Package leaflet: Information for the patient

DARZALEX 1,800 mg solution for injection
daratumumab

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What DARZALEX is and what it is used for
2. What you need to know before you are given DARZALEX
3. How DARZALEX is given
4. Possible side effects
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1. What DARZALEX is and what it is used for

What DARZALEX is
DARZALEX is a 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 abnormal blood cells in your body, so that your immune system can destroy these 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.

DARZALEX is also used in adults 18 years or older, who have a type of blood disorder called "AL amyloidosis." In AL amyloidosis, abnormal blood cells make excessive amounts of abnormal proteins that deposit in various organs, causing these organs to not function properly.

2. What you need to know before you are given DARZALEX

You must not be given DARZALEX
- if you are allergic to daratumumab or any of the other ingredients of this medicine (listed in section 6).

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 a subcutaneous injection using a small needle to inject the medicine under your skin. Before and after each injection, you will be given medicines which help to lower the chance of infusion-related reactions (see "Medicines given during treatment with DARZALEX" in section 3). 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 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). See section 4.

Tell your doctor or nurse straight away if you get any of the infusion-related reactions or related symptoms listed at the top of section 4. 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.

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 any symptoms of infection such as fever or any symptoms of decreased platelet counts such as bruising or bleeding.

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
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.

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.

Other medicines and DARZALEX
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines you can get without a prescription, and herbal medicines.

Pregnancy
If you are pregnant, think you maybe 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 solution for subcutaneous injection contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 15 mL, that is to say essentially 'sodium-free'.

DARZALEX solution for subcutaneous injection contains sorbitol
Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take this medicine.

3. How DARZALEX is given

How much is given
The dose of DARZALEX solution for subcutaneous injection is 1,800 mg.

DARZALEX may be given alone or together with other medicines used to treat multiple myeloma, or with other medicines used to treat AL amyloidosis. DARZALEX is usually 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.

How the medicine is given
DARZALEX 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.

Medicines given during treatment with DARZALEX
You may be given medicines to lower the chance of getting shingles.

Before each injection 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 injection of DARZALEX you will be given medicines (such as corticosteroids) to lower the chance of infusion-related reactions.

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).

If you are given more DARZALEX than you should
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.

4. 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 symptoms within 3-4 days after the injection. You may need other medicines, or the injection may need to be interrupted 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 1,000 people):
- severe allergic reaction which may include a swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing or an itchy rash (hives). See section 2.
- eye pain
- blurred vision.

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

Injection site reactions
Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX solution for subcutaneous injection. These reactions are common (may affect up to 1 in 10 people). Symptoms at the site of injection may include redness of the skin, itching, swelling, pain, bruising, rash, bleeding

Other side effects
Very common (may affect more than 1 in 10 people):
- fever
- feeling very tired
- diarrhoea
- constipation
- decreased appetite
- difficulty sleeping
- headache
- nerve damage that may cause tingling, numbness, or pain
- rash
- muscle spasms
- joint pain
- swollen hands, ankles or feet
- feeling weak
- back pain

- 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)
- COVID-19.

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
- urinary tract infection
- severe infection throughout the body (sepsis)
- dehydration
- 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)
- feeling dizzy
- fainting
- chest muscle pain
- flu
- chills
- itching
- unusual feeling in the skin (such as a tingling or crawling feeling)
- inflamed pancreas
- high blood pressure

Uncommon (may affect up to 1 in 100 people)
- inflamed liver (hepatitis)
- type of herpes virus infection (cytomegalovirus infection).

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DARZALEX

DARZALEX solution for subcutaneous injection will be stored at the hospital or clinic.

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

Do not use this medicine after the expiry date which is stated on the carton and the vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C). Do not freeze.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Your healthcare professional will throw away any medicines that are no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What DARZALEX contains

- The active substance is daratumumab. One mL of solution contains 120 mg daratumumab. One vial of 15 mL solution for injection contains 1,800 mg of daratumumab.
- The other ingredients are recombinant human hyaluronidase (rHuPH20), L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 20, sorbitol (E420), and water for injections (see "DARZALEX contains sodium and sorbitol" in section 2).

What DARZALEX looks like and contents of the pack
DARZALEX solution for subcutaneous injection is a colourless to yellow liquid.
DARZALEX solution for subcutaneous injection is supplied as a carton pack containing 1 single-dose glass vial.

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The following information is intended for healthcare professionals only:

DARZALEX solution for subcutaneous injection should be administered by a healthcare professional.

To prevent medication errors, it is important to check the vial labels to ensure that the appropriate formulation (intravenous or subcutaneous formulation) and dose is being given to the patient as prescribed. DARZALEX solution for injection should be given by subcutaneous injection only, using the dose specified. DARZALEX subcutaneous formulation is not intended for intravenous administration.

DARZALEX solution for subcutaneous injection is for single use only and is ready to use.

- DARZALEX solution for subcutaneous injection is compatible with polypropylene or polyethylene syringe material; polypropylene, polyethylene, or polyvinyl chloride (PVC) subcutaneous infusion sets; and stainless steel transfer and injection needles.
- DARZALEX solution for subcutaneous injection should be a clear to opalescent and colourless to yellow solution. Do not use if opaque particles, discolouration or other foreign particles are present.
- Remove the DARZALEX solution for subcutaneous injection vial from refrigerated storage (2 °C – 8 °C) and equilibrate to ambient temperature (15 °C–30 °C). The unpunctured vial may be stored at ambient temperature and ambient light for a maximum of 24 hours in the original carton to protect from light. Keep out of direct sunlight. Do not shake.
- Prepare the dosing syringe in controlled and validated aseptic conditions.
- To avoid needle clogging, attach the hypodermic injection needle or subcutaneous infusion set to the syringe immediately prior to injection.

Storage of prepared syringe

- If the syringe containing DARZALEX is not used immediately, store the solution of DARZALEX for up to 24 hours refrigerated followed by up to 12 hours at 15 °C-25 °C and ambient light. If stored in the refrigerator, allow the solution to reach ambient temperature before administration.

Administration

- Inject 15 mL DARZALEX solution for subcutaneous injection into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject DARZALEX solution for subcutaneous injection at other sites of the body as no data are available.
- Injection sites should be rotated for successive injections.
- DARZALEX solution for subcutaneous injection should never be injected into areas where the skin is red, bruised, tender, hard or areas where there are scars.
- Pause or slow down delivery rate if the patient experiences pain. In the event pain is not alleviated by slowing down the injection, a second injection site may be chosen on the opposite side of the abdomen to deliver the remainder of the dose.
- During treatment with DARZALEX solution for subcutaneous injection, do not administer other medicinal products for subcutaneous use at the same site as DARZALEX.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.