

Darzalex® 20 mg/mL concentrate for solution for infusion

Abbreviated Prescribing Information

Therapeutic Indication:

What DARZALEX is

DARZALEX is a cancer medicine that contains the active substance daratumumab. It belongs to a group of medicines called “monoclonal antibodies”. Monoclonal antibodies are proteins that have been designed to recognise and attach to specific targets in the body. Daratumumab has been designed to attach to specific cancer cells in your body, so that your immune system can destroy the cancer cells.

What DARZALEX is used for

DARZALEX is used in adults 18 years or older, who have a type of cancer called “multiple myeloma”. This is a cancer of your bone marrow.

Dose:

Your doctor will work out your dose and schedule of DARZALEX. The dose of DARZALEX will depend on your body weight. The usual starting dose of DARZALEX is 16 mg per kg of body weight. DARZALEX may be given alone or together with other medicines used to treat multiple myeloma.

When given alone, DARZALEX is given as follows:

- once a week for the first 8 weeks
- then once every 2 weeks for 16 weeks
- then once every 4 weeks after that as long as your condition does not worsen.

When DARZALEX is given together with other medicines 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.

How the medicine is given

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

Contraindications:

You must not be given DARZALEX

- if you are allergic to daratumumab or any of the other ingredients of this medicine.

Do not use DARZALEX if the above applies to you. If you are not sure, talk to your doctor or nurse before you are given DARZALEX.

Warnings and precautions

Talk to your doctor or nurse before you are given DARZALEX.

Infusion related reactions

DARZALEX is given as an infusion (drip) into a vein. Before and after each infusion of DARZALEX, you will be given medicines which help to lower the chance of infusion related reactions. These reactions can happen during the infusion or in the 3 days after the infusion.

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). Some serious allergic reactions and other severe infusion-related reactions have resulted in death.

Tell your doctor or nurse straight away if you get any of the infusion related reactions.

If you get infusion related reactions, 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.

These reactions are most likely to happen with the first infusion. If you have had an infusion related reaction once it is less likely to happen again. Your doctor may decide not to use DARZALEX if you have a strong infusion reaction.

Children and adolescents

Do not give DARZALEX to children or adolescents below 18 years of age. This is because it is not known how the medicine will affect them.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

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

Contraception

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

Breast feeding

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.

Driving and using machines

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

DARZALEX contains sodium

This medicine contains 9.3 mg sodium (main component of cooking/table salt) in each 5 mL vial. This is equivalent to 0.46% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 37.3 mg sodium (main component of cooking/table salt) in each 20 mL vial. This is equivalent to 1.86% of the recommended maximum daily dietary intake of sodium for an adult.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Infusion related reactions

Tell your doctor or nurse straight away if you get any of the following signs of an infusion related reaction during or in the 3 days after the infusion. You may need other medicines, or the infusion may need to be slowed down or stopped.

These reactions include the following symptoms:

Very common (may affect more than 1 in 10 people):

- chills
- sore throat, cough
- feeling sick (nausea)
- vomiting
- itchy, runny or blocked nose
- feeling short of breath or other breathing problems.

Common (may affect up to 1 in 10 people):

- chest discomfort
- dizziness or lightheadedness (hypotension)
- itching
- wheezing.

Rare (may affect up to 1 in 1000 people):

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

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

Other side effects

Very common (may affect more than 1 in 10 people):

- fever
 - feeling very tired
 - diarrhoea
 - constipation
 - decreased appetite
 - headache
 - nerve damage that may cause tingling, numbness, or pain
 - high blood pressure
 - muscle spasms
 - swollen hands, ankles or feet
 - feeling weak
 - back pain
 - chills
 - lung infection (pneumonia)
 - bronchitis
 - infections of the airways – such as nose, sinuses or throat
 - 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)
 - unusual feeling in the skin (such as a tingling or crawling feeling).
- Common** (may affect up to 1 in 10 people):
- irregular heart beat (atrial fibrillation)
 - build up of fluid in the lungs making you short of breath
 - flu
 - urinary tract infection
 - severe infection throughout the body (sepsis)
 - dehydration
 - fainting
 - high level of sugar in the blood
 - low level of calcium in the blood
 - low level of antibodies called ‘immunoglobulins’ in the blood which help fight infections (hypogammaglobulinemia)
 - inflamed pancreas
 - type of herpes virus infection (cytomegalovirus infection).
- Uncommon** (may affect up to 1 in 100 people) :
- inflamed liver (hepatitis).

Always read the full prescribing information.

Other less common side effects are listed in the full prescribing information.

Healthcare professionals are asked to report any suspected adverse reaction.

Darzalex Prescribing Information approval date 5/4/2022.



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