1.3.2.1 Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SYLVANT® 100 mg and 400 mg, powder for concentrate for solution for infusion

Siltuximab

Contains sugar. (SYLVANT 100 mg contains 186 mg of sucrose per vial and SYLVANT 400 mg contains 711 mg of sucrose per vial).

Read all of this leaflet carefully before you are given SYLVANT

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

SYLVANT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SYLVANT is and what it is used for

SYLVANT is used to treat Multicentric Castleman's Disease (MCD) in patients who do not have Human immunodeficiency virus (HIV) or human herpesvirus-8 (HHV-8) infection.

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

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 nodes and reduces symptoms of the illness, such as feeling tired, this should help you to carry out your normal daily tasks.

2. What you need to know before you receive SYLVANT

You should not receive SYLVANT:

- If you are hypersensitive (allergic) to siltuximab (SYLVANT) or any of the other ingredients of this medicine (listed in section 6). As with other medicines similar to SYLVANT, allergic reactions may occur.
- If you are pregnant or breastfeeding.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection 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 level 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 show up in blood tests of the liver;
- you get any new health problems or if any of them get worse.
- Allergic reactions:

Tell 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. (See also section 4.)

If any of the above apply to you (or you are unsure), talk to your doctor before you are given SYLVANT.

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 your treatment with SYLVANT immediately.

Children/ and adolescents

SYLVANT should not be administered to children under the age of 17.

Other medicines and SYLVANT

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

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

Pregnancy and breastfeeding and fertility

You should not receive SYLVANT if you are pregnant or breastfeeding your baby.

The safety of SYLVANT during pregnancy and whilst breastfeeding has not been established

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving SYLVANT.

It is not known if SYLVANT may affect the baby or a pregnant or breastfeeding 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.

You and your doctor should decide if you will take SYLVANT or breastfeed. It is not known if SYLVANT passes into breast milk.

Driving and using machinery

SYLVANT is not likely to affect you being able to drive, cycle, or use any tools or machines. It is not always possible to predict to what extent SYLVANT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SYLVANT affects them.

SYLVANT contains sucrose

SYLVANT contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SYLVANT.

3. How to give SYLVANT

Do not share medicines prescribed for you with any other person.

SYLVANT will be prepared and given to you by your doctor or nurse, in a hospital or clinic.

The usual dose is 11 mg/kg once every 3 weeks.

Your doctor will tell you how long your treatment with SYLVANT will last.

If you have the impression that the effect of SYLVANT is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself SYLVANT. It will be given to you by a person who is qualified to do so.

SYLVANT will be given as an “intravenous infusion” (a drip into a vein, usually in your arm).

It will be given slowly over a period of 1 hour.

During the infusion with SYLVANT you will be monitored for side effects.

If you receive more SYLVANT than you should

Since a healthcare professional will administer SYLVANT, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of SYLVANT

Since a health care provider will administer SYLVANT, it is unlikely that the dose will be missed.

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

SYLVANT can have side effects.

Not all side effects reported for SYLVANT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving SYLVANT, please consult your health care provider for advice.

If any of the following happens, stop receiving SYLVANT and tell your doctor immediately or go to the casualty department at your nearest hospital:

Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;

rash or itching;

fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SYLVANT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Signs of infection, e.g. redness, swelling, sore throat, coughing, feeling tired.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- drop in the number of white blood cells (neutropenia);
- drop in the number of platelets (thrombocytopenia);
- itchy skin rash (eczema);
- rash;
- high fat levels in your blood (hyperlipidaemia);
- high levels of cholesterol in the blood (hypercholesterolaemia),
- high level of ‘uric acid’ in the blood which may cause gout;
- abnormal kidney function test;
- swelling in the arms, legs, neck or face;
- high blood pressure;
- urinary tract infection;
- respiratory infections – such as of the nose, sinuses or throat;
- common cold;
- sore throat;
- stomach pain or discomfort;
- constipation;
- diarrhoea;
- heartburn;
- ulcers (sores) in the mouth;
- nausea;
- vomiting;
- feeling dizzy;
- headache;

- joint pain;
- arm or leg pain;
- weight gain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SYLVANT.

5. How to store SYLVANT

Store all medicines out of reach of children.

Store in a refrigerator between 2 °C – 8 °C.

Do not freeze.

Store in the original package in order to protect from light.

Do not use SYLVANT after the expiry date which is stated on the label and carton even if it is stored properly. The expiry date refers to the last day of that month.

Do not dispose unused medicine in drains or sewerage systems (e.g. toilets).

Do not store in a bathroom.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What SYLVANT contains:

The active substance is siltuximab.

The other ingredients are*:*

L-Histidine

L-Histidine monohydrochloride monohydrate

Polysorbate-80

Sucrose.

Contains sugar. (SYLVANT 100 mg contains 186 mg of sucrose per vial and SYLVANT 400 mg contains 711 mg of sucrose per vial).

What SYLVANT looks like and contents of the pack:

100 mg vial: The appearance of the lyophilised cake is a white solid with no meltback. The product is supplied (as a sterile, single-use lyophilised dosage form) in an 8R (8 mL) Type I clear colourless glass vial closed with a fluoropolymer coated 20 mm lyophilisation-type mist-grey stopper and a 20 mm silver aluminum seal with a flip-off button, packed in an outer carton.

400 mg vial: The appearance of the lyophilised cake is a white solid with no meltback. Once reconstituted, the solution is colourless and free of visible particulate matter. The product is supplied (as a sterile, single-use lyophilised dosage form) in a 30 mL Type I clear colourless glass vial closed with a fluoropolymer film coated 20 mm lyophilisation-type garnet stopper and a 20 mm silver aluminum seal with a flip-off button, packed in an outer carton.

Holder of Certificate of Registration and Manufacturer

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website