

SYLVANT®

Siltuximab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SYLVANT. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

If you have any concerns about using SYLVANT, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this information handy. You can refer to it later if you have any questions.

Please also refer to Consumer Medicine Information documents of other medicines your doctor may have prescribed for use in combination with SYLVANT.

What SYLVANT is used for

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

Multicentric Castleman's disease causes non-cancerous growths (tumours) to develop in the lymph nodes in the body. This disease may also make you feel tired, sweat at night, have a tingling feeling, and a loss of appetite.

Ask your doctor if you have any questions about why it has been prescribed for you.

How it works

SYLVANT contains the active ingredient siltuximab. SYLVANT blocks the action of a specific protein called "interleukin-6", which can cause inflammation. Blocking this protein helps to reduce the size of the affected lymph nodes and reduce the symptoms of the illness such as feeling tired. This should help you carry out your normal daily tasks.

Before you use SYLVANT

When you must not use it

Do not use SYLVANT if you know you are allergic to siltuximab or any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include skin rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.

Do not use it after the expiry date printed on the pack.

Do not use it if the packaging is torn or shows signs of being tampered with.

Before you start to use it

SYLVANT should be used with caution in some patients.

Tell your doctor, pharmacist or nurse before you are given SYLVANT if:

- you have an infection at the moment.

- you are due to have a vaccine or may need to have one in the near future - this is because some vaccines should not be given with SYLVANT.
- you have high levels of fats in your blood (hyperlipidaemia) - this is because SYLVANT may increase these levels. Your doctor may prescribe medicines to correct this.
- you had a risk of getting a hole or tear in the stomach or gut (gastrointestinal perforation) such as intestinal ulcers or diverticulitis. Signs of this include stomach pain getting worse, feeling sick (nausea), change in bowel habits and fever.
- you have kidney disease.
- you have liver disease or changes that show up in blood tests of the liver
- you get any new health problems or any of them get worse.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

SYLVANT might interact with other medicines. Using SYLVANT with certain other medicines may result in greater or lesser effects or even side effects from these medicines. Tell your doctor about

everything you are taking including prescription and non-prescription medicines, vitamins and herbal supplements so that your doctor can tell you whether you can continue the medicines you are taking or reduce the dose.

Be sure to tell your doctor if you are taking:

- theophylline, used to treat asthma
- warfarin (a blood thinner), used to stop your blood from clotting
- cyclosporin, used during and after organ transplants
- oral contraceptives to prevent pregnancy.

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 SYLVANT is given

SYLVANT will be prepared and given to you by a healthcare professional. SYLVANT is administered as an intravenous infusion, which means that the medicine will be administered to you through a needle placed in a vein in your arm. The infusion will be given to you over a period of about 1 hour. SYLVANT will be given every 3 weeks. During the infusion with SYLVANT, you will be monitored for side effects.

Follow your doctor's instructions carefully and do not stop receiving SYLVANT infusions without consulting your doctor first.

You will receive treatment until you and your doctor agree that you will no longer benefit from the treatment.

If you forget to use it

If you forget or miss your appointment to be given

SYLVANT, make another appointment as soon as possible.

Overdose

As this medicine will be given to you by your doctor or nurse, it is unlikely that you will be given too much. If you think you or anybody else has been given too much SYLVANT, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do. The side effects of having too much SYLVANT are not known.

You can contact the Poisons Information Centre by dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

You may need urgent medical attention.

While you are using SYLVANT

Things you must do

Follow your doctor's instructions carefully.

Tell your doctor if you are pregnant or are planning to become pregnant before using SYLVANT. SYLVANT is not recommended for use during pregnancy.

- It is not known if SYLVANT may affect the baby of a pregnant or breast-feeding woman. You must not become pregnant while you are being treated with SYLVANT and for 3 months after your treatment has finished. You should use effective methods of contraception during this time.
- It is not known if SYLVANT passes into breast milk. You and your doctor should decide if you will take SYLVANT or breast-feed. You should not do both.

Tell all of your doctors, dentists, and pharmacists who are treating you that you are taking SYLVANT before taking any new medicines that they may prescribe for you.

Ask your doctor or pharmacist before taking any other medicines.

These include herbal treatments and those bought in a pharmacy or supermarket.

Allergic reactions

Tell your doctor or nurse immediately if you have a severe allergic reaction during or after the infusion. Signs include: difficulty breathing, chest tightness, wheezing, severe dizziness or light-headedness, 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.

Things you must not do

Do not miss or stop the treatment without consulting your doctor first

Do not give SYLVANT to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how SYLVANT affects you.

SYLVANT may cause dizziness, tiredness or other effects in some people. Make sure you know how you react to SYLVANT before you drive a car, operate machinery, or do anything else that could be dangerous if you have side effects.

Side Effects

All medicines may have some unwanted side effects although not everyone will get them. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have about the risks of SYLVANT treatment.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving SYLVANT.

Tell your doctor if you notice any of the following and they worry you:

- respiratory infections including common cold and flu (high temperature, sore throat, runny nose, cough and chills)
- hayfever
- blocked nose
- shortness of breath
- cough
- sore throat
- ulcers (sores) in the mouth
- toothache
- itching
- rash or hives
- dry or red skin

- darkened areas of skin
- pain, including joint, arm, leg, back or neck pain
- swelling in the arms, legs, neck or face
- numbness or weakness in the arms, legs or muscles
- weight gain
- abdominal swelling
- stomach pain or discomfort
- constipation
- diarrhoea
- heartburn
- loss of appetite
- nausea
- vomiting
- feeling dizzy
- headache
- fever
- tiredness
- night sweats
- difficulty sleeping
- feeling thirsty
- feeling depressed
- feeling confused

These are mild side effects of SYLVANT but may require medical attention.

Other side effects from SYLVANT are:

- coughing, difficulty breathing and wheezing
- urinary tract infection (smelly, dark or cloudy urine. burning or stinging while urinating)
- difficulty passing urine
- blood in urine or stools
- prostate problems
- sudden, severe pain in the upper right abdomen and upper back
- hot, tender and red skin, sometimes with fever and chills
- ear infection or pain
- fungal infection
- bleeding or bruising easily, including nose bleeds
- fainting
- swollen or enlarged lymph nodes
- blurred vision

- high fat or cholesterol levels in your blood
- high level of uric acid in the blood which may cause gout
- abnormal kidney or liver function test
- high blood pressure or low blood pressure
- heart problems, including changes in heart beat

If these or any other effects occur, talk to your doctor without delay.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice signs of severe allergic (hypersensitivity) reaction like difficulty breathing, chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips, or skin rash.

As with other medications similar to SYLVANT, allergic reactions may occur. These may be serious side effects of SYLVANT. You may need urgent medical attention and your doctor may need to stop your treatment.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Do not hesitate to report any other side effects to your doctor or pharmacist.

After using SYLVANT

Storage

SYLVANT must be stored in the refrigerator (2°C-8°C). Heat and dampness can destroy some medicines.

SYLVANT should not be used after the expiration date stated on the label and carton even if it is stored properly.

Keep it where young children cannot reach it.

Product Description

What it looks like

SYLVANT is supplied in a vial as a powder for concentrate for solution for infusion. Each vial contains either 100 mg or 400 mg of siltuximab.

Ingredients

The active ingredient in SYLVANT is siltuximab. The other ingredients in SYLVANT are histidine, polysorbate-80, and sucrose.

Sponsor

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Registration Numbers

100mg vials
AUST R 229996

400mg vials
AUST R 229997

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