

DARZALEX[®]

Concentrate for solution for infusion

Daratumumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DARZALEX Concentrate for Solution for Infusion. 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 against the benefits this medicine is expected to have for you.

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

Keep this leaflet while you are being treated with DARZALEX.

You may need to read it again.

What DARZALEX is used for

DARZALEX 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 is used to treat adults with multiple myeloma (cancer of the bone marrow). It is prescribed for patients who have received one or more prior treatments.

Your doctor may have prescribed DARZALEX for another reason.

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

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

Before you are given DARZALEX

When you must not use it:

Do not use DARZALEX if:

- you know you are allergic (hypersensitive) to daratumumab or other ingredients of DARZALEX. 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, difficulty swallowing, swelling of the face, lips, mouth, tongue, throat or other parts of the body.

DARZALEX 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.

- Hepatitis B infection
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 if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, DARZALEX 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 and their partners must use a reliable method of contraception during and for 3 months after ceasing treatment with DARZALEX.

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

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

If you wish to restart breast-feeding after your DARZALEX 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.

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

How DARZALEX is given

How much is given:

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.

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

How it is given:

DARZALEX will be given to you by a doctor or nurse.

DARZALEX will be dissolved in sterile normal sodium chloride (salt) solution for injection.

It is given over several hours as a drip into a vein (“intravenous infusion”).

When it is given:

When given alone or with some medicines, 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
- DARZALEX may also be given with some medicines as follows:

- once a week for the first 9 weeks
- then once every 3 weeks for 15 weeks
- then once every 4 weeks after that

Medicines given during treatment with DARZALEX:

DARZALEX may be given alone or together with other medicines used to treat multiple myeloma (with lenalidomide and dexamethasone or with bortezomib and dexamethasone).

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

You may be given medicines to lower the chance of getting shingles. Before each infusion of DARZALEX 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 infusion of DARZALEX you will be given medicines by mouth (such as corticosteroids) to lower the chance of infusion reactions.

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:

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

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 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 having DARZALEX.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are having DARZALEX.

If you become pregnant or your partner becomes pregnant while

being given DARZALEX, tell your doctor immediately.

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

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 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 can affect the results of this blood test. Tell the person doing the test that you are using DARZALEX.

Hepatitis B

If you have ever had a hepatitis B infection, 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 increasingly tired or get yellowing of your skin or white part of your eyes.

Infusion-related reactions

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

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, 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 continue DARZALEX if you have a strong infusion reaction.

Things to be careful of

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

DARZALEX may cause tiredness and other effects in some people. Make sure you know how you react to DARZALEX 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 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.

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 you could get while being treated with DARZALEX:

– Infusion-related reactions

Tell your doctor or nurse right 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.

- chills
- sore throat, cough
- nausea
- vomiting
- itchy, runny or blocked nose
- feeling short of breath or other breathing problems
- chest discomfort
- dizziness or light-headedness (hypotension)
- itching
- wheezing
- severe allergic reaction (see below for symptoms)

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

- If you think you are having an allergic reaction to DARZALEX, 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
- difficulty swallowing
- swelling of the face, lips, mouth, tongue, throat or other parts of the body

– **Other side effects**

- fever
- feeling very tired
- flu
- headache
- diarrhoea
- constipation
- nerve damage that may cause tingling, numbness or pain
- muscle spasms
- swollen hands, ankles or feet
- lung infection (pneumonia)
- 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)
- low number of a type of blood cell called platelets which help to clot blood (thrombocytopenia)
- irregular heart beat (atrial fibrillation)
- chest pain
- other pain (eg back, joints)
- inflamed liver (hepatitis)
- small blisters in clusters on the skin (herpes)
- rash, itching

- redness of the skin or redness and pain at injection site
- decreased appetite

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 should be stored in a refrigerator (2 degrees to 8 degrees Celsius).

Do not freeze.

Store in the original package to protect from light.

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

What it looks like:

DARZALEX is available as a colourless to yellow, preservative free liquid concentrate for intravenous infusion after dilution.

DARZALEX is supplied as a carton pack containing one single-use glass vial.

Ingredients

Active ingredient:

- daratumumab 100 mg
(for DARZALEX 20mg/mL 5mL vials) OR
- daratumumab 400 mg
(for DARZALEX 20mg/mL 20mL vials)

Other ingredients:

- glacial acetic acid
- mannitol
- polysorbate 20

- sodium acetate trihydrate
- sodium chloride
- water for injection.

Sponsor

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