

PRODUCT MONOGRAPH  
INCLUDING PATIENT MEDICATION INFORMATION

<sup>Pr</sup>**TECENTRIQ**<sup>®</sup>

atezolizumab for injection

Concentrate for solution for infusion, 60 mg/mL  
1200 mg/20 mL and 840 mg/14 mL single use vials

For intravenous infusion

Professed Standard

ATC Code: L01FF05

Antineoplastic agent, monoclonal antibody

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## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

<sup>Pr</sup>TECENTRIQ®

**atezolizumab for injection, intravenous infusion, 1200 mg/20 mL and 840 mg/14 mL vial**

Read this carefully before you start taking Tecentriq and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Tecentriq.

#### What is Tecentriq used for?

##### Lung Cancer

- Tecentriq is used to treat a type of lung cancer called extensive-stage small cell lung cancer (ES-SCLC). Tecentriq is used if you have not received any prior chemotherapy for ES-SCLC. Tecentriq will be given to you in combination with carboplatin and etoposide.
- Tecentriq is used to treat a type of lung cancer called Non-Small Cell Lung Cancer (NSCLC).
  - Tecentriq may be used alone as a treatment for your lung cancer:
    - to help prevent your lung cancer from coming back after your tumor(s) has been removed by surgery and you have had chemotherapy,
    - you have stage 2 to stage 3A NSCLC (talk to your healthcare provider about what these stages mean), and
    - your tumour expresses PD-L1 on 50% or more of the tumour cells.
  - Tecentriq may be used alone as your first treatment when your lung cancer:
    - has spread or grown, and
    - your tumour expresses high PD-L1, and
    - your tumour does not have an abnormal EGFR or ALK gene
  - Tecentriq may be used with bevacizumab and the chemotherapy medicines carboplatin and paclitaxel as your first treatment when your lung cancer:
    - has spread or grown, and
    - is a type of lung cancer called “non-squamous non-small cell lung cancer”, and
    - your tumour does not have an abnormal EGFR or ALK gene
  - Tecentriq may be used when your lung cancer:
    - has spread or grown, and
    - you have tried chemotherapy that contains platinum, and it did not work or is no longer working.
    - If your tumour has an abnormal EGFR or ALK gene, you should have also tried a therapy for tumours with these abnormal genes, and it did not work or is no longer working.

##### Breast Cancer

- Tecentriq is used to treat a type of breast cancer called Triple-Negative Breast Cancer (TNBC). Tecentriq should be used with another drug called nab-paclitaxel when your breast cancer:
  - has spread or cannot be removed by surgery and
  - you have not received any chemotherapy since your cancer has spread and your doctor has tested your cancer and found the presence of a specific protein on your cancer called programmed death-ligand 1 (PD-L1).Tecentriq should not be used with paclitaxel (a different medicine than nab-paclitaxel) for the treatment of TNBC when the cancer has spread or cannot be removed by surgery.

## **Liver Cancer**

- Tecentriq is used to treat a type of liver cancer called hepatocellular carcinoma (HCC). Tecentriq should be used with another drug called bevacizumab when your liver cancer:
  - has spread to other parts of your body or cannot be removed by surgery or cannot be treated locally within the liver, **and**
  - you have not received other medicines to treat your liver cancer.

## **How does Tecentriq work?**

Tecentriq works by attaching to a specific protein in your body called “PD-L1”. This protein makes the immune system in your body not work as well. By attaching to the protein, Tecentriq helps your immune system to fight your cancer.

## **What are the ingredients in Tecentriq?**

Medicinal ingredient: atezolizumab

Non-medicinal ingredients: glacial acetic acid, L-histidine, polysorbate 20, sucrose, and water for injection.

## **Tecentriq comes in the following dosage forms:**

Concentrate for solution for infusion. Each vial contains either 840 mg (in 14 mL) or 1200 mg (in 20 mL) of atezolizumab. Each mL contains 60 mg of atezolizumab.

## **Do not use Tecentriq if:**

- you are allergic to atezolizumab or any of the other ingredients in Tecentriq

## **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Tecentriq. Talk about any health conditions or problems you may have, including if you:**

- have immune system problems such as rheumatoid arthritis, Crohn’s disease, ulcerative colitis, or lupus;
- have had an organ transplant;
- have breathing or lung problems such as inflammation of the lungs (pneumonitis);
- have liver problems;
- have heart problems;
- have kidney problems;
- have muscle weakness and muscle pain;
- have problems with your hormone producing glands including your thyroid, pituitary, adrenal glands, and pancreas;
- have diabetes;
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré Syndrome;
- 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);
- are taking medicine(s) that affect the immune system such as a steroid;
- have previously experienced severe rash or blistering skin condition
- have been given a live, attenuated vaccine;
- are taking medicine to treat an infection; or

- have any other medical conditions.

### **Pregnancy**

- are pregnant or plan to become pregnant
  - Tecentriq can harm your unborn baby. Your healthcare provider should do a pregnancy test before you start treatment with TECENTRIQ.
  - If you are able to become pregnant, you should use an effective method of birth control during your treatment with Tecentriq and for at least 5 months after your last dose of Tecentriq. Talk to your healthcare provider about birth control methods that you can use during this time.
  - Tell your healthcare provider right away if you become pregnant during treatment with Tecentriq.

### **Breast-feeding**

- are breastfeeding or plan to breastfeed
  - Tecentriq may pass into your breast milk. You should not breast-feed for at least 5 months after the last dose.
  - You and your doctor should decide whether you will breast-feed or take Tecentriq. You should not do both.

### **Other warnings you should know about:**

- **Children and adolescents:** Tecentriq should not be given to children or adolescents. This is because the effects of Tecentriq in people younger than 18 years of age are not known.
- **Females of Childbearing Potential:** TECENTRIQ may cause fertility problems, which may affect the ability to have children. Talk to your healthcare provider if you have concerns about fertility.
- **Driving and using machines:** It is not known whether Tecentriq affects your ability to drive or use tools or machines. However, if you feel tired, do not drive or use tools or machines until you feel better.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **How to take Tecentriq:**

- Tecentriq is given through an intravenous infusion (IV). A method of putting the medicine directly into the bloodstream through a vein.
- Your first infusion will be given over 60 minutes.
  - Your healthcare professional will monitor you carefully during the first infusion.
  - If you do not have an infusion reaction during the first infusion, the next infusions will be given to you over a period of 30 minutes.
- Your healthcare professional will decide how many treatments you need.

### **Usual dose:**

- For lung cancer (first-line small cell lung cancer; adjuvant treatment, first-line and second-line non-small cell lung cancer), breast cancer and liver cancer, the recommended dose of Tecentriq is 840 mg every 2 weeks, 1200 mg every 3 weeks or 1680 mg every 4 weeks.

### **Overdose:**

If you think you, or a person you are caring for, have taken too much Tecentriq, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.
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**Missed Dose:**

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

**What are possible side effects from using Tecentriq?**

These are not all the possible side effects you may have when taking Tecentriq. If you experience any side effects not listed here, tell your healthcare professional.

The following side effects have been reported in clinical trials with Tecentriq:

**Very common** (may affect more than 1 in 10 people):

- feeling very tired with no energy (fatigue);
- lack of energy (asthenia);
- decreased appetite;
- nausea;
- fever;
- chills;
- diarrhea;
- hair loss;
- constipation;
- swelling;
- headache;
- vomiting;
- rash;
- shortness of breath;
- cough;
- lung infection;
- itching of the skin;
- stomach pain;
- joint pain;
- nerve pain;
- back pain;
- muscle pain;
- dizziness;
- urinary tract infection;
- leg swelling caused by the retention of fluid in leg tissues (peripheral edema);
- underactive thyroid gland (hypothyroidism);
- elevated liver enzymes - may be a sign of an inflamed liver (shown in blood tests);
- low neutrophil (a white blood cell) levels in the blood (shown in blood tests); and
- difficulty sleeping (insomnia);
- change in your sense of taste (dysgeusia);
- inflammation of mouth and lips;
- flu-like illness.

**Common** (may affect up to 1 in 10 people):

- low blood sugar, magnesium, potassium or sodium levels in the blood (shown in blood tests);
- high blood sugar (shown in blood tests);
- sore throat;
- dry skin;
- low blood pressure;
- high blood pressure;
- pain in the bones;
- low platelet count, which may make you more likely to bruise or bleed;
- nasal congestion;
- low oxygen levels which may cause shortness of breath;
- inflammation of the lungs;
- kidney pain;
- abnormal voice;
- coughing up blood;
- overactive thyroid gland (hyperthyroidism);
- difficulty swallowing;
- sensitivity to light;
- acne-like skin problems;
- shingles;
- elevated creatinine levels (shown in blood tests);
- skin infection (cellulitis);
- blood clot in the lungs (pulmonary embolism) and
- fainting.

In addition to the above mentioned side effects, the following may also occur when Tecentriq is given in combination with chemotherapy and/or with bevacizumab. If you are given Tecentriq in combination with chemotherapy and/or with bevacizumab, then you should also read the Patient Medication Information for these products as well.

**Very common** (may affect more than 1 in 10 people):

- bleeding
- low number of red blood cells - which can cause tiredness and shortness of breath;
- low white blood cell count with and without fever – which can increase the risk of infection;
- mouth blisters or sores;
- low levels of magnesium – which can cause weakness and muscle cramping; and numbness and pain in the arms and legs.

Your healthcare professional will test your blood to check you for certain side effects.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>VERY COMMON</b>			
Inflammation or problems of the nerves (neuropathy): symptoms may include		✓	

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
muscle weakness and numbness, tingling in hands and feet			
<b>COMMON</b>			
Inflammation of the lung (pneumonia, pneumonitis): symptoms may include new or worsening cough, shortness of breath, and chest pain		✓	
Inflammation of the intestines (colitis): symptoms may include diarrhea (watery, loose or soft stools), blood in stools, or dark, tarry, sticky stools, and stomach pain		✓	
Inflammation of the thyroid and adrenal glands (hypothyroidism, hyperthyroidism, or adrenal insufficiency): symptoms may include tiredness, weight loss, weight gain, change in mood, hair loss, constipation, dizziness, and sweating		✓	
Severe reactions associated with infusion (events occurring during or within one day of having the infusion): symptoms may include fever, chills, shortness of breath, or wheezing, swelling of face or lips, itching or rash, and flushing		✓	
Severe infections: symptoms may include fever, cough, frequent urination, flu-like symptoms, and pain when urinating		✓	
Skin problems which can cause rash, itching, redness, skin blistering, sores, peeling		✓	
Inflammation of the bladder (cystitis): symptoms may include persistent urge to urinate, cloudy or bloody urine, burning feeling when urinating, small amounts of urine frequently		✓	
Problems with the sac that surrounds the heart that can make the heart work poorly (pericardial disorders): shortness of breath or difficulty breathing, chest pain, feeling faint or light headed, swelling in the stomach or legs		✓	
<b>UNCOMMON</b>			

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
Inflammation of the liver (hepatitis): symptoms may include yellowing of skin or eyes, nausea, vomiting, bleeding or bruising more easily than normal, dark urine, and stomach pain		✓	
Inflammation of the pancreas (pancreatitis): symptoms may include abdominal pain, nausea and vomiting		✓	
Type 1 diabetes mellitus, including acid in the blood produced from diabetes (diabetic ketoacidosis): symptoms may include feeling more hungry or thirsty than usual, need to urinate more often, weight loss, and feeling tired		✓	
Inflammation of the pituitary gland (symptoms may include issues with regulating body temperature)		✓	
Severe skin reactions: very severe blistering skin condition, may appear with ulcers of the skin and digestive tract, and may lead to the loss of a large portion of skin		✓	
<b>RARE</b>			
Inflammation of the brain (encephalitis) or inflammation of the membrane around the spinal cord and brain (meningitis): symptoms may include neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion and sleepiness		✓	
Inflammation of the eyes: symptoms may include blurry vision, double vision, or other vision problems, and eye pain or redness		✓	
Inflammation of the heart muscles (myocarditis): symptoms may include chest pain, shortness of breath, irregular heartbeat, decreased exercise tolerance, ankle swelling		✓	
Inflammation of the muscles (myositis): symptoms may include muscle weakness and muscle pain that may lead to difficulty moving, breathing, swallowing, and/or dark brown or red colour urine		✓	



Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Inflammation of the kidneys (nephritis): symptoms may include changes in urine output and colour, pain in pelvis, and swelling of the body		✓	
Inflammation of the pituitary gland (hypophysitis): symptoms may include fatigue and headaches that will not go away, increased thirst, increased urination, and changes in vision		✓	
A condition of muscle weakness of the face or inability to move the muscles of the face caused by nerve damage (immune-mediated facial palsy): symptoms may include weakness and/or drooping of the face, trouble with speaking, blinking, swallowing saliva or eating		✓	
Inflammation of spinal cord (immune-mediated myelitis): symptoms may include pain, muscle weakness, paralysis, muscle spasms, loss of balance, numbness or tingling, bladder and bowel dysfunction		✓	
Certain white blood cells destroy other blood cells and build up in and damage organs (bone marrow, liver, and spleen) (hemophagocytic lymphohistiocytosis): symptoms may include fever, enlargement of your liver or spleen, swollen lymph nodes, skin rash, jaundice (yellow colour of your skin and eyes), coughing, trouble breathing, stomach ache, vomiting, diarrhea, headache, trouble walking, visual problems, and weakness		✓	
<b>Unknown frequency</b>			
Aplastic anemia: Insufficient production of new blood cells		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Tecentriq will be stored by your healthcare professionals at the hospital or clinic. The storage details are as follows:

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the vial label after "EXP". The expiry date refers to the last day of that month.
- Store in a refrigerator (2-8°C). Do not freeze.
- Do not shake.
- Keep the vial in the outer carton in order to protect from light.
- Do not throw away any medicines via wastewater or household waste. Your healthcare professional will throw away any medicines that are no longer being used. These measures will help to protect the environment.

### If you want more information about Tecentriq:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website ([www.rochecanada.com](http://www.rochecanada.com)), or by calling 1-888-762-4388.

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