PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

PrTECENTRIQ®

atezolizumab

Concentrate for solution for infusion, 60 mg/mL

1200 mg/20 mL single use vials

Professed Standard

Antineoplastic agent

TECENTRIQ® has been issued marketing authorization **with conditions,** pending the results of studies to verify its clinical benefit. Patients should be advised of the nature of the authorization. For further information for TECENTRIQ®, please refer to Health Canada's Notice of Compliance with conditions - drug products website: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/index-eng.php

TECENTRIQ® is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- Have disease progression during or following platinum-containing chemotherapy
- Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

TECENTRIQ® has been issued marketing authorization **without conditions** for:

- adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have disease progression on a therapy for these aberrations prior to receiving TECENTRIQ.

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This product has been authorized under the Notice of Compliance with Conditions (NOC/c) policy for one of its indicated uses.

What is a Notice of Compliance with Conditions (NOC/c)?

An NOC/c is a form of market approval granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada.

Products approved under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

What will be different about this Product Monograph?

The following Product Monograph will contain boxed text at the beginning of each major section clearly stating the nature of the market authorization. Sections for which NOC/c status holds particular significance will be identified in the left margin by the symbol NOC/c. These sections may include, but are not limited to, the following:

- Indications and Clinical Uses;
- Action;
- Warnings and Precautions;
- Adverse Reactions;
- Dosage and Administration; and
- Clinical Trials.

Adverse Drug Reaction Reporting and Re-Issuance of the Product Monograph

Health care providers are encouraged to report Adverse Drug Reactions associated with normal use of these and all drug products to Health Canada's Canada Vigilance Program at 1-866-234-2345. The Product Monograph will be re-issued in the event of serious safety concerns previously unidentified or at such time as the sponsor provides the additional data in support of the product's clinical benefit. Once the latter has occurred, and in accordance with the NOC/c policy, the conditions associated with market authorization will be removed.

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READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrTECENTRIQ® (te-SEN-trik)
atezolizumab, concentrate for solution for infusion

Read this carefully before you start taking TECENTRIQ and each time you get an infusion. 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?

Bladder Cancer

- TECENTRIQ is used to treat a type of bladder cancer called urothelial carcinoma that cannot be removed by surgery or has spread to other parts of the body. TECENTRIQ is used after you have tried chemotherapy and it did not work or is no longer working.

Lung Cancer

- TECENTRIQ is used to treat a type of lung cancer called Non-Small Cell Lung Cancer (NSCLC) that cannot be removed by surgery or has spread to other parts of the body. TECENTRIQ is used after you have tried platinum-based chemotherapy, and it did not work or is no longer working.

For the following indication, TECENTRIQ has been approved **with conditions** (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

TECENTRIQ is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- Have disease progression during or following platinum-containing chemotherapy
- Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

For the following indication, TECENTRIQ® has been issued marketing authorization **without conditions** for the treatment of:

- adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have disease progression on a therapy for these aberrations prior to receiving TECENTRIQ.

What is a Notice of Compliance with Conditions (NOC/c)?
A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

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 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 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
- are taking medicine(s) that affect the immune system such as a steroid
- have been given a live, attenuated vaccine
- are taking medicine to treat an infection

- have any other medical conditions
- are pregnant or plan to become pregnant
    - TECENTRIQ can harm your unborn baby.
    - 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.
- are breastfeeding or plan to breastfeed
    - TECENTRIQ may pass into your breast milk.
    - 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.
- **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:
- The recommended dose of TECENTRIQ is 1200 milligrams (mg) every three weeks.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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 feel when taking TECENTRIQ. If you experience any side effects not listed here, contact your healthcare professional. Please also see the warnings above.

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)
- loss of appetite
- nausea
- fever
- chills
- diarrhea
- vomiting
- rash
- shortness of breath
- itching of the skin
- stomach pain
- joint pain

Common (may affect up to 1 in 10 people):
- lack of energy (asthenia)
- elevated liver enzymes - may be a sign of an inflamed liver (shown in blood tests)
- low blood sugar, potassium or sodium levels in the blood (shown in blood tests)
- flu-like illness
- low blood pressure
- pain in the muscles and bones
- low platelet count, which my make you more likely to bruise or bleed
- underactive thyroid gland (hypothyroidism)
- nasal congestion
- low oxygen levels which may cause shortness of breath
- inflammation of the lungs

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

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
COMMON Inflammation of the lung (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, 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, and dizziness		✓
Severe reactions associated with infusion (events occurring during or within one day of having the infusion): symptoms may include fever, chills, shortness of breath, and flushing		✓
Severe infections: symptoms may include fever, cough, frequent urination, flu-like symptoms, and pain when urinating		✓
UNCOMMON 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		✓
RARE Inflammation or problems of the nerves (neuropathy): symptoms may include muscle weakness and numbness, tingling in hands and feet		✓
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 kidneys (nephritis): symptoms may include changes in urine output and color, pain in pelvis, and swelling of the body		✓

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

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect™ (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 1908C
    Ottawa, ON
    K1A 0K9

    Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect™ (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

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), or by calling 1-888-762-4388.

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