

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr **DARZALEX**[®] **daratumumab concentrate for solution for infusion**

Read this carefully before you start taking **DARZALEX**[®] (Dar'-zah-lex) and each time you get an infusion. 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**[®].

What is DARZALEX[®] used for?

DARZALEX[®] 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.

How does DARZALEX[®] work?

DARZALEX[®] 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**[®] with other multiple myeloma medicines, or you may have used other multiple myeloma drugs previously. **DARZALEX**[®] works differently compared to these other medicines.

What are the ingredients in DARZALEX[®]?

Medicinal ingredients: daratumumab.

Non-medicinal ingredients: glacial acetic acid, sodium acetate trihydrate, sodium chloride, mannitol, polysorbate 20, water for injection.

DARZALEX[®] comes in the following dosage forms:

DARZALEX[®] is provided as a concentrate that must be diluted in a sodium chloride solution and is then administered by intravenous infusion. It comes in vials. Each vial of 5 mL concentrate contains 100 mg of daratumumab (concentration of 20 mg/mL). Each vial of 20 mL concentrate contains 400 mg of daratumumab (concentration of 20 mg/mL).

Do not use DARZALEX[®] if:

- You are allergic to daratumumab or any of the other ingredients in **DARZALEX**[®].

If you are not sure, talk to your doctor or nurse before you are given **DARZALEX**[®].

To help avoid side effects and ensure proper use, talk to your healthcare professional before you are given DARZALEX[®]. 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**[®], tell your doctor or nurse immediately. You and your doctor will decide if the benefit of receiving **DARZALEX**[®] is greater than the risk to your baby. Women who are being treated with **DARZALEX**[®] must use effective

contraception during treatment and for at least 3 months after treatment. DARZALEX[®] 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 infusion:
 - 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 infection

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

Other warnings you should know about:

Infusion-related reactions:

Before and after each infusion of DARZALEX[®], you will be given medicines that help to lower the chance of infusion-related reactions. These reactions can happen during the infusion or in the 3 days after the infusion. These reactions are most likely to happen at the first infusion.

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)

If you have an infusion-related reaction, you may need other medicines, or the infusion may need to be slowed down or stopped. When these reactions go away or get better, the infusion can be started again. Your doctor may decide not to use DARZALEX[®] if you have a severe infusion-related reaction.

Infections:

DARZALEX[®] 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

Tell your doctor if you have ever had or might now have a hepatitis B infection. This is because DARZALEX[®] 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[®]. Tell your doctor right away if you get worsening tiredness or yellowing of your skin or white part of your eyes.

Changes in blood tests:

DARZALEX[®] 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[®]. Your healthcare provider should do blood tests to match your blood type before you start treatment with DARZALEX[®]. Tell all of your healthcare providers that you are being treated with DARZALEX[®] before receiving blood transfusions.

Decreased blood cell counts:

DARZALEX[®] 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[®] 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[®] is given in combination with bortezomib, you must also read the patient medication information for bortezomib.

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[®]:

DARZALEX[®] will be given to you by a doctor or nurse. It is given over several hours as a drip into a vein (“intravenous infusion”).

Usual dose:

Your doctor will determine your dose of DARZALEX[®]. This will depend on your body weight.

The usual starting dose of DARZALEX[®] is 16 mg of daratumumab per kilogram of body weight. DARZALEX[®] may be given alone or together with other medicines used to treat multiple myeloma (i.e. bortezomib, lenalidomide, dexamethasone, melphalan, or prednisone).

When given alone or with some medicines, DARZALEX[®] 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[®] is given together with, your doctor may change the time between doses as well as how many treatments you will receive.

In the first week your doctor may give you the DARZALEX[®] dose split over two consecutive days.

Other medicines given during treatment with DARZALEX[®]:

Before each infusion of DARZALEX[®] 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 infusion of DARZALEX[®] you will be given other medicines (such as corticosteroids) to lower the chance of a reaction after your infusion.

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[®] 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®?

DARZALEX® 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®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects of DARZALEX® (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
- stomach ache
- 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)		✓	
Common (less than 1 in 10 but more than 1 in 100)			
Infusion-related reactions. Symptoms can include: <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 			✓
Lung infections such as: <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)		✓	
Infections such as: <ul style="list-style-type: none"> • sepsis or septic shock (symptoms like high fever, increased heart rate or breathing, and confusion) 		✓	

<ul style="list-style-type: none"> 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)		✓	
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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect[®] (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect[®] (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting).

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[®] will be stored in a refrigerator at 2-8°C.

If you want more information about DARZALEX[®]:

- 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:

Janssen Inc.

Toronto, Ontario, M3C 1L9

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