Tecentriq®

atezolizumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tecentriq. 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 taking Tecentriq against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tecentriq is used for

Tecentriq contains the active ingredient atezolizumab.

Tecentriq works by attaching to a specific protein in your body called 'PD-L1'. This protein makes the immune system in the body work less well. By attaching to the protein, Tecentriq helps your immune system to fight your cancer.

Tecentriq is used to treat:

- a cancer that affects the lungs, called non-small cell lung cancer. It is used when the cancer is advanced, or spread to other parts of the body, and has come back after previous treatment.
- a cancer that affects the bladder and the urinary system, called urothelial carcinoma. It is used when the cancer is advanced, or spread to other parts of the body. It is used if you cannot receive cisplatin or any other platinum treatment or when the cancer has come back after previous treatment.
- a cancer that affects the breasts called triple-negative breast cancer (TNBC). It is used when the cancer is advanced or has spread to other parts of the body and if you have not received prior chemotherapy for this type of cancer. Tecentriq will be given to you together with a chemotherapy medicine called nanoparticle albumin-bound paclitaxel, commonly referred to as nab-paclitaxel.

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

Your doctor may have prescribed it for another reason.

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

If you are given Tecentriq together with nab-paclitaxel it is important that you also read the Consumer Medicine Information for these medicines. Ask your doctor if you have any questions about nab-paclitaxel.

Before you are given Tecentriq

If you are not sure if you should start receiving Tecentriq, talk to your doctor.

When you must not take it

Do not take Tecentriq if you have an allergy to:

- atezolizumab or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Before you start to take it

Tell your doctor:

- **if you have immune system problems such as Crohn's disease, ulcerative colitis, or lupus**
- **if you have inflammation of the lungs (called 'pneumonitis')**
- **if you have liver problems, such as hepatitis**
- **if you have thyroid problems**
- **if are pregnant or plan to become pregnant.**

  Tecentriq may impair the ability of women to fall pregnant during treatment.

  Tecentriq can harm your unborn baby.

  If you are a woman who is able to become pregnant, you should use an effective method of birth control during your treatment with Tecentriq and for at least 5 months after your last dose of Tecentriq. Talk to your healthcare provider about birth control methods that you can use during this time.

  Tell your doctor right away if you become pregnant during treatment with Tecentriq.

- **Tell your doctor if you are breastfeeding or plan to breastfeed.**

  It is not known if Tecentriq passes into your breastmilk.

  Do not breastfeed during treatment with Tecentriq.
- **Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell him/her before you start taking Tecentriq.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving Tecentriq.

How Tecentriq is given

Follow all directions given to you by your doctor or nurse carefully.

They may differ from the information contained in this leaflet.

Tecentriq must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.

Tecentriq is given by a drip into a vein (called an "intravenous infusion" or "IV").

The recommended dose is 1200 milligrams (mg) every three weeks if you haven non-small cell lung cancer or urothelial carcinoma If you have triple-negative breast cancer the recommended dose is 840 mg every two weeks,

If you are given other medicines with Tecentriq, your doctor will determine how much of these to give to you.

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.

The number of infusions you will be given depends on how you respond to treatment.

Your doctor will keep giving you Tecentriq until you no longer benefit from it. However, it may be stopped if the side effects become too much of a problem.

If you miss a dose

As Tecentriq is given under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss your appointment to receive Tecentriq, make another appointment as soon as possible.

If you take too much (overdose)

As Tecentriq is given under the supervision of your doctor, it is unlikely that you will be given too much. However, if you experience any side effects after being given Tecentriq, tell your doctor immediately.

While you are using Tecentriq

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tecentriq.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you are pregnant, think you might be pregnant or are planning to become pregnant.

Do not have Tecentriq if you are pregnant unless your doctor has told you to.

This is because the effect of Tecentriq in pregnant women is not known - it is possible that it could harm your unborn baby.

If you are a woman who is able to become pregnant, you must use effective contraception while you are being treated with Tecentriq and for at least 5 months after the last dose.

If you become pregnant while you are being treated with Tecentriq tell your doctor.

Ask your doctor if you should stop breast-feeding or if you should stop treatment with Tecentriq.

It is not known whether Tecentriq gets into breast milk. A risk to the breast-fed infant cannot be excluded.

Things to be careful of

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

It is not known whether Tecentriq may impair your ability to drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tecentriq.

All medicines can have side effects. Sometimes they are serious, most of

the time they are not. You may need medical treatment if you get some of the side effects.

When Tecentriq is given with other medicines to treat cancer it may be difficult for your doctor to tell whether the side effects are due to Tecentriq or due to other medicines.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor straight away if you notice any of the side effects below or if they get worse. They may happen weeks or months after your last dose. Do not try to treat yourself with other medicines. Side effects reported in clinical trials when Tecentriq was given alone (monotherapy).

- joint pain
- loss of appetite
- diarrhoea
- shortness of breath
- feeling tired with no energy (fatigue)
- itching of the skin
- nausea
- fever
- rash
- vomiting
- difficulty swallowing
- flu-like symptoms
- nasal congestion
- stomach or back pain
- pain in the muscles and bones
- infection of the urinary tract
- cough
- throat pain
- common cold

Side effects reported in clinical trials when Tecentriq was given in combination with chemotherapy (in addition to those above).

- Low white blood cell count which can increase the risk of infection
- Effect on peripheral nerves (pain, numbness, tingling or loss of feeling)

If any of the following happen, tell your doctor immediately:

- 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, pituitary and adrenal glands (hypothyroidism, hyperthyroidism, hypophysitis or adrenal insufficiency): symptoms may include tiredness, weight loss, weight gain, changes in mood or behaviour, visual disturbances, increased sensitivity to cold or heat, slow or rapid heart rate, hair loss, constipation, headache, and dizziness
- type 1 diabetes mellitus, 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, numbness or tingling in hands and feet
- inflammation of the pancreas (pancreatitis): symptoms may include abdominal pain, nausea and vomiting
- inflammation of the heart muscle (myocarditis) characterised by shortness of breath, feeling tired, irregular heart beat or chest pain
- inflammation of the kidneys (nephritis): symptoms may include dark and/or frothy urine, high blood pressure, swelling to face, feet, legs and hands (oedema)
- severe reactions associated with infusion (events occurring during or within one day of having the infusion) may include fever, chills, shortness of breath and flushing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects can only be found when your doctor does tests from time to time to check your progress. (for example, elevated liver enzymes, low potassium or sodium levels low platelet count, low blood pressure, high blood sugar).

Product description

Storage

Tecentriq will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2 °C and 8 °C.

Availability

Tecentriq is supplied as a single-dose glass vial containing 1200 mg of active ingredient in 20 mL solution. It is diluted before infusion into a vein.

What Tecentriq looks like

Tecentriq is a colourless to slightly yellow solution.

Ingredients

Each vial of Tecentriq contains 1200 mg of the active ingredient atezolizumab.

It also contains:

- glacial acetic acid
- histidine
- sucrose
- polysorbate 20
- water for injections.

This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

Manufacturer

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