PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DARZALEX 1 800 mg solution for injection

daratumumab

Contains sugar: Each 15 mL vial of solution for injection contains 735,1 mg of sorbitol (E420).

Read all of this leaflet carefully before you are given DARZALEX 1 800 mg solution for injection

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What DARZALEX 1 800 mg solution for injection is and what it is used for
2. What you need to know before you are given DARZALEX1 800 mg solution for injection
3. How DARZALEX 1 800 mg solution for injection is given
4. Possible side effects
5. How to store DARZALEX 1 800 mg solution for injection
6. Contents of the pack and other information

1. What DARZALEX 1 800 mg solution for injection is and what it is used for

What DARZALEX 1 800 mg solution for injection is

DARZALEX is a cancer medicine that contains the active substance daratumumab. It 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.

What DARZALEX 1 800 mg solution for injection is used for

DARZALEX 1 800 mg solution for injection 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 1 800 mg solution for injection 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 1 800 mg solution for injection

You must not be given DARZALEX 1 800 mg solution for injection:

- have previously had a severe hypersensitivity (allergic) reaction to daratumumab or any of the other ingredients of DARZALEX (listed in section 6).
- are pregnant or breastfeeding (see Pregnancy and breastfeeding).
- have recently received a live attenuated vaccine (see Warnings and precautions).

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection:

Special care should be taken with DARZALEX 1 800 mg solution for injection:

Infusion-related reactions

DARZALEX 1 800 mg solution for injection is given as a subcutaneous injection using a small needle to inject the medication under your skin. Before and after each infusion of DARZALEX 1 800 mg solution for injection, you will be given medicines which help to lower the chance of infusion-related reactions (see Medicines given during treatment with DARZALEX 1 800 mg solution for injection). These reactions are most likely to happen with the first injection and most reactions occur on the day of the 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 1 800 mg solution for injection 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 any itchy rash (hives).

Tell your doctor or nurse right away if you get any of the infusion-related reactions listed under POSSIBLE SIDE EFFECTS below.

If you get infusion-related reactions, you may need other medicines, or the injections may need to be stopped. When these reactions go away or get better the injection can be started again.

Blood transfusions

If you need a blood transfusion, you will have a blood test first to match your blood type. DARZALEX 1 800 mg solution for injection can affect the results of this blood test. Tell the person doing the test that you are using DARZALEX.

Decreased blood cell counts

DARZALEX 1 800 mg solution for injection can decrease white blood cell counts which help fight infections, and blood cells called platelets which help to clot blood. Tell your doctor or nurse if you develop fever or if you have signs of bruising or bleeding.

Hepatitis B

Tell your doctor if you have ever had or might now have a hepatitis B infection. This is because DARZALEX 1 800 mg solution for injection 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 DARZALEX1 800 mg solution for injection. Tell your doctor right away if you get worsening tiredness or yellowing of your skin or white part of your eyes.

Use with vaccines

It is not recommended to receive live viral or live bacterial vaccines with monoclonal antibody medicines.

Children and adolescents

Do not give DARZALEX 1 800 mg solution for injection to children or young people below 18 years of age. This is because it is not known how the medicine will affect them.

Other medicines and DARZALEX 1 800 mg solution for injection

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think that you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before you are given this medicine.

Pregnancy

Women who are pregnant or who may become pregnant must not receive DARZALEX 1 800 mg solution for injection.

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 1 800 mg solution for injection should use effective contraception during treatment and for 3 months after treatment.

Breastfeeding

Women who are receiving DARZALEX 1 800 mg solution for injection should not breastfeed their babies.

Driving and using machines

DARZALEX 1 800 mg solution for injection may make you feel tired.

Do not drive because DARZALEX 1 800 mg solution for injection could interfere with your ability to drive safely.

Do not operate any tools or machinery.

DARZALEX 1 800 mg solution for injection contains sugar (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 1 800 mg solution for injection is given

Do not share medicines prescribed for you with any other person.

How the medicine is given

DARZALEX 1 800 mg solution for injection 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.

How much is given

Your doctor will work out your dose and schedule of DARZALEX 1 800 mg solution for injection.

The dose of DARZALEX 1 800 mg solution for injection is 1 800 mg.

DARZALEX 1 800 mg solution for injection may be given alone or together with other medicines used to treat multiple myeloma, or with other medicines used to treat AL amyloidosis.

DARZALEX 1 800 mg solution for injection 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 1 800 mg solution for injection is given together with other medicines your doctor may change the time between doses as well as how many treatments you will receive.

Medicines given during treatment with DARZALEX 1 800 mg solution for injection

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

Before each injection of DARZALEX 1 800 mg solution for injection 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 1 800 mg solution for injection 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 1 800 mg solution for injection 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 1 800 mg solution for injection

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.

If you stop treatment with DARZALEX 1 800 mg solution for injection

You should not stop receiving DARZALEX 1 800 mg solution for injection without discussing with your doctor first.

4. Possible side effects

DARZALEX 1 800 mg solution for injection can have side effects. Not all side effects reported for DARZALEX 1 800 mg solution for injection are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DARZALEX 1 800 mg solution for injection, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, tell your doctor or nurse straight away or go to the casualty department at your nearest hospital:

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.

- chills
- sore throat, cough
- feeling sick (nausea)
- vomiting
- itchy, runny or blocked nose
- feeling short of breath or other breathing problems
- chest discomfort
- dizziness or lightheadedness (hypotension)
- itching
- wheezing
- eye pain
- blurred vision

These are all very serious side effects. If you have any of the above, you may need urgent medical attention or hospitalisation.

Allergic reactions

If any of the following happens, tell your doctor or nurse immediately or go to the casualty department at your nearest hospital:

- swollen face, lips, mouth, tongue or throat
- difficulty swallowing or breathing

- an itchy rash (hives)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DARZALEX 1 800 mg solution for injection. You may need urgent medical attention or hospitalisation.

Injection site reactions

Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX 1 800 mg solution for subcutaneous injection. These reactions are frequent. Symptoms at the site of injection may include redness of the skin, itching, swelling, pain, bruising, rash, bleeding.

Tell your doctor if you notice any of the following:

Frequent side effects

- fever
- feeling very tired
- diarrhoea
- constipation
- loss of appetite
- difficulty sleeping
- headache
- nerve damage that may cause tingling, numbness, or pain
- muscle spasms
- joint pain
- rash
- swollen hands, ankles or feet
- feeling weak
- pain in the back

- 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)
- irregular heart beat (atrial fibrillation)
- build up of fluid in the lungs making you short of breath
- urinary tract infection
- severe infection througout 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

Less frequent side effects

- a type of herpes virus infection (cytomegalovirus infection)
- inflamed liver (hepatitis)
- Hepatitis B virus reactivation
- COVID-19

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist as soon as possible.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/index/8
By reporting side effects, you can help provide more information on the safety of DARZALEX 1 800 mg solution for injection.

Alternatively, you may report side effects experienced with DARZALEX 1 800 mg solution for injection directly to Janssen Pharmaceutica (see section 'Holder of the Certificate of Registration' for contact details or visit www.janssen.com).

5 How to store DARZALEX 1 800 mg solution for injection

- DARZALEX 1 800 mg solution for injection will be stored at the hospital or clinic.
- Store all medicines out of reach of children.

- Do not use this medicine after the expiry date which is stated on the carton and 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.
- Medicines should not be disposed of via wastewater or household waste (i.e. drains or sewerage systems (e.g. toilets). 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 1 800 mg solution for injection contains

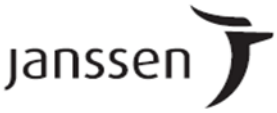
- The active substance is daratumumab.
- One mL of solution contains 120 mg daratumumab. One vial of 15 mL solution for injection contains 1 800 mg of daratumumab.
- The other ingredients are recombinant human hyaluronidase (rHuPH20), L-histidine, L-histidine hydrochloride monohydrate, L-methionine,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

What DARZALEX 1 800 mg solution for injection looks like and contents of the pack

DARZALEX 1 800 mg solution for injection is a clear to opalescent and colourless to yellow solution.

DARZALEX 1 800 mg solution for injection is supplied as a carton pack containing 1 glass vial.

Holder of certificate of registration



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Access to the corresponding Professional Information

is included in the carton, accompanying this patient information leaflet.