylline). Effect on CYP450 can persist for several weeks after stopping therapy. Caution with CYP3A4 substrates where decrease in effectiveness is undesirable (e.g. oral contraceptives). **LEGAL CATEGORY:** POM. **PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S):** SYLVANT 100 mg powder for concentrate for solution for infusion, 1 vial per pack, EU/1/14/928/001; SYLVANT 400 mg powder for concentrate for solution for infusion, 1 vial per pack, EU/1/14/928/002. **MARKETING AUTHORISATION HOLDER:** EUSA Pharma (Netherlands) B.V., Johannes Vermeerplein 11, 1071 DV, Amsterdam, Netherlands. **FURTHER INFORMATION IS AVAILABLE FROM:** EUSA Pharma UK Ltd, Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4TZ, UK

Adverse events should be reported as per local regulatory authorities requirements. Adverse events should also be reported to EUSA Pharma safety@eusapharma.com

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