



Information booklet for patients using Tecentriq (Atezolizumab) 60 mg/ml

The format and content of this booklet
were approved by the Ministry of Health in

Dear Patient,

This booklet contains important safety information that you must be aware of before and during treatment with Tecentriq (atezolizumab).

The information in this booklet is not meant to replace your doctor's discretion. For any additional questions, consult your doctor.

For complete information about this medicine, refer to the leaflet published in the Israeli Drug Registry on the Ministry of Health website or on the Roche website, www.roche.co.il.

We wish you the best of health!

What is Tecentriq?

Tecentriq is a prescription drug used to treat certain types of cancer.

How does Tecentriq work?

Tecentriq works by binding to a specific protein in the body, called PD-L1. This protein suppresses the activity of the immune system, thus preventing it from attacking cancer cells. By binding to the PD-L1 protein, Tecentriq enables the immune system to attack and destroy the cancer cells.

How is Tecentriq administered?

Tecentriq can be administered in various doses and at different intervals, according to your doctor's instructions. Treatment is administered intravenously by the medical team for 30 – 60 minutes.



For 30 – 60 minutes



**In various doses
Administered intravenously**

What do I need to tell my doctor before receiving treatment with Tecentriq?

Before beginning treatment, you must provide your doctor complete information on your medical background, including illnesses you have or have had in the past, medicines you take regularly, including prescription and non-prescription medicines, vitamins, herbal supplements, as well as any sensitivity to medicines.

This treatment is not suitable for everyone. Do not take Tecentriq if you are sensitive to atezolizumab or to any of the medicine's components (glacial acetic acid, L-histidine, sucrose, polysorbate 20).

It is also important to inform your doctor before treatment with Tecentriq, if:

- You have immune system disorders (such as Crohn's disease, ulcerative colitis or lupus); you have a condition that affects your nervous system (such as myasthenia gravis or Guillain-Barré syndrome); you have had an organ transplant; you have undergone or are scheduled to undergo a donor (allogeneic) stem cell transplant, or you have received radiation therapy to your chest area.
- You are pregnant or planning to become pregnant. Tecentriq may harm the fetus. You must inform your doctor immediately if you discover that you are pregnant or think you might be pregnant.

If you are able to become pregnant:

- You must take a pregnancy test before starting treatment with Tecentriq.
- You must use an effective means of contraception for the duration of treatment and for at least 5 months from the date of your last dose of Tecentriq.
- You are breastfeeding or plan to breastfeed. It is not known whether Tecentriq passes into breast milk. Do not breastfeed for the duration of treatment and for at least 5 months from the date of your last dose of Tecentriq.

Important safety information about Tecentriq

Tecentriq is a medicine that can treat certain types of cancer by recruiting your immune system. As with every medicine, the use of Tecentriq may cause side effects in some users. Tecentriq may cause your immune system to attack healthy organs and tissues in various parts of the body and may affect how they function. These disorders may be serious or life-threatening and may even lead to death. You may have more than one disorder at the same time. They can occur at any time during treatment or even after your treatment has ended.

Contact your doctor immediately if you have any symptom of the problems listed below, or if these symptoms get worse:

- Lung disorder – cough, shortness of breath, chest pain.
- Intestinal disorder – diarrhea (watery stools) or increase in bowel movements, blood or mucus in the stool or black sticky stools, sharp pain or tenderness in the abdomen.
- Liver disorder – yellowing of the skin or of the whites of the eyes, severe nausea or vomiting, pain on right side of the stomach area, dark (tea-colored) urine, more frequent bleeding or bruising than usual.
- Hormonal gland disorder – persistent or unusual headaches, sensitivity of eyes to light, eye problems, rapid heartbeat, increased perspiration, extreme fatigue, weight gain or loss, increased appetite or thirst, increased frequency of urination, hair loss, feeling cold, constipation, deepening of the voice, dizziness or fainting, changes in mood or behavior (such as decreased libido, excessive irritability or forgetfulness).
- Kidney disorder – decreased urine output, blood in the urine, swollen ankles, loss of appetite.
- Skin disorder – rash, itching, blisters or peeling of the skin; ulcers in the region of the mouth, nose, throat or genitals; fever or flu-like symptoms; swollen lymph nodes.
- There may be additional disorder in other organs. These are not all of the signs and symptoms that may occur with Tecentriq. You must contact your doctor immediately if you suffer from any symptom of the problems listed below, or if these symptoms get worse:

Chest pain, irregular heartbeat, shortness of breath or swollen ankles. Confusion, sleepiness, memory disorder, changes in mood or behavior, stiff neck, difficulty maintaining balance, numbness or a tingling sensation in your hands or feet. Blurry

vision, double vision, sensitivity of eyes to light, eye pain, changes in vision. Severe or persistent pain or weakness in muscles, muscle cramps. Low red blood cell count, bruising.

- Infusion reactions which may be severe or life-threatening – signs and symptoms may include chills or tremors, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling faint, neck or back pain.
- Complications, including **graft-versus-host disease (GVHD)**, in people who have undergone donor (allogeneic) bone marrow transplant – these complications may be serious and might lead to death and may occur if you underwent the transplant before or after treatment with Tecentriq.

Receiving immediate medical treatment may prevent these problems from becoming more severe. If you are having severe side effects, your doctor may postpone or immediately discontinue treatment with Tecentriq and give you additional medicines.

There are additional side effects that may occur following treatment with Tecentriq that are not listed above. Complete information about the side effects and how frequently they occur appears in the Patient Information Leaflet. Inform your doctor about any change or deterioration in your condition during treatment.

Side effects can be reported to the Ministry of Health using the online form at: <http://sideeffects.health.gov.il>

In addition, you can report directly to Roche by email:

israel.drugsafety@roche.com or by telephone: 09-9737722

References:

Tecentriq Prescribing Information

Roche Pharmaceuticals (Israel) Ltd.
6 Hacharash St., PO Box 6391
Hod Hasharon 4524079
09-9737899
www.roche.co.il

The format and content of this booklet were approved by the Ministry of Health in

Dear Patient,

It is important that you carry this information card with you at all times and present it to every healthcare practitioner participating in your treatment.

Oncologist name: _____

Contact details: _____

Patient name: _____

My contact details: _____

Emergency contact name: _____

Contact details: _____

Important information for medical personnel

This patient is being treated with Tecentriq (Atezolizumab). This drug may cause side effects related to the immune system involving the lungs, liver, intestines, endocrine glands, heart, pancreas, kidneys, and other organs, as well as infusion-related reactions

Early diagnosis and appropriate treatment are essential in order to minimize the implications of side effects related to the immune system.

In case of suspected side effects related to the immune system, make sure that an adequate assessment is performed to verify this etiology and rule out other causes. Depending on the severity of the condition, treatment with Tecentriq should be suspended and other medications administered. Precise instructions can be found in the drug leaflet on the Ministry of Health website or on the Roche website, www.roche.co.il.

For further information contact the patient's oncologist.

Side effects can be reported to the Ministry of Health using the online form at: <http://sideeffects.health.gov.il>

In addition, a report can be sent directly to Roche by email: israel.drugsafety@roche.com or by telephone: 09-9737722