

## **Patient Card – Tecentriq® (atezolizumab)**

**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 new signs or 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 hypothyroidism or diabetes), musculoskeletal problems (myositis), nervous system problems (neuropathies), pancreas problems (pancreatitis), heart problems (myocarditis, pericardial disorder), kidney problems (nephritis), and build-up of certain white blood cells (histiocytes and lymphocytes) in various organs (hemophagocytic lymphohistiocytosis). 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, 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

**Brain:** neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion, sleepiness

**Musculoskeletal:** inflammation or damage of the muscles; muscle pain and weakness.

**Nerves:** abnormal sensations such as numbness, coldness or burning, bladder and bowel problems, weakness in the arm and leg muscles, or face muscles, double vision, difficulties with speech and chewing, pain, stiffness, and tingling in your hands and feet.

**Pancreas:** abdominal pain, nausea, vomiting

**Heart:** chest pain which could worsen with deep breathing, shortness of breath, irregular heartbeat, decreased exercise tolerance, swelling of the ankles, legs or abdomen, cough, fatigue, fainting

**Kidneys:** changes in urine output and color, pain in pelvis, and swelling of the body that may lead to failure of the kidneys

**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.**

## IMPORTANT Reminders for Patients

Like all medicines, Tecentriq® (atezolizumab) may cause side-effects, although not everybody gets them. It is important to tell your doctor **immediately** if you develop any of the signs or symptoms listed on this card after starting treatment with atezolizumab. Before you start atezolizumab 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)
- Have a significant cardiovascular (heart) disease or blood disorders or organ damage due to inadequate blood flow
- 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 atezolizumab
- Have been given medicines to suppress your immune system such as corticosteroids, since these medicines may interfere with the effect of atezolizumab
- Have been given a live, attenuated vaccine such as influenza intranasal vaccine, yellow fever vaccine
- Have been given medicines to treat infections (antibiotics) in the past two weeks

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

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

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

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

**Name of oncologist:**

**Contact number:**

**After-hours contact number:**

**My name:**

**My contact number:**

**Emergency contact:**

**Emergency contact number:**

**IMPORTANT Information for Health Care Providers**

This patient is being treated with Tecentriq® (atezolizumab), which can cause immune-mediated adverse reactions that involve the lungs, liver, intestines, hormone glands, heart, pancreas, kidney, and other organs, as well as infusion-related reactions. Early diagnosis and appropriate management are essential to minimize any consequences of immune-mediated adverse reactions.

For suspected immune-mediated 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 atezolizumab available at “SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN E. GABRIELIAN CJSC” website via [www.pharm.am](http://www.pharm.am). 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, pericardial disorder, pancreatitis, nephritis, myositis, hemophagocytic lymphohistiocytosis and infusion related reactions. Other immune-mediated adverse reactions reported in patients receiving atezolizumab include: neuropathies (Guillain-Barré syndrome, myasthenic syndrome / Myasthenia Gravis, facial paresis), myelitis and meningoencephalitis.

Please consult the Summary of Product Characteristics for Tecentriq® at “SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN E. GABRIELIAN CJSC” website via address: 49/5 Komitas av., 0051 Yerevan, Armenia or website: [www.pharm.am](http://www.pharm.am) or phone: +374 60 830073

*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 **and which may be linked with the use of Tecentriq (atezolizumab)**. You can also report side effects directly via contacts presented as follows: “SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN E. GABRIELIAN CJSC via*

*following contacts: address: 49/5 Komitas av., 0051 Yerevan, Armenia; HOT LINE: (+ 374 10) 20-05-05, (+374 96) 22-05-05, email: [vigilance@pharm.am](mailto:vigilance@pharm.am).*

*By reporting side effects you can help provide more information on the safety of this medicine. Adverse reactions should also be reported to Roche. Please contact to the Local person for Pharmacovigilance of Roche Products in Armenia, via mob.: +374 91 796688 or email address: [gayaneh.ghazaryan@gmail.com](mailto:gayaneh.ghazaryan@gmail.com); or Nune Karapetyan, Local backup for Pharmacovigilance of Roche Products in Armenia via mob.: +374 91 721153 or email address: [nune.karapetyan.roche@gmail.com](mailto:nune.karapetyan.roche@gmail.com).*

*Moreover you may contact to Local Safety Responsible Georgia/Armenia, Roche Georgia LLC via tel: +995 322 506284, +995 322 507284 or emailing to [georgia.safety@roche.com](mailto:georgia.safety@roche.com).*

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