What is the most important information I should know about TECENTRIQ?

TECENTRIQ is a medicine that may treat certain cancers by working with your immune system. TECENTRIQ can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during your treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:

**Lung problems.**
- cough
- shortness of breath
- chest pain

**Intestinal problems.**
- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness

**Liver problems.**
- yellowing of your skin or the whites of your eyes
- dark urine (tea colored)
- severe nausea or vomiting
- bleeding or bruising more easily than normal
- pain on the right side of your stomach area (abdomen)
- urine tinged with blood
- bloating or swelling of your ankles

**Hormone gland problems.**
- headaches that will not go away or unusual headaches
- urinating more often than usual
- eye sensitivity to light
- feeling cold
- rapid heart beat
- constipation
- increased sweating
- your voice gets deeper
- extreme tiredness
- dizziness or fainting
- weight gain or weight loss
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- feeling more hungry or thirsty than usual
- dark urine
- increased sweating
- rapid heart beat
- hair loss
- extreme tiredness
- constipation
- increased sweating
- your voice gets deeper
- weight gain or weight loss
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- feeling more hungry or thirsty than usual
- hard stools
- loose stools
- skin blisters or peeling
- fever or flu-like symptoms
- skin blisters or peeling
- fever or flu-like symptoms
- dry skin
- increased sweating
- rapid heart beat

**Kidney problems.**
- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- loss of appetite

**Skin problems.**
- rash
- itching
- painful sores or ulcers in mouth or nose, throat, or genital area
- skin blistering or peeling
- fever or flu-like symptoms
- swollen lymph nodes

**Problems can also happen in other organs.**
These are not all of the signs and symptoms of immune system problems that can happen with TECENTRIQ. Call or see your healthcare provider right away for any new or worse signs or symptoms including:

- Chest pain, irregular heartbeat, shortness of breath, or swelling of ankles
- Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- Double vision, blurry vision, sensitivity to light, eye pain, changes in eye sight
- Persistent or severe muscle pain or weakness, muscle cramps
- Low red blood cells, bruising

**Infusion reactions that can sometimes be severe or life-threatening.** Signs and symptoms of infusion reactions may include:

- chills or shaking
- itching or rash
- flushing
- shortness of breath or wheezing
- dizziness
- feeling like passing out
- fever
- back or neck pain

Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem
cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with TECENTRIQ. Your healthcare provider will monitor you for these complications.

**Getting medical treatment right away may help keep these problems from becoming more serious.** Your healthcare provider will check you for these problems during your treatment with TECENTRIQ. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with TECENTRIQ if you have severe side effects.

**What is TECENTRIQ?**

TECENTRIQ is a prescription medicine used to treat adults with:

- a type of bladder and urinary tract cancer called urothelial carcinoma. TECENTRIQ may be used when your bladder cancer has spread or cannot be removed by surgery, and you have any one of the following conditions:
  - you are not able to take chemotherapy that contains a medicine called cisplatin, and your cancer tests positive for “PD-L1”, or
  - you are not able to take chemotherapy that contains any platinum regardless of “PD-L1” status, or
  - you have tried chemotherapy that contains platinum, and it did not work or is no longer working.

- a type of lung cancer called non-small cell lung cancer (NSCLC).
  - TECENTRIQ may be used alone as your first treatment when your lung cancer:
    - has spread or grown, and
    - your cancer tests positive for “high PD-L1”, and
    - your tumor does not have an abnormal “EGFR” or “ALK” gene.
  - TECENTRIQ may be used with the medicines bevacizumab, paclitaxel, and carboplatin as your first treatment when your lung cancer:
    - has spread or grown, and
    - is a type called “non-squamous NSCLC”, and
    - your tumor does not have an abnormal “EGFR” or “ALK” gene.
  - TECENTRIQ may be used with the medicines paclitaxel protein-bound and carboplatin as your first treatment when your lung cancer:
    - has spread or grown, and
    - is a type called “non-squamous NSCLC”, and
    - your tumor does not have an abnormal “EGFR” or “ALK” gene.
  - TECENTRIQ may also be used alone 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 tumor has an abnormal “EGFR” or “ALK” gene, you should have also tried an FDA-approved therapy for tumors with these abnormal genes, and it did not work or is no longer working.

- a type of breast cancer called triple-negative breast cancer (TNBC). TECENTRIQ may be used with the medicine paclitaxel protein-bound when your breast cancer:
  - has spread or cannot be removed by surgery, and
  - your cancer tests positive for “PD-L1”.

- a type of lung cancer called small cell lung cancer (SCLC). TECENTRIQ may be used with the chemotherapy medicines carboplatin and etoposide as your first treatment when your lung cancer:
  - is a type called “extensive-stage SCLC,” which means that it has spread or grown.

- a type of liver cancer called hepatocellular carcinoma (HCC). TECENTRIQ may be used with the medicine bevacizumab when your liver cancer:
  - has spread or cannot be removed by surgery, and
  - you have not received other medicines by mouth or injection through your vein (IV) to treat your cancer.

- a type of skin cancer called melanoma. TECENTRIQ may be used with the medicines cobimetinib and vemurafenib when your melanoma:
  - has spread to other parts of the body or cannot be removed by surgery, and
  - has a certain type of abnormal “BRAF” gene. Your healthcare provider will perform a test to make sure this TECENTRIQ combination is right for you.

It is not known if TECENTRIQ is safe and effective in children.
Before receiving TECENTRIQ, tell your healthcare provider about all of your medical conditions, including 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.

**Females who are able to become pregnant:**
- Your healthcare provider should do a pregnancy test before you start treatment with TECENTRIQ.
- 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 breast milk. Do not breastfeed during treatment and for at least 5 months after the last dose of TECENTRIQ.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

### How will I receive TECENTRIQ?
- Your healthcare provider will give you TECENTRIQ into your vein through an intravenous (IV) line over 30 to 60 minutes.
- TECENTRIQ is usually given every 2, 3, or 4 weeks.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will test your blood to check you for certain side effects.
- For treatment of a type of skin cancer called melanoma, your healthcare provider will also prescribe you cobimetinib and vemurafenib. Take cobimetinib and vemurafenib exactly as your healthcare provider tells you.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment

### What are the possible side effects of TECENTRIQ?
TECENTRIQ can cause serious side effects, including:
- See “What is the most important information I should know about TECENTRIQ?”

#### The most common side effects of TECENTRIQ when used alone include:
- feeling tired or weak
- nausea
- cough
- shortness of breath
- decreased appetite

#### The most common side effects of TECENTRIQ when used in lung cancer with other anti-cancer medicines include:
- feeling tired or weak
- nausea
- hair loss
- constipation
- diarrhea
- decreased appetite

#### The most common side effects of TECENTRIQ when used in triple-negative breast cancer with paclitaxel protein-bound include:
- hair loss
- tingling or numbness in hands or feet
- feeling tired
- nausea
- diarrhea
- low red blood cells (anemia)
- constipation
- cough
- headache
- low white blood cells
- vomiting
- decreased appetite

#### The most common side effects of TECENTRIQ when used in hepatocellular carcinoma with bevacizumab include:
- high blood pressure
- feeling tired or weak
- too much protein in the urine

#### The most common side effects of TECENTRIQ when used in melanoma with cobimetinib and vemurafenib include:
- skin rash
- joint, muscle, or bone pain
- feeling tired or weak
- liver injury
- fever
- nausea
- itching
- swelling of legs or arms
- mouth swelling (sometimes with sores)
- low thyroid hormone levels
- sunburn or sun sensitivity

TECENTRIQ may cause fertility problems in females, which may affect the ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of TECENTRIQ.
### General information about the safe and effective use of TECENTRIQ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about TECENTRIQ that is written for health professionals.

### What are the ingredients in TECENTRIQ?

**Active ingredient:** atezolizumab  
**Inactive ingredients:** glacial acetic acid, L-histidine, polysorbate 20 and sucrose

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