

Patient Card **TECENTRIQ**[®] 1200mg/20ml

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.

THERAPEUTIC INDICATIONS:

- ▶ Urothelial Carcinoma
- ▶ Non-Small Cell Lung Cancer
- ▶ Small Cell Lung Cancer
- ▶ Hepatocellular Carcinom

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 (for example neuropathies or myelitis), 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

Kidney problems: decrease in your amount of urine, blood in your urine, swelling of your ankles, and loss of appetite.

Heart: (Myocarditis and Pericardial disorders); shortness of breath, decreased exercise tolerance, feeling tired, chest pain, swelling of the ankles or legs, irregular heartbeat, and fainting.

Build up certain white blood cells: (histiocytes and lymphocytes): (haemophagocytic lymphohistiocytosis);enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities, and heart problems.

Severe infections: fever, cough, flu-like symptoms, and pain when urinating, frequent urination or back pain.

Severe infusion reaction: chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feeling like passing out, fever , back or neck pain.

Please refer to patient leaflet (PIL) for more information

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 immune system problems such as Crohn's disease, ulcerative colitis, or lupus.
- ▶ Have received an organ transplant.

- ▶ Have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic).
- ▶ Have received radiation treatment to your chest area.
- ▶ Have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome.
- ▶ Are pregnant or plan to become pregnant. TECENTRIQ can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with **TECENTRIQ®**.

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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®**, 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.

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[®] For more 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 the national spontaneous reporting systems to:



The National Pharmacovigilance Centre
Land Line: 19999.
Fax: +966112057662
Email: npc.drug@sfda.gov.sa



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This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA)