PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Tecentriq® 840 mg (Concentrate for solution for infusion)

Tecentriq® 1 200 mg (Concentrate for solution for infusion)

The active substance is atezolizumab

Contains sugar (sucrose 21 mg/mL)

Read all of this leaflet carefully before you start taking Tecentriq

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

What is in this leaflet

1. What Tecentriq is and what it is used for

What Tecentriq is

Tecentriq is an anti-cancer medicine that contains the active substance atezolizumab. It belongs to a group of medicines called monoclonal antibodies. A monoclonal antibody is a type of protein designed to recognise and attach to a specific target in the body.

What Tecentriq is used for

Tecentriq is used to treat adults with:

- a cancer that affects the bladder and the urinary system, called urothelial carcinoma. It is used when this cancer has:
  - spread to other parts of the body
  - come back after previous treatment
  - or, if you cannot receive cisplatin treatment, and your doctor has tested your cancer and found high levels of a specific protein in your body called programmed death-ligand 1 (PD-L1).
- a cancer that affects the lungs, called non-small cell lung cancer. It is used when this cancer has:
  - spread to other parts of the body
  - come back after previous treatment.
- A cancer that affects the breast, called triple negative breast cancer.
- A cancer of the liver which cannot be removed surgically, called hepatocellular carcinoma. You will receive Tecentriq with another medicine called bevacizumab.

How Tecentriq works

Tecentriq works by attaching to a specific protein in your body called programmed death-ligand 1 (PD-L1). This protein suppresses the body's immune (defence) system, thereby protecting cancer cells from being attacked by the immune cells. By attaching to the protein, Tecentriq helps your immune system to fight your cancer.

2. Tecentriq should not be administered to you

Do not receive Tecentriq

- If you are allergic to atezolizumab or to any of the other ingredients of this medicine, listed in "What Tecentriq contains". If you are not sure, talk to your doctor or nurse before taking Tecentriq.
- If you need to be vaccinated or have been given a live, attenuated vaccine. You can only be administered Tecentriq two months after you were last vaccinated.

- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Talk to your doctor or healthcare professional before you receive Tecentriq if you:

- have an auto-immune disease (a condition where the body attacks its own cells)
- have been told that your cancer has spread to your brain
- have any history of inflammation of your lungs (called pneumonitis)
- have or have had chronic viral infection of the liver, including hepatitis B (HBV) or hepatitis C (HCV)
- have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)
- have an abnormally functioning thyroid gland
- have had serious side effects because of other antibody therapies that help your immune system to fight cancer
- have been given medicines to stimulate your immune system
- have been given medicines to suppress your immune system

If any of the above applies to you (or you are not sure), talk to your doctor or nurse before you are given Tecentriq.

Tecentriq may cause some side effects that you must tell your doctor about straight away. They may happen weeks or months after your last dose. Tell your doctor straight away if you notice any of the symptoms below:

- inflammation of the lung (pneumonitis): symptoms may include new or worsening cough, shortness of breath, and chest pain
- inflammation of the liver (hepatitis): symptoms may include yellowing of skin or eyes, nausea, vomiting, bleeding or bruising, dark urine, and stomach pain
- inflammation of the intestines (colitis): symptoms may include diarrhoea (watery, loose or soft stools), blood in stools, and stomach pain.

- inflammation of the thyroid, adrenal glands and the pituitary gland (hypothyroidism, hyperthyroidism, adrenal insufficiency or hypophysitis): symptoms may include tiredness, weight loss, weight gain, change in mood, hair loss, constipation, dizziness, headaches, increased thirst, increased urination and changes in vision.
- type 1 diabetes, including acid in the blood produced from diabetes (diabetic ketoacidosis): symptoms may include feeling more hungry or thirsty than usual, need to urinate more often, weight loss, and feeling tired
- inflammation of the brain (encephalitis) or inflammation of the membrane around the spinal cord and brain (meningitis): symptoms may include neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion and sleepiness
- inflammation or problems of the nerves (neuropathy): symptoms may include muscle weakness and numbness, tingling in hands and feet
- inflammation of the pancreas (pancreatitis): symptoms may include abdominal pain, nausea and vomiting
- inflammation of the heart muscle (myocarditis): symptoms may include shortness of breath, decreased exercise tolerance, feeling tired, chest pain, swelling of the ankles or legs, irregular heart beat, and fainting
- inflammation of the muscles (myositis); symptoms may include muscle weakness, fatigue after walking or standing, tripping or falling, and trouble swallowing or breathing
- severe reactions associated with infusion (events occurring during the infusion or within one day of the infusion): may include fever, chills, shortness of breath and flushing
- you experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (signs of severe skin reactions), see section 4, Possible side effects. If you experience any of these effects your doctor may stop your treatment with Tecentriq and ask you to see a dermatologist.

If you notice any of the symptoms above, tell your doctor straight away.

Do not try to treat yourself with other medicines. Your doctor may:

- Give you other medicines to prevent complications and reduce symptoms.
- Delay giving your next dose of Tecentriq.
- Stop your treatment with Tecentriq.

Tests and checks

Before your treatment, your doctor will check your general health. You will also have blood tests during your treatment.

Children and adolescents

This medicine should not be given to children or adolescents below 18 years of age. This is because the effects of Tecentriq in this age group are not known.

Other medicines and Tecentriq

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

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Contraception

- You will not be given Tecentriq if you are pregnant. This is because the effect of Tecentriq could harm your unborn baby.
- If you could become pregnant, you must use effective contraception;
  - while you are being treated with Tecentriq and
  - for 5 months after the last dose.

Pregnancy

- Women who are pregnant or plan to be come pregnant must not use Tecentriq (see" Do not receive Tecentriq"). This is because Tecentriq could harm your unborn baby.
- If you become pregnant while you are being treated with Tecentriq tell your doctor.

Breastfeeding

Women receiving Tecentriq should not breastfeed their babies, nor for 5 months after the last infusion. This type of medicine is likely to be excreted in breast milk and may harm your baby.

Driving and using machines

Tecentriq has an influence on your ability to drive and use machines. If you feel tired, do not drive or use machines until you feel better. This is more likely to occur shortly after your infusion has been given.

Tecentriq contains sugar (sucrose) which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How you are given Tecentriq

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

Always follow your doctor's instruction exactly. You should check with your doctor or pharmacist if you are unsure.

How much Tecentriq is given

The recommended dose is:

- 840 milligrams (mg) every 2 weeks
- 1 200 milligrams (mg) every 3 weeks or
- 1 680 milligrams (mg) every 4 weeks.

You will not be expected to give yourself Tecentriq. It will be given to you by a person who is qualified to do so.

How Tecentriq is given

Tecentriq is given as a drip into a vein (an intravenous infusion).

Your first infusion will be given over 60 minutes.

- Your doctor will monitor you carefully during the first infusion.
- If you do not have an infusion reaction during the first infusion, the next infusions will be given to you over a period of 30 minutes.

Your doctor will tell you how long your treatment with Tecentriq will last. Do not stop treatment early after receiving Tecentriq.

If you have the impression that the effect of Tecentriq is too strong or too weak, tell your doctor or pharmacist.

If you receive more Tecentriq than you should

If you receive more Tecentriq than you should, talk to a doctor straight away. Take the medicine package and this leaflet with you.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you miss a dose of Tecentriq

If you miss an appointment, make another one straight away. For the treatment to be fully effective, it is very important to keep having the infusions.

Effects when treatment with Tecentriq is stopped

Do not stop treatment with Tecentriq unless you have discussed this with your doctor. This is because stopping treatment may stop the effect of the medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Tecentriq can have side effects.

Not all side effects reported for Tecentriq are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Severe skin reactions

If you get a severe skin reaction, tell your doctor immediately.

The signs may include:

- A severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis which are also known as SJS and TEN).
- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).

Frequent

- fever
- nausea
- vomiting
- feeling very tired with no energy (fatigue)
- lack of energy
- itching of the skin
- diarrhoea
- joint pain
- rash
- loss of appetite
- shortness of breath
- urinary tract infection
- back pain

- cough
- headache
- leukopenia
- peripheral oedema
- alopecia
- hypertension
- inflammation of the lungs
- low oxygen levels which may cause shortness of breath as a consequence of inflamed lungs (pneumonitis)
- stomach pain
- inflammation of the liver
- elevated liver enzymes (shown in tests) - may be a sign of an inflamed liver
- difficulty swallowing
- blood tests showing low levels of potassium (hypokalaemia) or sodium (hyponatraemia)
- low blood pressure (hypotension)
- underactive thyroid gland (hypothyroidism)
- allergic reaction (infusion-related reaction or hypersensitivity)
- flu-like illness
- pain in the muscles and bones
- chills
- overactive thyroid gland (hyperthyroidism)
- inflammation of the intestines
- low platelet count, which may make you more likely to bruise or bleed
- blocked nose (nasal congestion)
- abnormal kidney test (possible kidney damage)
- dry skin

Less frequent

- inflammation of the pancreas
- high levels of amylase - may be a sign of an inflamed pancreas (shown in blood tests)
- numbness or paralysis - these may be signs of Guillain-Barré syndrome
- inflammation of the membrane around the spinal cord and brain
- low levels of adrenal hormones
- type 1 diabetes
- high levels of lipase - may be a sign of an inflamed pancreas (shown in blood tests)
- inflammation of the heart muscle
- inflammation of the brain
- myasthenia gravis - an illness that can cause muscle weakness
- inflammation of the pituitary gland situated at the base of the brain
- inflammation of muscles (myositis)
- red, dry, scaly patches of thickened skin (psoriasis)
- a severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth. Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (severe cutaneous adverse reactions)
- inflammation of the kidneys

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

Reporting of side effects

If you get 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 to SAHPRA via the “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 Tecentriq.

5. How to store Tecentriq

Store all medicines out of reach of children.

Store between 2 - 8 °C. Do not freeze. Do not shake.

The diluted solution for infusion should be used immediately. If the solution is not used immediately, it can be stored for up to 30 days at 2°C - 8°C, or 8 hours at ambient temperature (≤ 25°C).

Store in the original package.

Keep the container in the outer carton to protect from light.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Tecentriq contains

Tecentriq is supplied as single-use vials containing preservative-free, colourless to slightly yellow solution, at an active ingredient concentration of 60 mg/mL, as follows:

- 14 mL vial containing a total of 840 mg atezolizumab
- 20 mL vial containing a total of 1 200 mg atezolizumab

Contains sugar (sucrose 21 mg/mL).

Excipients: Glacial acetic acid, L-histadine, polysorbate 20, sucrose, water for injections.

What Tecentriq looks like and contents of the pack

A clear, colourless to slightly yellowish liquid, packed in a type I glass-vial with a butyl rubber stopper containing 20 mL of solution.

Pack of one vial.

Holder of Certificate of Registration

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Roche Ethical Assistance Line toll-free: 0800 21 21 25

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