My information

Name of oncologist: _____

Contact number: _____

After-hours contact number: _____

My name: _____

My contact number: _____

Emergency contact: _____

Emergency contact number: _____

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.

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 minimise 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 www.medicines.ie and 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 on this card) 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, infusion-related reactions, neuropathies (Guillain-Barré syndrome, myasthenic syndrome/Myasthenia Gravis, facial paresis) myelitis and meningoencephalitis.

Please consult the Summary of Product Characteristics for Tecentriq® available at www.medicines.ie and www.ema.europa.eu.

Reporting of suspected adverse events or reactions

Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions (see details below).

Where possible, healthcare professionals should report adverse events or reactions by brand name and batch number.

In the event of a suspected adverse event, please report it to:
The Drug Surveillance Centre,
Roche Products (Ireland) Limited,
3004 Lake Drive, Citywest,
Naas Road, Dublin 24, Ireland.
Telephone: 00 353 (0)1 4690700
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions (side effects) or medicines errors may be reported using the Medicines Authority ADR reporting form, which is available online at: http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:
Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority,
Sir Temi Żammit Buildings, Malta Life Sciences Park,
San Ġwann SĠN 3000, Malta.
Email: postlicensing.medicinesauthority@gov.mt

Further information

For electronic copies of this risk minimisation material, refer to the Malta Medicines Authority website [http://www.medicinesauthority.gov.mt/rmm] and download the required material. Alternatively if you would like hard copies, please contact Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24, Ireland by mail, telephone (00 353 (0)1 4690700), or email (ireland.drug_surveillance_centre@roche.com).

For further information about this medicine, please contact Medical Information at Roche Products (Ireland) Limited by telephone (00 353 (0)1 4690700), or email (Ireland.druginfo@roche.com).

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FOR USE IN MALTA

Tecentriq® (atezolizumab) Patient Card

Please read this material along with the Package Leaflet supplied with this medicine or also available on www.medicines.ie and www.ema.europa.eu before taking this medicine.

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 (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:** diarrhoea (watery, loose or soft stools), blood in stools, stomach pain
- **Brain:** neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion, sleepiness

- **Hormone glands:** tiredness, weight gain, change in mood, hair loss, constipation, dizziness, vision changes
  - Type 1 diabetes including a serious, sometimes life-threatening problem due to acid in the blood produced from diabetes (diabetic ketoacidosis): feeling more hungry or thirsty than usual, need to urinate more often, weight loss, feeling tired or having difficulty thinking clearly, breath that smells sweet or fruity, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, nausea or vomiting, stomach pain and deep or fast breathing

- **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 colour, 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
- **Haemophagocytic lymphohistiocytosis** (Enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities and heart problems.

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

Tecentriq® (atezolizumab) is a medicine to treat adults with different types of tumours (e.g. urothelial carcinoma, non-small cell lung cancer, small cell lung cancer, triple negative breast cancer) as monotherapy or in combination with other anticancer medicines.

For a complete list of current indications, please refer to the Tecentriq® (atezolizumab) Package Leaflet available at www.medicines.ie and www.ema.europa.eu. 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) infection 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.

Reporting of side effects

If you get any side effects, talk to the doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly (see details below).

By reporting side effects you can help provide more information on the safety of this medicine.

Please report side effects to:
Post: The Drug Surveillance Centre, Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24, Ireland.
Telephone: 00 353 (0)1 4690700;
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, side effects may be reported using the Medicines Authority ADR reporting form, which is available online at: http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:

Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Email: postlicensing.medicinesauthority@gov.mt

Further information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.