

Consumer Indication

What is SYLVANT™?

SYLVANT™ (siltuximab) is a prescription medicine used to treat people with multicentric Castleman's disease (MCD) who do not have human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8) infection.

It is not known if SYLVANT™ is safe and effective in children.

Important Safety Information

Who should not receive SYLVANT™?

Do not receive SYLVANT™ if you have had a severe allergic reaction to siltuximab or any of the ingredients in SYLVANT™.

What should I tell my healthcare provider before receiving SYLVANT™?

Before you receive SYLVANT™, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection. You should not receive SYLVANT™ if you have a severe infection.
- have had a recent vaccination or are scheduled to receive any vaccinations. You should not receive a live vaccine during your treatment with SYLVANT™.
- have or have had any stomach or bowel (intestine) problems, such as diverticulitis or ulcers. Tell your healthcare provider if you have pain in your stomach area.
- are pregnant or plan to become pregnant. It is not known if SYLVANT™ will harm your unborn baby. You should not become pregnant while receiving treatment with SYLVANT™. Females who are able to become pregnant should use effective birth control during treatment with SYLVANT™ and for 3 months after stopping treatment.
- are breastfeeding or plan to breastfeed. It is not known if SYLVANT™ passes into your breast milk. You and your healthcare provider should decide if you will take SYLVANT™ or breastfeed. You should not do both.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of SYLVANT™?

SYLVANT™ may cause serious side effects, including:

- **Infections.** SYLVANT™ may lower your ability to fight infections. Tell your healthcare provider right away if you have any signs or symptoms of an infection during treatment with SYLVANT™.
- **Infusion and allergic reactions.** If you have an infusion or allergic reaction while receiving SYLVANT™, your healthcare provider will stop your infusion and treat your reaction. If you have a severe infusion or allergic reaction your healthcare provider may stop your treatment completely. Tell your healthcare provider or get medical help right away if you have any of these symptoms during or after your infusion of SYLVANT™: trouble breathing, chest tightness, wheezing, dizziness or light-headedness, swelling of the lips, or skin rash.

The most common side effects of SYLVANT™ include: rash, itching, upper respiratory tract infection, weight gain, and increased blood level of uric acid.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of SYLVANT™.

Call your doctor for medical advice about side effects.

General information about the safe and effective use of SYLVANT™

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider or pharmacist for information about SYLVANT™ that is written for health professionals.

Report any signs of new or worsening medical conditions to your healthcare provider.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088 (1-800-332-1088).

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