DARZALEX® SC

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 DARZALEX SC?

DARZALEX SC contains the active ingredient daratumumab. DARZALEX SC is used in adults who have a type of cancer called "multiple myeloma" (cancer of the bone marrow). DARZALEX SC is also used in adults who have a type of blood disorder called "AL amyloidosis".

For more information, see Section 1. Why am I using DARZALEX SC? in the full CMI.

2. What should I know before I use DARZALEX SC?

Do not use if you have ever had an allergic reaction to DARZALEX SC 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 DARZALEX SC? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DARZALEX SC 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 DARZALEX SC is given?

DARZALEX SC will be given to you by a doctor or nurse as an injection under your skin (subcutaneous injection). Your doctor will work out your dose and schedule of DARZALEX SC. The recommended dose of DARZALEX SC is 1800 mg. DARZALEX SC may be given alone or together with other medicines used to treat multiple myeloma or AL amyloidosis.

More instructions can be found in Section 4. How DARZALEX SC is given? in the full CMI.

5. What should I know while using DARZALEX SC?

Things you should do	• Call your doctor or nurse straight away if you experience any of the infusion-related reactions listed Section 6. Are there any side effects? • Women who are being given DARZALEX SC should use effective contraception during treatment and for 3 months after treatment. Tell your doctor immediately if you become pregnant or your partner becomes pregnant while being given DARZALEX SC. • Be sure to keep all your doctor's appointments so your progress can be checked. • If you need to have a blood test, tell the person doing the test that you are using DARZALEX SC. • Tell any other doctors, dentists and pharmacists who are treating you that you are using DARZALEX SC.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how DARZALEX SC affects you. You may feel tired after taking DARZALEX SC which may affect your ability to drive or use machines.

For more information, see Section 5. What should I know while using DARZALEX SC? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are infusion-related reactions (chills, sore throat, cough, nausea, vomiting, itchy, runny or blocked nose, feeling short of breath or other breathing problems). 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.

DARZALEX® SC

Active ingredient(s): *daratumumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DARZALEX SC. **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 DARZALEX SC.**

Where to find information in this leaflet:

1. Why am I using DARZALEX SC?
2. What should I know before I use DARZALEX SC?
3. What if I am taking other medicines?
4. How DARZALEX SC is given?
5. What should I know while using DARZALEX SC?
6. Are there any side effects?
7. Product details

1. Why am I using DARZALEX SC?

DARZALEX SC contains the active ingredient daratumumab. DARZALEX SC is an anti-cancer medicine and belongs to a group of medicines called "monoclonal antibodies". One of the ways monoclonal antibodies work is by attaching themselves to specific abnormal blood cells in your body, so your immune system can destroy them.

DARZALEX SC is used in adults who have a type of cancer called "multiple myeloma". This is a cancer of your bone marrow.

DARZALEX SC is also used in adults who have a type of blood disorder called "AL amyloidosis". In AL amyloidosis, abnormal blood cells make excessive amounts of abnormal proteins that deposit in various organs, causing these organs to not function properly.

2. What should I know before I use DARZALEX SC?

Warnings

Do not use DARZALEX SC if:

- you are allergic to daratumumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions, especially the following:
  - blood disorder with a low level of white blood cells or platelets. This disorder may become worse during treatment with DARZALEX SC.
  - Hepatitis B infection

    DARZALEX SC could cause hepatitis B virus to become active again. Your doctor will check you for signs of this infection before, during and for some time after treatment with DARZALEX SC.
- Sorbitol

  Sorbitol is a source of fructose. If you have hereditary fructose intolerance (HFI), a rare genetic disorder, you must not receive DARZALEX SC which contains sorbitol. Patients with HFI cannot break down fructose, which may cause serious side effects.

  You must tell your doctor before receiving this medicine if you have HFI.

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 5. What should I know while using DARZALEX SC? and 6. Are there any side effects?

Pregnancy and breastfeeding

Talk to your doctor or nurse before you are given DARZALEX SC if you are pregnant, think you might be pregnant or are planning to have a baby.

If you become pregnant while being treated with this medicine, tell your doctor or nurse right away. You and your doctor will decide if the benefit of having the medicine is greater than the risk to your baby.

Women who are being given DARZALEX SC should use effective contraception during treatment and for 3 months after treatment.

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

You and your doctor will decide if the benefit of breast-feeding is greater than the risk to your baby. This is because the medicine may pass into the mother's milk and it is not known how it will affect the baby.

Children and adolescents below 18 years of age

DARZALEX SC should not be given to children or young people below 18 years of age. This is because it is not known how the medicine will affect them.

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.

These medicines may be affected by DARZALEX SC or may affect how well DARZALEX SC works. Your doctor or pharmacist can tell you what to do if you are using any other medicines.

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

4. How DARZALEX SC is given?

How much is given:

Your doctor will work out your dose and schedule of DARZALEX SC. The recommended dose of DARZALEX SC is 1800 mg.

DARZALEX SC may be given alone or together with other medicines used to treat multiple myeloma, or with other medicines used to treat AL amyloidosis.

Ask your doctor if you want to know more about the dose of DARZALEX SC you receive.

How it is given

DARZALEX SC will be given to you by a doctor or nurse as an injection under your skin (subcutaneous injection) over approximately 3 to 5 minutes. It is given in the stomach area (abdomen), not in other sites of the body, and not into areas of the abdomen where the skin is red, bruised, tender, hard or where there are scars. If you experience pain during the injection, the doctor or nurse may interrupt the injection and give you the remaining injection in another area of your abdomen.

When it is give:

Your doctor will tell you when DARZALEX SC will be given. The frequency depends on whether it is given alone or together with other medicines used to treat multiple myeloma, or with other medicines used to treat AL amyloidosis.

Medicines given during treatment with DARZALEX SC:

DARZALEX SC may be given alone or together with other medicines used to treat multiple myeloma such as

- with bortezomib, thalidomide and dexamethasone, or
- with bortezomib, lenalidomide and dexamethasone, or
- with bortezomib, melphalan and prednisone, or
- with lenalidomide and dexamethasone or
- with bortezomib and dexamethasone, or
- with pomalidomide and dexamethasone, or
- with carfilzomib and dexamethasone.

DARZALEX SC may also be given together with other medicines used to treat AL amyloidosis (with bortezomib, cyclophosphamide and dexamethasone).

Read the Consumer Medicine Information for all medicines you take in combination with DARZALEX SC.

Before each injection of DARZALEX SC you will be given medicines which help to lower the chance of infusion-related reactions. These may include:

- medicines for an allergic reaction (anti-histamines)
- medicines for inflammation (corticosteroids)
- medicines for fever (such as paracetamol).

After each injection of DARZALEX SC you will be given medicines (such as corticosteroids) to lower the chance of infusion-related reactions.

You may also be given medicines to lower the chance of getting shingles.

People with breathing problems:

If you have breathing problems, such as asthma or Chronic Obstructive Pulmonary Disease (COPD), you may be given medicines to inhale which help your breathing problems:

- medicines to help the airways in your lungs stay open (bronchodilators)
- medicines to lower swelling and irritation in your lungs (corticosteroids)

What do I do if I receive too much? (overdose)

This medicine will be given by your doctor or nurse. In the unlikely event that you are given too much (an overdose) your doctor will check you for side effects.

If you forget your appointment to have DARZALEX SC

It is very important to go to all your appointments to make sure your treatment works. If you miss an appointment, make another one as soon as possible.

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

5. What should I know while using DARZALEX SC?

Things you should do

- **Be sure to keep all your doctor's appointments so your progress can be checked.** Your doctor will want to do some blood, urine and other tests from time to time to check on your progress and detect any unwanted side effects.
- **Keep follow up appointments with your doctor.** It is important to have your follow-up doses of DARZALEX SC at the appropriate times to get the best effects from your treatment.
- Be sure to follow your doctor's instructions about other medicines you should take, and other things you should do.
- Tell any other doctors, dentists and pharmacists who are treating you that you are using DARZALEX SC.
- If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are using DARZALEX SC.
- If you need to have a blood test, tell the person doing the test that you are using DARZALEX SC.
- If you become pregnant or your partner becomes pregnant while being given DARZALEX SC, tell your doctor immediately.

Decreased blood cell counts

DARZALEX SC can decrease white blood cell counts which help fight infections, and blood cells called platelets which help to clot blood.

Tell your doctor or nurse if you develop fever or if you have signs of bruising or bleeding.

Blood transfusions

If you need a blood transfusion, you will have a blood test first to match your blood type. DARZALEX SC can affect the results of this blood test. Tell the person doing the test that you are using DARZALEX SC.

Hepatitis B

If you have ever had a hepatitis B infection, DARZALEX SC could cause hepatitis B virus to become active again. Your doctor will check you for signs of this infection before, during and for some time after treatment with DARZALEX SC. Tell your doctor right away if you get increasingly tired or get yellowing of your skin or white part of your eyes.

Infusion-related reactions

Before and after each injection of DARZALEX SC, you will be given medicines which help to lower the chance of infusion-related reactions (see "Medicines given during treatment with DARZALEX SC").

These reactions are most likely to happen with the first injection and most reactions occur on the day of injection. If you have had an infusion-related reaction once it is less likely to happen again. However, delayed reactions can happen up to 3-4 days after the injection. Your doctor may decide not to use DARZALEX SC if you have a strong reaction after the injection.

In some cases you may have a severe allergic reaction which may include a swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing or an itchy rash (hives).

Tell your doctor or nurse right away if you get any of the infusion-related reactions listed under "Serious side effects" table below.

If you get infusion related reactions, you may need other medicines to treat your symptoms, or the injections may need to be stopped. When these reactions go away, or get better, the injection can be started again.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DARZALEX SC affects you.

You may feel tired after taking DARZALEX SC which may affect your ability to drive or use machines.

Looking after your medicine

DARZALEX SC is usually stored in the hospital, clinic or at the pharmacy.

Your doctor, pharmacist or nurse is responsible for storing this medicine and disposing of any unused product correctly.

Unopened vials:

DARZALEX SC should be stored in a refrigerator (2 to 8 degrees Celsius) and equilibrated to ambient temperature (15 to 30 degrees Celsius) before use. The unpunctured vial may be stored at ambient temperature and ambient light for a maximum of 24 hours.

Do not freeze.

Store in the original package to protect from light. Do not shake.

Prepared syringe:

If the syringe containing DARZALEX SC is not used immediately, it can be stored for up to 24 hours refrigerated followed by up to 12 hours at 15 to 25 degrees Celsius and ambient light. The syringe should be discarded if it is not used within 24 hours of being refrigerated or within 12 hours of being at 15 to 25 degrees Celsius. If stored in the refrigerator, allow the solution to come to ambient temperature before administration.

Keep this medicine out of the sight and reach of children.

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
Injection site reactions: • redness of the skin • itching • swelling • pain • bruising • rash • bleeding **Stomach or gut related:** • constipation • diarrhoea • decreased appetite • abdominal pain **Muscle or nerve related:** • muscle spasm • muscle and joint pain (including back pain and chest muscle pain) • nerve damage that may cause tingling, numbness or pain **Infection related:** • flu • lung infection (pneumonia) • bronchitis • infections of the airways – such as nose, sinuses or throat • COVID-19 infection • urinary tract infection	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• small blisters in clusters on the skin (herpes) • a type of herpes virus infection (cytomegalovirus infection) **Blood related:** • low number of red blood cells which carry oxygen in the blood (anaemia) • low number of white blood cells which help fight infections (neutropenia, lymphopenia, leukopenia) • low number of a type of blood cell called platelets which help to clot blood (thrombocytopenia) • high level of sugar in the blood • low level of calcium in the blood • low level of potassium in the blood • low level of antibodies called 'immunoglobulins' in the blood which help fight infections (hypogammaglobulinemia). **Others:** • fever • feeling very tired or weak • feeling dizzy • fainting • headache • rash • dehydration • difficulty sleeping • chills • itching • unusual feeling in the skin (such as tingling or crawling feeling) • high blood pressure • low blood pressure • weight loss • swollen hands, ankles or feet • build up of fluid in the lungs making you short of breath	

Serious side effects

Serious side effects	What to do
Infusion-related reactions: • chills • sore throat, cough • feeling sick (nausea) • vomiting • itchy, runny or blocked nose	**Tell your doctor or nurse right away if you get any of the signs of an infusion-related reaction up to 3-4 days after the injection. You may need other medicines, or the injection may need to be interrupted or stopped.**
Heart related: • irregular heartbeat (atrial fibrillation) • heart disorders (heart failure, heart attack)	**Tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital.**
Infection related: • severe infection throughout the body (sepsis) • inflamed liver (hepatitis) • inflamed pancreas	

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 DARZALEX SC contains

Active ingredient (main ingredient)	daratumumab 1800 mg (120 mg/mL)
Other ingredients (inactive ingredients)	• vorhyaluronidase alfa • histidine • histidine hydrochloride monohydrate • sorbitol • methionine • polysorbate 20 • water for injections

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

What DARZALEX SC looks like

DARZALEX SC is a colourless to yellow, clear to opalescent, preservative-free solution for subcutaneous administration.

DARZALEX SC is supplied as a carton pack containing one single use glass vial. (Aust R 322685).

Who distributes DARZALEX SC

JANSSEN-CILAG Pty Ltd

17 Khartoum Rd

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

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