

**Medication Guide**  
**etapidi® (tislelizumab-jsgr)**  
**injection**

**What is the most important information I should know about etapidi?**

etapidi is a medicine that may treat certain cancers by working with your immune system. etapidi 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 treatment or even after your treatment has ended.

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

**Lung problems**

- new or worsening cough
- shortness of breath
- chest pain

**Intestinal problems**

- diarrhea (loose stools) or more 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
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

**Hormone gland problems**

- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

**Kidney problems**

- decrease in your amount of urine
- blood in your urine
- swelling in your ankles
- loss of appetite

**Skin problems**

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

**Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with etapidi. Call or see your healthcare provider right away for new or worsening symptoms, which may include:**

- chest pain, irregular heartbeat, shortness of breath, 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 eyesight
- 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 or symptoms of infusion reactions may include:**

- chills or shaking
- dizziness

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

**Rejection of a transplanted organ or tissue.** Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ or tissue transplant that you have had.

**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 etapidi. 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 etapidi. 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 etapidi if you have severe side effects.

### What is etapidi?

etapidi is a prescription medicine used to treat adults with:

- cancer of the tube that connects your throat to your stomach (esophageal cancer).
  - etapidi may be used in combination with chemotherapy that contains platinum as your first treatment when your esophageal cancer:
    - is a type called squamous cell carcinoma, **and**
    - cannot be removed with surgery or has spread to other parts of the body (metastatic), **and**
    - your tumor tests positive for “PD-L1.”
  - etapidi may be used alone when your esophageal cancer:
    - is a type called squamous cell carcinoma, **and**
    - cannot be removed with surgery or has spread to other parts of the body (metastatic), **and**
    - you have had previous treatment that did not include a PD-(L)1 inhibitor medicine.
- cancer of the stomach (gastric cancer) or cancer where the esophagus joins the stomach (gastroesophageal junction cancer).
  - etapidi may be used in combination with chemotherapy that contains platinum and fluoropyrimidine as your first treatment when your gastric or gastroesophageal junction cancer:
    - cannot be removed with surgery or has spread to other parts of the body (metastatic), **and**
    - your tumor tests positive for “PD-L1.”

It is not known if etapidi is safe and effective in children.

**Before receiving etapidi, 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 or tissue transplant, including corneal 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. etapidi can harm your unborn baby.

### Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with etapidi.
- You should use an effective method of birth control during your treatment and for 4 months after your last dose of etapidi. 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 or think you may be pregnant during treatment with etapidi.
- are breastfeeding or plan to breastfeed. It is not known if etapidi passes into your breast milk. Do not breastfeed during treatment with etapidi and for 4 months after your last dose of etapidi.

**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 etapidi?

- Your healthcare provider will give you etapidi into your vein through an intravenous (IV) line over 30 to 120 minutes depending on the dose you are receiving.
- etapidi is usually given every 2, 3, 4, or 6 weeks depending on the dose you are receiving.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will do blood tests to check you for certain side effects.
- If you miss any appointment, call your healthcare provider as soon as possible to reschedule your appointment.

### What are the possible side effects of etapidi?

**etapidi may cause serious side effects. See “What is the most important information I should know about etapidi?”**

**The most common side effects of etapidi when used in combination with platinum-containing chemotherapy include:**

- decreased white blood cell count
- decreased salt (sodium) in your blood
- increased glucose in your blood
- decreased red blood cell count (anemia)
- tiredness
- decreased appetite
- increase in certain liver blood tests
- decreased potassium in your blood
- increase in certain kidney blood tests
- decreased calcium in your blood
- diarrhea
- mouth sores
- vomiting

**The most common side effects of etapidi when used alone include:**

- increased blood sugar
- decreased red blood cell (anemia) and white blood cell counts
- decreased salt (sodium) in your blood
- decreased albumin in the blood
- increase in certain liver blood tests
- tiredness
- muscle and bone pain
- decreased weight
- cough

**The most common side effects of etapidi in combination with platinum and fluoropyrimidine-based chemotherapy include:**

- nausea
- tiredness
- decreased appetite
- decreased red blood cell count (anemia)
- numbness, pain, tingling, or burning in your hands or feet
- vomiting
- decreased platelet count
- decreased white blood cell count
- increase in certain liver blood tests
- diarrhea
- stomach-area (abdominal) pain
- decreased weight
- fever

These are not all the possible side effects of etapidi.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### General information about the safe and effective use of etapidi.

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

### What are the ingredients in etapidi? Active

**ingredient:** tiselizumab-jsgr

**Inactive ingredients:** citric acid monohydrate, histidine, L-histidine hydrochloride monohydrate, polysorbate 20, sodium citrate, trehalose, and Water for Injection.

Manufactured by: BeOne Medicines USA, Inc. Pennington, NJ 08534  
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For more information, go to [www.etapidi.com](http://www.etapidi.com)