

DARZALEX[®] SC

Solution for injection

Daratumumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DARZALEX SC Solution for injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given DARZALEX SC against the benefits this medicine is expected to have for you.

If you have any concerns about being given DARZALEX SC ask your doctor.

Keep this leaflet while you are being treated with DARZALEX SC.

You may need to read it again.

What DARZALEX SC is used for

DARZALEX SC is an anti-cancer medicine and contains the active substance daratumumab. This belongs to a group of

medicines called “monoclonal antibodies”. One of the ways monoclonal antibodies work is by attaching themselves to specific cancer cells in your body, so your immune system can destroy them.

DARZALEX SC is used to treat adults with multiple myeloma (cancer of the bone marrow).

Your doctor may have prescribed DARZALEX SC for another reason.

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

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

Before you are given DARZALEX SC

When you must not use it:

Do not use DARZALEX SC if:

- you know you are allergic (hypersensitive) to daratumumab or other ingredients of DARZALEX SC. See Product Description at the end of this leaflet for a list of ingredients.

Symptoms of an allergic reaction may include 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.

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.

Before you start to use it:

Tell your doctor if you have or have had any 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.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, DARZALEX SC is not recommended for use during pregnancy.

Tell your doctor if you are trying to make your partner pregnant.

Both men and women receiving DARZALEX SC and their partners must use a reliable method of contraception during and for 3 months after ceasing treatment with DARZALEX SC.

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

It is not known whether DARZALEX SC passes into breast milk. Therefore there is a possibility that the breastfed baby may be affected.

If you wish to restart breastfeeding after your DARZALEX SC treatment, you must discuss this with your doctor or nurse, who will tell you when it is safe to do so.

If you have not told your doctor about any of the above, tell them before you start treatment with DARZALEX SC.

Taking other medicines:

Tell your doctor if you are taking any other medicines, including vitamins and herbal supplements and including medicines you can buy with or without a prescription from a 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.

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.

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 given:

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.

Medicines given during treatment with DARZALEX SC:

DARZALEX SC may be given alone or together with other medicines used to treat multiple myeloma (with bortezomib, thalidomide and dexamethasone, or with bortezomib, melphalan and prednisone, or with lenalidomide and dexamethasone or with bortezomib 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.

While you are using DARZALEX SC

Things you must 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 become pregnant or your partner becomes pregnant while being given DARZALEX SC, tell your doctor immediately.

If you need to have a blood test, tell the person doing the test that you are using DARZALEX SC.

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 if you develop fever or if you have signs of bruising or bleeding.

The following precautions should be taken to reduce your risk of infection or bleeding:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat,

lower back or side pain or find it is painful or difficult to urinate.

- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.

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 at the top of the Side Effects section.

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.

Things to be careful of

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

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

Side Effects

Like all medicines, DARZALEX SC can cause side effects, although not everybody gets them. Some of these effects may be serious. However, there may be ways to reduce the discomfort of these effects. You may need medical treatment if you get some of the side effects.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with DARZALEX SC.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Below is a list of the more common side effects that you could get while being treated with DARZALEX SC:

- Infusion-related reactions

Tell your doctor or nurse right away if you get any of the following 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.

- chills
- sore throat, cough
- feeling sick (nausea)

- vomiting
- itchy, runny or blocked nose
- feeling short of breath or other breathing problems
- chest discomfort
- dizziness or light-headedness (hypotension)
- itching
- wheezing

If you get any of the infusion-related reactions above, tell your doctor or nurse right away.

- **Injection site reactions**

Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX SC.

These reactions may include:

- redness of the skin
- itching
- swelling

- **Other side effects**

- fever
- chills

- feeling very tired
- feeling weak
- feeling dizzy
- flu
- headache
- diarrhoea
- constipation
- decreased appetite
- difficulty sleeping
- nerve damage that may cause tingling, numbness or pain
- muscle spasms
- swollen hands, ankles or feet
- other pain (eg back, joints)
- lung infection (pneumonia)
- bronchitis
- infections of the airways – such as nose, sinuses or throat
- build-up of fluid in the lungs making you short of breath

- 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
- irregular heart beat (atrial fibrillation)
- urinary tract infection
- severe infection throughout the body (sepsis)
- dehydration
- chest pain
- high blood pressure
- rash, itching
- inflamed liver (hepatitis)
- inflamed pancreas
- small blisters in clusters on the skin (herpes)
- a type of herpes virus infection (cytomegalovirus infection)

- unusual feeling in the skin (such as tingling or crawling feeling)

If you think you are having an allergic reaction to DARZALEX SC, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

Symptoms usually include some or all of the following:

- 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

Other side effects not listed above may also occur in some people.

Tell your doctor, nurse or pharmacist if you notice any other effect that is making you feel unwell.

Product Description

Storage

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 4 hours at ambient temperature (15 to 30 degrees Celsius) and ambient light. The syringe should be discarded if it is not used within 4 hours of storage at ambient temperature and ambient light,

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

What it looks like:

DARZALEX SC is available as 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.

Ingredients

Active ingredient:

- daratumumab 1800 mg (120 mg/mL)

Other ingredients:

- vorhyaluronidase alfa

- histidine
- histidine hydrochloride monohydrate
- sorbitol
- methionine
- polysorbate 20
- water for injections.

Sponsor

JANSSEN-CILAG Pty Ltd

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Registration numbers

DARZALEX SC 1800 mg/15mL (AUST R 322685)

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