

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SYLVANT

SYLVANT contains the active ingredient siltuximab. SYLVANT is 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.

For more information, see Section [1. Why am I using SYLVANT?](#) in the full CMI.

2. What should I know before I use SYLVANT?

Do not use if you have ever had an allergic reaction to siltuximab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SYLVANT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SYLVANT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SYLVANT?

- SYLVANT will be prepared and given to you by a healthcare professional. SYLVANT is administered as an intravenous infusion.
- The infusion will be given to you over a period of about 1 hour. SYLVANT will be given every 3 weeks.

More instructions can be found in Section [4. How do I use SYLVANT?](#) in the full CMI.

5. What should I know while using SYLVANT?

Things you should do	<ul style="list-style-type: none">• Tell all 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.• Tell your doctor if you are pregnant or are planning to become pregnant before using SYLVANT. SYLVANT is not recommended for use during pregnancy.• Tell your doctor or nurse immediately if you have a severe allergic reaction during or after the infusion.• Tell your doctor immediately, if you get any signs of infection during treatment with SYLVANT.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how SYLVANT affects you.
Looking after your medicine	<ul style="list-style-type: none">• SYLVANT must be stored in the refrigerator (2°C-8°C). Heat and dampness can destroy some medicines.• Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while using SYLVANT?](#) in the full CMI.

6. Are there any side effects?

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Some side effects are serious like 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using SYLVANT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SYLVANT.**

Where to find information in this leaflet:

- [1. Why am I using SYLVANT?](#)
- [2. What should I know before I use SYLVANT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SYLVANT?](#)
- [5. What should I know while using SYLVANT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SYLVANT?

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.

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

Multicentric Castlemans 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.

2. What should I know before I use SYLVANT?

Warnings

Do not use SYLVANT if:

- you are allergic to siltuximab, or any of the 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.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have an infection at the moment.
- 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.
- 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.
- 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.
- have kidney disease.
- have liver disease or changes that show up in blood tests of the liver
- 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.

SYLVANT should be used with caution in some patients.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with SYLVANT and affect how it works.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SYLVANT.

4. How do I use 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 SYLVANT

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

If you are given too much SYLVANT

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 should immediately:

- phone the Poisons Information Centre **by calling**
Australia: **13 11 26**
New Zealand: **0800 POISON or 0800764766** or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SYLVANT?

Things you should do

Follow your doctor's instructions carefully.

Call your doctor straight away 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.
- 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.

Remind any doctor, dentist or pharmacist you visit that you are using SYLVANT.

Ask your doctor or pharmacist before taking any other medicines. These include herbal treatments and those bought in a pharmacy or supermarket.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Infection related</p> <ul style="list-style-type: none"> 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 <p>Skin related</p> <ul style="list-style-type: none"> itching rash or hives dry or red skin darkened areas of skin <p>Muscle related</p> <ul style="list-style-type: none"> pain, including joint, arm, leg, back or neck pain swelling in the arms, legs, neck or face <p>Body as a whole</p> <ul style="list-style-type: none"> weight gain <p>Gastrointestinal related</p> <ul style="list-style-type: none"> abdominal swelling stomach pain or discomfort constipation diarrhoea heartburn loss of appetite 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> nausea vomiting feeling thirsty <p>Nervous system related</p> <ul style="list-style-type: none"> feeling dizzy headache fever tiredness night sweats numbness or weakness in the arms, legs or muscles <p>Mental health related</p> <ul style="list-style-type: none"> feeling depressed feeling confused difficulty sleeping 	
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Serious side effects

Serious side effects	What to do
<p>Respiratory related</p> <ul style="list-style-type: none"> coughing, difficulty breathing and wheezing <p>Urinary related</p> <ul style="list-style-type: none"> urinary tract infection (smelly, dark or cloudy urine, burning or stinging while urinating) difficulty passing urine blood in urine or stools <p>Reproductive system related</p> <ul style="list-style-type: none"> prostate problems <p>Gastrointestinal related</p> <ul style="list-style-type: none"> sudden, severe pain in the upper right abdomen and upper back <p>Skin related</p> <ul style="list-style-type: none"> hot, tender and red skin, sometimes with fever and chills <p>Infection related</p> <ul style="list-style-type: none"> ear infection or pain fungal infection <p>Nervous system related</p> <ul style="list-style-type: none"> fainting <p>Immune related</p> <ul style="list-style-type: none"> swollen or enlarged lymph nodes <p>Eye related</p> <ul style="list-style-type: none"> blurred vision <p>Blood related</p> <ul style="list-style-type: none"> high fat or cholesterol levels in your blood 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>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.</p>

<ul style="list-style-type: none"> • high level of uric acid in the blood which may cause gout • abnormal kidney or liver function test • bleeding or bruising easily, including nose bleeds <p>Heart-related</p> <ul style="list-style-type: none"> • high blood pressure or low blood pressure • heart problems, including changes in heart beat <p>Signs of severe allergic (hypersensitivity) reaction like</p> <ul style="list-style-type: none"> • difficulty breathing, chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips, or skin rash. 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SYLVANT contains

Active ingredient (main ingredient)	siltuximab
Other ingredients (inactive ingredients)	histidine polysorbate-80 sucrose

Do not take this medicine if you are allergic to any of these ingredients.

What SYLVANT 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.

100mg vials: AUST R 229996

400 mg vials: AUST R 229997

Who distributes SYLVANT

Australia

Recordati Rare Diseases Australia Pty Ltd

Level 10

100 Arthur Street

North Sydney

NSW 2060

Australia

Phone: +61 (0) 408 061 403

rrdaustraliainfo@recordati.com

New Zealand

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AUCKLAND 1644

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