READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

[Pr]SYLVANT®

pronounced SILL-vant
siltuximab for injection

Read this carefully before you start taking SYLVANT® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about SYLVANT®.

What is SYLVANT® used for?

- SYLVANT® is a prescription medicine that is used to treat adults with multicentric Castleman's disease (MCD) in patients who do not have human immunodeficiency virus (HIV, which causes AIDS) or human herpes virus-8 (HHV-8) infection.
- MCD causes non-cancerous growths (benign tumours) to develop in your lymph nodes ('glands'). You may also feel weak or tired, have fever or sweat a lot, especially at night, have tingling, burning or weakness in your arms or legs, or a loss of appetite.

How does SYLVANT® work?

SYLVANT® blocks the action of a specific protein called "interleukin-6", which can cause inflammation. Blocking this protein helps to reduce the size of your affected lymph.

What are the ingredients in SYLVANT®?

Medicinal ingredients: siltuximab
Non-medicinal ingredients: L-histidine and L-histidine monohydrochloride monohydrate, polysorbate 80, and sucrose.

SYLVANT® comes in the following dosage forms:

Lyophilized (freeze-dried) powder in vials containing 100 mg or 400 mg of siltuximab.

Do not use SYLVANT® if:

- you have had a severe allergic reaction to SYLVANT®, or any of the other ingredients in SYLVANT®. As with other medicines similar to SYLVANT®, allergic reactions may occur.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SYLVANT®. Talk about any health conditions or problems you may have, including if you:

- have an infection. This is because SYLVANT® may lower your ability to feel or fight infections, and infections may get worse, such as pneumonia or blood poisoning (also called sepsis). Tell your doctor right away if you get any symptoms of infection during treatment with SYLVANT®, including: cough or flu-like symptoms; feeling tired or unwell; painful, red or hot skin; or fever.
- have HIV (AIDS) or HHV-8 infection. Your doctor will do tests to confirm you do not have either of these, before starting treatment with SYLVANT®.

- A history of stomach or bowel disease such as ulcers, diverticulitis or colitis (Crohn's disease). This is because several patients treated with SYLVANT® but who did not have Castleman's disease had serious side effects called perforated bowel (holes in the bowel).
- are due to have a vaccine. This is because SYLVANT® may interfere with some vaccines. Your doctor may give you recommended vaccinations before you start SYLVANT® treatment.
- have high level of fats in your blood (high cholesterol or triglycerides). This is because SYLVANT® may increase these levels or interact with medications used to treat these high levels. Your doctor may prescribe a medicine to help treat this.
- have kidney disease.
- have liver disease or changes that show up in blood tests of the liver.
- are pregnant or could become pregnant. You should not get pregnant while on SYLVANT® or within 3 months after receiving treatment with SYLVANT®. Babies born to mothers treated with SYLVANT® may have more infections, and you should talk to your doctor before live vaccines are given to these infants. Talk to your doctor about stopping SYLVANT® if you are pregnant or planning to become pregnant. You should use effective birth control during treatment and for at least 3 months after stopping SYLVANT® therapy.
- are on birth control pills or other hormone replacement. SYLVANT® can make hormone treatments including birth-control pills less effective, and you could become pregnant even though you don't miss a pill. You should use additional birth control during treatment and for at least 3 months after stopping SYLVANT® therapy.
- men receiving SYLVANT® and their female partners must use effective birth control during and for at least 3 months after treatment with SYLVANT®.
- are breastfeeding or planning to breastfeed. It is not known if SYLVANT® passes into breast milk, but your breastfed baby may also be at increased risk for infections. You and your doctor should decide if you will take SYLVANT® or breast-feed.
- have any allergies to this drug or its ingredients.
- have hypertension (high blood pressure).
- have high level of red blood cells
- get any new health problems or if any of them get worse

Allergic reactions
Tell your doctor immediately if you have a severe allergic reaction during or after the infusion. Signs include: difficulty breathing, chest tightness, wheezing, severe dizziness or lightheadedness, swelling of the lips or skin rash.

Infections
You may be more likely to get infections while you are being treated with SYLVANT®. These infections may be serious, such as pneumonia or blood poisoning (also called "sepsis"). Tell your doctor immediately, if you get any signs of infection during treatment with SYLVANT®. Signs include:
- cough
- flu-like symptoms
- feeling unwell
- red or hot skin
- fever

Your doctor may stop giving you SYLVANT® right away.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Taking SYLVANT® with some medicines may increase or decrease their effects, or cause side effects. The following may interact with SYLVANT®:

- Theophylline (used to treat asthma)
- Warfarin (used to stop your blood from clotting or to thin your blood)
- Statins such as atorvastatin (used for high cholesterol)
- Cyclosporine (used for organ transplants)
- Hormone treatments including birth control pills.

Your doctor will tell you whether you can continue the medicines you are taking or reduce the dose.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before you are given SYLVANT®.

How to take SYLVANT®:

SYLVANT® will be given to you by your doctor or nurse, in a hospital or clinic. SYLVANT® is given as an "intravenous infusion" (a drip into a vein, usually in your arm) slowly over one hour. During the infusion of SYLVANT®, you will be checked for side effects.

Usual dose:

SYLVANT® is dosed by body weight, which is usually 11 mg per kilogram. Your dose may be adjusted by your doctor.

Overdose:

As this medicine will be given to you by your doctor or nurse, it is unlikely that you will be given too much. There are no known side effects of having too much SYLVANT®.

If you think you have been given too much SYLVANT®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you forget or miss your appointment to be given SYLVANT®, make another appointment as soon as possible.

What are possible side effects from using SYLVANT®?

These are not all the possible side effects you may feel when taking SYLVANT®. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effects of SYLVANT® include: infections, colds, itching, and rash. Other common side effects include:

- drop in the number of white blood cells (neutropenia) which can decrease your body's ability to fight infections

- drop in the number of platelets (thrombocytopenia) which can cause easy bleeding and bruising
- high fat levels in your blood (cholesterol and triglycerides)
- high level of ‘uric acid’ in the blood which may cause gout
- abnormal kidney function test
- swelling in the arms, legs, neck or face
- pain in joints, arms or legs
- sore throat
- high blood pressure
- low blood pressure
- common cold
- stomach pain or discomfort
- weight gain
- constipation
- diarrhea
- nausea
- vomiting
- heartburn
- ulcers (sores) in the mouth
- dizziness

In addition, there are possible serious side effects and they are listed in the table below.

Serious side effects and what to do about them			
Symptom / effect	Talk with your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Common (up to 1 in 10 people)			
As with other medications similar to SYLVANT®, allergic reactions may occur. Tell your doctor immediately if you notice signs of severe allergic (hypersensitivity) reaction such as trouble swallowing, wheezing, feeling dizzy or lightheaded, hives, or swelling of the lips, tongue or mouth. If any of these occur, SYLVANT® may need to be stopped immediately and you may need emergency treatment.		✓	✓
High blood pressure. You may not have any symptoms, or you could have headache, blurred or double vision		✓	✓
Rash		✓	✓
Uncommon (less than 1% of patients)			
Fever, easy bleeding, easy bruising		✓	✓
Stomach pain, blood in stool		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:
- Online at MedEffect® (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 1908C
    Ottawa, ON
    K1A 0K9

    Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store SYLVANT® in the refrigerator. Do not use SYLVANT® after the expiration date stated on the label and carton, even if it is stored properly.

Keep out of reach and sight of children.

If you want more information about SYLVANT®:
- Talk to your healthcare professional
- For questions or concerns, please contact Recordati Rare Diseases Canada Inc., by calling 1-888-575-8344.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://hc-sc.gc.ca/index-eng.php); or by calling 1-888-575-8344.

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Last Revised: 30 July 2024