

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrDARZALEX® SC

daratumumab injection

1800 mg/15 mL (120 mg/mL) Solution for Subcutaneous Injection

Read this carefully before you start taking Darzalex SC (Dar'-zah-lex) and each time you get an injection. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Darzalex SC.

What is Darzalex SC used for?

Darzalex SC is used in adults 18 years or older to treat:

- A type of cancer called multiple myeloma. This is a cancer of your plasma cells which are found in your bone marrow.
- Patients newly diagnosed with a blood disorder called light chain (AL) amyloidosis. In AL amyloidosis, abnormal blood cells make excessive amounts of abnormal protein that deposit in various organs, causing these organs to not function properly.

How does Darzalex SC work?

Darzalex SC contains the active substance daratumumab. Daratumumab belongs to a group of medicines called monoclonal antibodies. Daratumumab attaches to myeloma cells and works in multiple ways to kill the cancer cells. You may be prescribed Darzalex SC with other multiple myeloma medicines, or you may have used other multiple myeloma drugs previously. Darzalex SC works differently compared to these other medicines. In AL amyloidosis, daratumumab attaches to specific abnormal blood cells in our body so your immune system can destroy them.

What are the ingredients in Darzalex SC?

Medicinal ingredients: daratumumab.

Non-medicinal ingredients: recombinant human hyaluronidase (rHuPH20), L-histidine, L-histidine hydrochloride monohydrate, sorbitol, L-methionine, polysorbate 20, water for injection.

Darzalex SC comes in the following dosage form:

Darzalex SC is provided as a solution that is administered by subcutaneous (under the skin) injection. It comes in 15 mL vials. Each vial of solution contains 1800 mg of daratumumab (120 mg/mL).

Do not use Darzalex SC if:

- You are allergic to daratumumab or any of the other ingredients in Darzalex SC.

If you are not sure, talk to your doctor or nurse before you are given Darzalex SC.

To help avoid side effects and ensure proper use, talk to your healthcare professional

before you are given Darzalex SC. Talk about any health conditions or problems you may have, including if:

- You are pregnant, think you might be pregnant or are planning to have a baby. If you become pregnant while being treated with Darzalex SC, tell your doctor or nurse immediately. You and your doctor will decide if the benefit of receiving Darzalex SC is greater than the risk to your baby. Women who are being treated with Darzalex SC must use effective contraception during treatment and for at least 3 months after treatment. Darzalex SC may harm your unborn baby.
- You are producing breast milk. 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 if it will affect the baby.
- You have breathing problems, such as asthma or Chronic Obstructive Pulmonary Disease (COPD). You will be given medicines to inhale which will help if you have breathing problems after the injection:
 - medicines to help the airways in your lungs stay open (bronchodilators)
 - medicines to lower swelling and irritation in your lungs (corticosteroids)
- You had shingles (herpes zoster).
- You had or might now have a hepatitis B virus infection
- You have a history of heart problems. Darzalex SC should not be used in light chain (AL) amyloidosis patients with highly advanced heart disease outside of clinical trials.

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

Other warnings you should know about:

Infusion-related reactions (systemic reactions related to administration):

Before and after each injection of Darzalex SC, you will be given medicines that help to lower the chance of infusion-related reactions. These reactions can happen when you are given the medication or in the 3 days after the injection. These reactions are most likely to happen at the first injection.

Tell your doctor or nurse immediately if you get any of the symptoms of an infusion-related reaction. These symptoms include:

- chills
- sore throat/throat tightness
- fever
- cough
- feeling sick
- itchy, runny or blocked nose
- feeling short of breath or other breathing problems including wheezing
- increased blood pressure
- dizziness or light-headedness
- headache
- rash or hives

- nausea
- vomiting
- itchiness

Although rare, you may have a severe allergic reaction. Tell your doctor or nurse immediately if you get any of the symptoms of a severe allergic reaction, which include:

- swollen face, lips, mouth, tongue or throat
- difficulty swallowing or breathing
- an itchy rash (hives)

Your doctor may decide not to use Darzalex SC if you have a severe infusion-related reaction.

Injection site reactions:

Skin reactions at or near the injection site (local), including injection site reactions, can happen with Darzalex SC. Symptoms may include itching, swelling, pain, bruising, bleeding, or redness of the skin.

Infections:

Darzalex SC may increase the occurrence of infections. These infections could be severe, life-threatening or potentially fatal. Tell your healthcare provider if you develop fever, feel very tired, have a cough or have flu-like symptoms.

Hepatitis B virus

Tell your doctor if you have ever had or might now have a hepatitis B virus infection. This is because 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 worsening tiredness or yellowing of your skin or white part of your eyes.

Heart problems in patients with light chain (AL) amyloidosis:

Heart problems, in some cases fatal, have occurred. Your healthcare provider will monitor you closely during treatment with Darzalex SC. Call your healthcare provider right away if any of the following symptoms occur: chest pain, feeling faint, swollen legs, shortness of breath, or abnormal heart rhythm.

Changes in blood tests:

Darzalex SC can affect the results of blood tests to match your blood type. This interference can last for up to 6 months after your final dose of Darzalex SC. Your healthcare provider should do blood tests to match your blood type before you start treatment with Darzalex SC. Tell all of your healthcare providers that you are being treated with Darzalex SC before receiving blood transfusions.

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

Pregnancy:

Lenalidomide is expected to be harmful for an unborn baby. When Darzalex SC is given in combination with lenalidomide, you must also read the patient medication information for lenalidomide. When lenalidomide is used, you must follow the pregnancy prevention programme for lenalidomide. Bortezomib may cause harm for an unborn baby. When Darzalex SC is given in combination with bortezomib, you must also read the patient medication information for bortezomib. Cyclophosphamide may cause harm for an unborn baby. When Darzalex SC is given in combination with cyclophosphamide, you must also read the patient medication information for cyclophosphamide.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How you will be treated with Darzalex SC:

Darzalex SC will be given to you by a doctor or nurse. It is given as an injection under your skin (“subcutaneous injection”) over approximately 3 to 5 minutes. It is given in the stomach area (abdomen).

Usual dose:

The usual dose of Darzalex SC is 1800 mg of daratumumab (1800 mg/15 mL). Darzalex SC may be given alone or together with other medicines used to treat multiple myeloma (i.e. bortezomib, lenalidomide, dexamethasone, melphalan, or prednisone). For AL amyloidosis, Darzalex SC is given with bortezomib, cyclophosphamide and dexamethasone.

When given alone or with some medicines, Darzalex SC is given as follows:

- once a week for the first 6, 8 or 9 weeks
- then once every 2 or 3 weeks for 15, 16 or up to 48 weeks
- then once every 4 weeks after that as long as your condition does not worsen

Depending on which other medicines Darzalex SC is given together with, your doctor may change the time between doses as well as how many treatments you will receive.

Other medicines given during treatment with Darzalex SC:

Before each injection of Darzalex SC you will be given other medicines that 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 acetaminophen)

After each injection of Darzalex SC you will be given other medicines (such as corticosteroids) to lower the chance of a reaction after your injection.

People with breathing problems:

If you have breathing problems, such as asthma or Chronic Obstructive Pulmonary Disease (COPD), you will 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)

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

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 think you have been given too much Darzalex SC contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

It is very important to go to all your appointments. If you miss an appointment, tell your doctor and make another one as soon as possible.

What are possible side effects from using Darzalex SC?

Darzalex SC is generally well-tolerated, however, like all medicines, this medicine can cause side effects.

These are not all the possible side effects you may feel when taking Darzalex SC. If you experience any side effects not listed here, contact your healthcare professional.

Side effects of Darzalex SC (taken alone or in combination with other drugs) that may affect more than 1 in 5 people ($\geq 20\%$) include:

- feeling tired
- nausea
- diarrhea
- constipation
- back pain
- cough
- low number of red blood cells (anemia)
- low number of white blood cells (neutropenia)
- low number of a type of blood cell called platelets (thrombocytopenia)
- fever
- swelling
- infections of the airways – such as nose, sinuses or throat
- peripheral sensory neuropathy (numbness or tingling in feet or hands)

Other side effects affecting more than 1 in 20 people ($\geq 5\%$) include:

- chills
- muscle spasms
- headache
- dizziness

- loss of appetite
- feeling very weak
- difficulty falling asleep
- vomiting
- stomachache
- pain in the chest, arms, legs, muscles, joints, or bones
- pain in the mouth or throat
- rash or itchy skin
- lung infection (such as pneumonia)
- flu or flu-like illness, stuffy nose
- prickling or burning sensation on the skin (paresthesia)
- trembling or shaking hands (tremor)
- altered taste
- urinary tract infection
- low number of white blood cells (lymphopenia, leukopenia)
- decrease in levels of calcium in your blood
- decrease in levels of potassium in your blood
- increase in blood sugar
- increased (hypertension) or decreased (hypotension) blood pressure
- anxiety or depression
- kidney impairment
- shortness of breath (including due to build-up of fluid in the lungs)
- weight decrease
- blurry vision

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Very Common (more than 1 in 10)			
Low number of blood cells such as: <ul style="list-style-type: none"> • platelets (thrombocytopenia) • white blood cells (neutropenia) • red blood cells (anemia) (symptoms like fatigue, loss of energy, weakness, shortness of breath)		✓	
Upper respiratory tract infections (infected nose, sinuses or throat; cold)		✓	
Common (less than 1 in 10 but more than 1 in 100)			

<p>Infusion-related reactions. Symptoms can include:</p> <ul style="list-style-type: none"> • chills • sore throat, cough • feeling sick • itchy, runny or blocked nose • feeling short of breath or other breathing problems • increased blood pressure 			✓
<p>Lung infections such as:</p> <ul style="list-style-type: none"> • pneumonia • flu • bronchitis • lower respiratory tract infections (symptoms of lung infections may include congestion, cough, sore throat, body ache, tiredness and fever) 		✓	
<p>Infections such as:</p> <ul style="list-style-type: none"> • sepsis or septic shock (symptoms like high fever, increased heart rate or breathing, and confusion) • urinary tract infection (symptoms like pain or burning when urinating, bloody or cloudy or foul smelling urine) 		✓	
High fever		✓	
Irregular or rapid heartbeat (atrial fibrillation)		✓	
Bleeding problems (symptoms like blood in your stools, coughing up blood)		✓	
Severe diarrhea (symptoms like increased number of bowel movements, watery or bloody stool, stomach pain and/or cramps)		✓	
Inflamed pancreas (pancreatitis; symptoms may include abdominal pain, fever, nausea, vomiting)		✓	
Uncommon (less than 1 in 100 but more than 1 in 1,000)			
A type of herpes virus infection called cytomegalovirus infection, which can cause fever, sore throat, fatigue or swollen glands. This virus can cause infections in other parts of the body, such as the lung (cough or breathing		✓	

trouble), eyes (change in vision or eye pain), and intestines (diarrhea or stomach pain).			
Rare (less than 1 in 1,000 but more than 1 in 10,000)			
Severe allergic reaction. Symptoms can include: <ul style="list-style-type: none"> swollen face, lips, mouth, tongue or throat difficulty swallowing or breathing an itchy rash (hives) 			✓

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Darzalex SC will be stored in a refrigerator at 2-8°C.

If you want more information about Darzalex SC:

- Talk to your healthcare professional
- For questions or concerns, please contact the manufacturer, Janssen Inc., at www.janssen.com/canada
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer’s website (<http://www.janssen.com/canada>), or by calling 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by:

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Last Revised: April 2021

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