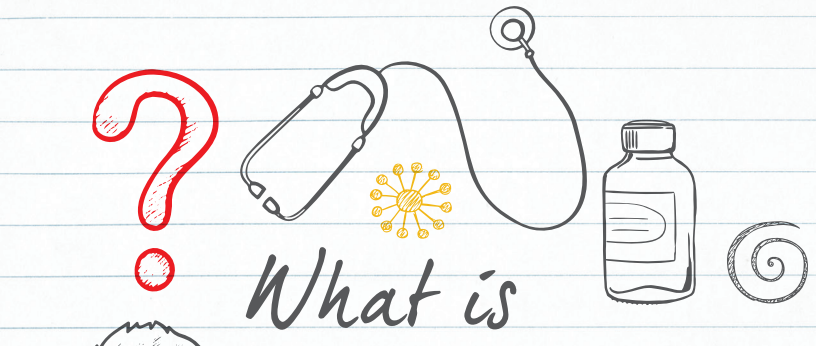
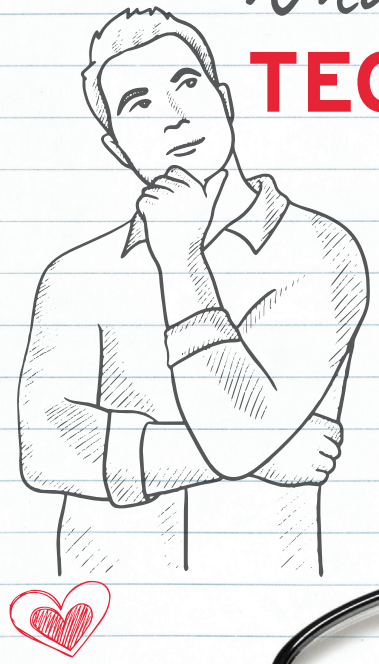
# TECENTRIQ®

## *Patient Brochure*

TECENTRIQ®
atezolizumab



# What is TECENTRIQ®



## TECENTRIQ®
## is a prescription medicine used in the treatment of

**LUNG CANCER**

- Small cell lung cancer (SCLC) and
- Non-small cell lung cancer (NSCLC)

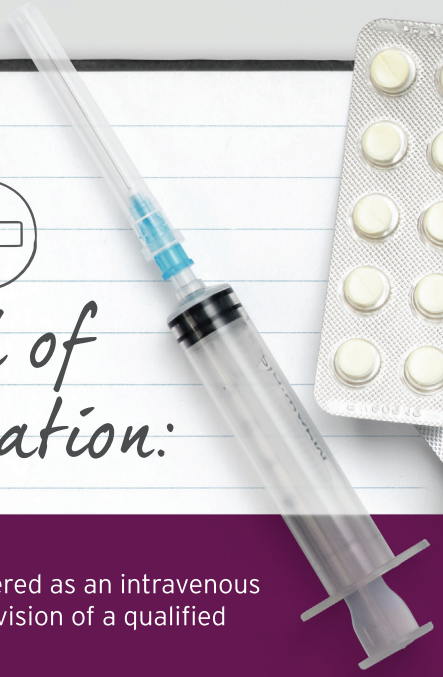
**TRIPLE NEGATIVE BREAST CANCER (TNBC)**

(whose tumors have PD-L1 expression ≥ 1%)

**LIVER CANCER (HEPATOCELLULAR CARCINOMA) (HCC)**

TECENTRIQ® may be used alone or in combination with other medications. Your physician will advise the treatment.

# Method of Administration:



TECENTRIQ® is administered as an intravenous infusion under the supervision of a qualified healthcare professional.

The initial dose of TECENTRIQ® must be administered over 60 minutes. If the first infusion is tolerated, all subsequent infusions may be administered over 30 minutes.

The recommended dose of TECENTRIQ® in monotherapy or combination therapy is:

| 840 mg | 1200 mg | 1680 mg |
|---|---|---|
| administered by IV infusion every 2 weeks | administered by IV infusion every 3 weeks | administered by IV infusion every 4 weeks |

Your physician will be advising on the appropriate dose for you.

# Important Safety Information about TECENTRIQ®

## WHAT IS THE MOST IMPORTANT INFORMATION ABOUT TECENTRIQ®?

TECENTRIQ® can cause your immune system to attack normal organs and tissues in many areas of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death.

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider may treat you with corticosteroids or hormone replacement medicines. Your healthcare provider may delay or completely stop treatment with TECENTRIQ® if you have severe side effects.

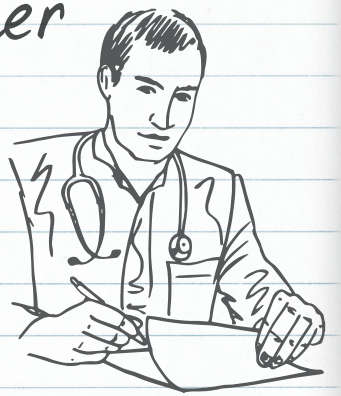
Call or see your healthcare provider right away if you get any symptoms of the following problems or these symptoms get worse.

# TECENTRIQ®

*can cause serious side effects, including:*

- **LUNG PROBLEMS (PNEUMONITIS) -** signs and symptoms may include new or worsening cough, shortness of breath, and chest pain
- **LIVER PROBLEMS (HEPATITIS) -** signs and symptoms of hepatitis may include yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), drowsiness, dark urine (tea colored), bleeding or bruising more easily than normal, and feeling less hungry than usual
- **INTESTINAL PROBLEMS (COLITIS) -** signs and symptoms of colitis may include diarrhea (loose stools) or more bowel movements than usual, blood in your stools or dark, tarry, sticky stools, and severe stomach area (abdomen) pain or tenderness
- **HORMONE GLAND PROBLEMS (ESPECIALLY THE PITUITARY, THYROID, ADRENAL GLANDS, AND PANCREAS) -** signs and symptoms that your hormone glands are not working properly may include headaches that will not go away or unusual headaches, extreme tiredness, weight gain or weight loss, dizzines or fainting, feeling more hungry or thirsty than usual, hair loss, changes in mood or behavior (such as decreased sex drive, irritability, or forgetfulness), feeling cold, constipation, your voice gets deeper, urinating more often than usual, nausea or vomiting, and stomach area (abdomen) pain
- **NERVOUS SYSTEM PROBLEMS (NEUROPATHY, MENINGITIS, ENCEPHALITIS) -** signs and symptoms of nervous system problems may include severe muscle weakness, numbness or tingling in hands and feet, fever, confusion, changes in mood or behavior, extreme sensitivity to light, and neck stiffness
- **INFLAMMATION OF THE EYES -** signs and symptoms may include eye pain or redness, blurry vision, double vision, or other vision problems
- **MUSCLE INFLAMMATION (MYOSITIS) -** Immune system attacks the healthy muscles and blood vessels, indicated by symmetrical proximal muscle weakness and skin rashes and for some chronic pain
- **SEVERE INFECTIONS -** signs and symptoms may include fever, flu-like symptoms, cough, pain when urinating and frequent urination
- **INFLAMMATION OF THE PANCREAS (PANCREATITIS) -** symptoms may include abdominal pain, nausea, vomiting and fever
- **INFLAMMATION OF THE KIDNEY (NEPHRITIS) -** symptoms may include swelling of the body, burning sensation during urination, blood in urine, pain in pelvis
- **INFLAMMATION OF THE HEART MUSCLE (MYOCARDITIS) -** symptoms may include shortness of breath, decreased exercise tolerance, fatigue, chest pain, swelling of the ankles or legs, irregular heartbeat, or fainting
- **INFUSION REACTIONS -** signs and symptoms of infusion reactions may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling like passing out, back or neck pain, and swelling of your face or lips

# Before you receive TECENTRIQ®, tell your healthcare provider about all your medical conditions, including 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 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)
- 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 TECENTRIQ®
- Have been given medicines to suppress your immune system such as corticosteroids, since these medicines may interfere with the effect of TECENTRIQ®
- Have been given a live, attenuated vaccine such as influenza intranasal vaccine, yellow fever vaccine
- Are pregnant or intend 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 and for at least 5 months after the last dose of TECENTRIQ®
- Are breastfeeding or plan to breastfeed
  - It is not known if TECENTRIQ® passes into your breastmilk
  - Do not breastfeed during treatment

Inform your healthcare provider about all the medicines you take, including prescription and over-the counter medicines, vitamins and herbal supplements. 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 brochure or if you notice any signs or symptoms not listed here, please contact your doctor immediately. Getting medical treatment early may stop the problem from becoming more serious.

Please contact your Oncologist for more information.

# Notes

**Abbreviated Prescribing Information**

Before prescribing TECENTRIQ®, please consult the full local prescribing information by visiting www.roche.com.sg/en/pharma/tecentriq.html or by scanning the following QR code.

**THERAPEUTIC INDICATIONS**

- Early-stage Non-Small Cell Lung Cancer (NSCLC):
  - TECENTRIQ®, as monotherapy is indicated as adjuvant treatment following complete resection for adult patients with Stage II to IIIA (7th edition of the UICC/AJCC-staging system) NSCLC whose tumors have PD-L1 expression on ≥ 50% of tumor cells (TC) and whose disease has not progressed following platinum-based adjuvant chemotherapy.
- Metastatic NSCLC:
  - TECENTRIQ®, in combination with Avastin, paclitaxel and carboplatin, is indicated for the treatment of patients with metastatic non-squamous NSCLC who had not received prior chemotherapy.
  - TECENTRIQ® as monotherapy is indicated for the treatment of patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving TECENTRIQ®.
  - TECENTRIQ®, in combination with nab-paclitaxel and carboplatin is indicated for first line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumor aberrations.
  - TECENTRIQ® as monotherapy is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have a PD-L1 expression ≥ 50% TC or ≥ 10% tumor-infiltrating immune cells (IC) and who do not have EGFR or ALK genomic tumor aberrations.
- Small Cell Lung Cancer (SCLC):
  - TECENTRIQ® in combination with carboplatin and etoposide, is indicated for the first line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).
- Triple Negative Breast Cancer (TNBC):
  - TECENTRIQ® in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic TNBC whose tumors have PD-L1 expression ≥ 1% on IC, and who have not received prior chemotherapy for metastatic disease.
- Hepatocellular carcinoma (HCC):
  - TECENTRIQ® in combination with Avastin, is indicated for the treatment of patients with unresectable HCC who have not received prior systemic therapy.

**DOSAGE AND METHOD OF ADMINISTRATION**

- TECENTRIQ® must be administered as an intravenous (IV) infusion under the supervision of a qualified healthcare professional. Do not administer as an IV push or bolus and do not co-administer other medicinal products through the same infusion line. The initial dose of TECENTRIQ® must be administered over 60 minutes. If the first infusion is tolerated, all subsequent infusions may be administered over 30 minutes.
- The recommended dose of TECENTRIQ® in monotherapy or combination therapy is:
  - 840 mg administered by IV infusion every 2 weeks, or
  - 1200 mg administered by IV infusion every 3 weeks, or
  - 1680 mg administered by IV infusion every 4 weeks.
- TECENTRIQ® monotherapy
  - Early-stage NSCLC, 1L metastatic NSCLC
    Patients should be selected for treatment based on the tumor expression of PD-L1 confirmed by a validated test.
- TECENTRIQ® combination therapy
  For the use of TECENTRIQ® in combination therapy, please also refer to the full prescribing information for the combination product. TECENTRIQ® should be administered prior to the combination therapy if given on the same day
  - 1L non-squamous metastatic NSCLC
    TECENTRIQ® in combination with Avastin, paclitaxel, and carboplatin
    During the induction phase, TECENTRIQ® is administered according to its dosing schedules by IV infusion, and Avastin, paclitaxel, and carboplatin are administered every 3 weeks for four or six cycles.
    The induction phase is followed by a maintenance phase without chemotherapy in which TECENTRIQ® is administered according to its dosing schedules by IV infusion, and Avastin is administered every 3 weeks.
    TECENTRIQ® in combination with nab-paclitaxel and carboplatin
    During the induction phase, TECENTRIQ® is administered according to its dosing schedules by IV infusion, and nab-paclitaxel and carboplatin are administered every 3 weeks for four or six cycles. For each 21-day cycle, nab-paclitaxel and carboplatin are administered on day 1. In addition, nab-paclitaxel is administered on days 8 and 15.
    The induction phase is followed by a maintenance phase without chemotherapy in which TECENTRIQ® is administered according to its dosing schedule.
  - 1L ES-SCLC
    TECENTRIQ® in combination with carboplatin and etoposide
    During the induction phase, TECENTRIQ® is administered according to its dosing schedules by IV infusion, and carboplatin and etoposide are administered by IV infusion every three weeks for four cycles. Carboplatin and etoposide are administered on day 1 of each cycle, and etoposide is also administered on days 2 and 3.
    The induction phase is followed by a maintenance phase without chemotherapy in which TECENTRIQ® is administered according to its dosing schedules by IV infusion.
  - 1L TNBC
    TECENTRIQ® in combination with nab-paclitaxel
    TECENTRIQ® is administered according to its dosing schedules by IV infusion and 100 mg/m$^2$ nab-paclitaxel is administered on days 1, 8 and 15 during each 28-day cycle.
    Patients should be selected for treatment based on the tumor expression of PD-L1 confirmed by a validated test.
  - HCC
    TECENTRIQ® in combination with Avastin
    TECENTRIQ® is administered according to its dosing schedules by IV infusion, and Avastin 15 mg/kg is administered every 3 weeks.

The safety and efficacy of alternating or switching between TECENTRIQ® and products that are biosimilar but not deemed interchangeable to TECENTRIQ® has not been established. Therefore, the benefit/risk of alternating or switching needs to be carefully considered.

**SAFETY REPORTING FOR POTENTIAL UNDESIRABLE EFFECTS:** Please report any adverse events to the local Roche Adverse Event email at singapore.drugsafety@roche.com or call (65) 6735 0550. This will enable Roche to better understand the safety of TECENTRIQ®, and to provide appropriate information to Health Authorities, Healthcare Providers and patients.

Reference: TECENTRIQ® Prescribing Information updated September 2022.

This document has been approved by HSA as of 13-10-2022.

**Roche Singapore Pte. Ltd.**
1 Paya Lebar Link #09-03 PLQ 1, Paya Lebar Quarter,
Singapore 408533

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atezolizumab

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