# PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS: S4

## DARZALEX 20 mg/mL concentrate for solution for infusion

## Daratumumab

Contains sugar: Each DARZALEX 100 mg and DARZALEX 400 mg vial contains 0,14 mg and 0,55 mg mannitol respectively

## Read all of this leaflet carefully before you are given DARZALEX

- 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 is and what it is used for

**What DARZALEX 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 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.

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

**You must not be given DARZALEX:**

- if you have previously had a severe hypersensitivity (allergic) reaction to daratumumab or any of the other ingredients of DARZALEX (listed in section 6).
- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding).
- if you 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:

*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 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 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 strong infusion reaction.

*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.

*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 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 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.

*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 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**

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.
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.

Breastfeeding

Women who are receiving DARZALEX should not breastfeed their babies.

**Driving and using machines**

DARZALEX may make you feel tired.

Do not drive because DARZALEX could interfere with your ability to drive safely.

Do not operate any tools or machinery.

**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.

**DARZALEX contains sugar (mannitol)**

If you have been told that you have an intolerance to some sugars, you should not receive DARZALEX.

## 3. How DARZALEX is given

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

You will not be expected to give yourself DARZALEX, it will be given to you by a doctor or nurse. It is given as a drip into a vein (“intravenous infusion”) over several hours.

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:

- you will be given the medicine once a week for the first 8 weeks,
- then once every 2 weeks for 16 weeks,
- then once every 4 weeks after that.

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.

**Medicines given during treatment 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 (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.

**If you stop treatment with DARZALEX**

You should not stop receiving DARZALEX without discussing with your doctor first.

## 4. Possible side effects

DARZALEX can have side effects. Not all side effects reported for DARZALEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects

while taking DARZALEX, 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 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 are frequent.

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

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. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- fever
- feeling very tired
- loss of appetite
- flu
- pain in the back
- diarrhoea
- constipation
- chest discomfort
- itching
- wheezing
- headache
- nerve damage that may cause tingling, numbness, or pain
- high blood pressure
- muscle spasms
- swollen hands, ankles or feet
- bronchitis
- feeling weak
- 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, 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)
- 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
- inflamed pancreas

Less frequent side effects

- inflamed liver (hepatitis)
- Hepatitis B virus reactivation

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.

Alternatively, you may report side effects experienced with DARZALEX 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

- DARZALEX 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 contains**

- The active substance is daratumumab.
- One mL of concentrate contains 20 mg daratumumab. Each vial of 5 mL concentrate contains 100 mg of daratumumab. Each vial of 20 mL concentrate contains 400 mg of daratumumab.
- The other ingredients are glacial acetic acid, mannitol (E421), polysorbate 20, sodium acetate trihydrate, sodium chloride and water for injections (see DARZALEX contains sodium and DARZALEX contains sugar (mannitol) in section 2).

**What DARZALEX looks like and contents of the pack**

DARZALEX is a concentrate for solution for infusion and is a colourless to yellow preservative free liquid concentrate.

DARZALEX 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.