Patient Alert Card – TECENTRIQ®
(atezolizumab)

IMPORTANT SAFETY INFORMATION

▼ This medicinal product is subject to additional monitoring.
This will allow quick identification of new safety information.

Risk Minimisation Material, version 3. Approved by Fimea 12th of April 2019.

IMPORTANT:

Tecentriq® (atezolizumab) can cause serious side effects in many parts of your body that need to be treated right away

Symptoms may occur at any time during treatment or even after your treatment has ended

Call your doctor right away if you develop any of these symptoms listed on this card or if your symptoms should get worse

Also tell your doctor if you experience any other symptoms not listed on this card

Do not try to treat your symptoms on your own

Carry this card with you at all times, especially when you travel, whenever you go to the Accident and Emergency department, or when you see another doctor.

SELECT IMPORTANT SAFETY INFORMATION

Serious side effects may include lung problems (pneumonitis), liver problems (hepatitis), intestinal problems (colitis), problems in hormone glands (for example thyroid problems or diabetes), nervous system, and other organs. These events may result in signs or symptoms such as:

Lungs: new or worsening cough, shortness of breath, chest pain.
Liver: yellowing of skin or the whites of eyes, severe nausea or vomiting, bleeding or bruising, dark urine, stomach pain.
Intestines: diarrhea (watery, loose or soft stools), blood in stools, stomach pain.
Hormone glands: extreme tiredness, persistent headache, weight loss, weight gain, change in mood, hair loss, constipation, dizziness, feeling more hungry or thirsty than usual, need to urinate more often, increased sensitivity to cold or heat.
Heart: chest pain, shortness of breath, irregular heartbeat, decreased exercise tolerance, ankle swelling.
Brain: neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion, sleepiness.
Nerves: severe muscle weakness and numbness, tingling in your hands and feet.

Pancreas: abdominal pain, nausea, vomiting
Kidneys: changes in urine output and color, pain in pelvis, and swelling of the body
Reactions associated with infusion (during or within 1 day of infusion): fever, chills, shortness of breath, flushing.

Getting medical treatment immediately may stop the problems from becoming serious. Your doctor may decide to give you other medicines to prevent complications and reduce your symptoms, and may withhold the next dose or stop your treatment.

My information

Name of oncologist:

Contact number:

After-hours contact number:

My name:

My contact number:

Emergency contact:

Emergency contact number:

Kohderyhmä potilaat: FI/FAPD/1709/0032b(2) 5.2019

IMPORTANT Reminders for Patients

Tecentriq® (atezolizumab) is a medicine to treat adults with locally advanced or metastatic urothelial carcinoma and non small cell lung cancer. Like all medicines, this medicine may cause side-effects, although not everybody gets them. It is important to tell your doctor immediately if you develop any of the symptoms listed on this card after starting treatment with Tecentriq®. Before you start Tecentriq® or during your treatment, you should also tell your doctor immediately if you:

- Have an autoimmune disease (a condition where the body attacks its own cells, examples include autoimmune thyroid disease, systemic lupus erythematosus (SLE), Sjogren's syndrome, multiple sclerosis, rheumatoid arthritis, vasculitis, glomerulonephritis.)
- Have been told that your cancer has spread to your brain
- Have any history of inflammation of your lungs (pneumonitis)

- Have or have had chronic viral infection of the liver, including hepatitis B (HBV) or hepatitis C (HCV)
- Have human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS)
- Experienced 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 such as interferons or interleukin-2 as these medicines may worsen the side effects of Tecentriq®
- Have been given medicines to suppress your immune system such as corticosteroids, since these medicines may interfere with the effect of Tecentriq®
- Have been given a live, attenuated vaccine such as influenza intranasal vaccine, yellow fever vaccine

Important information for Health Care Providers

This patient is being treated with Tecentriq® (atezolizumab), which can cause immune-related adverse reactions that involve the lungs, liver, intestines, hormone glands, heart and other organs, as well as infusion-related reactions. Early diagnosis and appropriate management are essential to minimize any consequences of immune-related adverse reactions.
For suspected immune-related adverse reactions, ensure adequate evaluation to confirm aetiology or exclude other cause. Based on the severity of the adverse reaction, withhold Tecentriq® and administer corticosteroids. Specific guidelines for managing immune-related adverse reactions are provided in the **Summary of Product Characteristics** for Tecentriq® and Physician Education Materials available at www.ema.europa.eu. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Restart Tecentriq® if the adverse reaction remains at Grade 1 or less within 12 weeks after onset of adverse reaction and corticosteroid dose is ≤ 10 mg prednisone or equivalent per day.

Please contact the patient's Oncologist (details above) for more information.

Assess patients for signs and symptoms of pneumonitis, hepatitis, colitis, endocrinopathies (including hypophysitis, adrenal insufficiency, type 1 diabetes mellitus, hypothyroidism, hyperthyroidism), myocarditis, pancreatitis, nephritis and infusion related reactions. Other immune-related adverse reactions reported in patients receiving Tecentriq® include: neuropathies (Guillain-Barré syndrome, myasthenic syndrome / Myasthenia Gravis), and meningoencephalitis.

Please consult the Summary of Product Characteristics for Tecentriq® at **www.ema.europa.eu**

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via Finnish Medicines Agency Fimea. By reporting side effects you can help provide more information on the safety of this medicine. Adverse reactions should also be reported to Roche Finland Local Safety Unit (finland.laaketurva@roche.com, tel. 010 554 500).

It is important that you carry this card with you **at all times**. Please ensure you show this card to **all** Healthcare Professionals (nurses, pharmacists and dentists), to any doctor involved in your treatment, and at any visits to the hospital.

If you develop any symptoms listed on this card or if you notice any symptoms not listed on this card, please contact your doctor immediately. Getting medical treatment early may stop the problem from becoming more serious.

You should not start any other medicines during your treatment without talking to your doctor first.

If you have any further questions about your treatment or on the use of this medicine, please contact your doctor.