

MEDICATION GUIDE
TIVDAK (TIV-dack)
(tisotumab vedotin-tftv)
for injection, for intravenous use

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

TIVDAK can cause serious side effects, including:

Eye problems. Eye problems are common with TIVDAK, and can also be severe. TIVDAK can cause changes to the surface of your eye that can lead to dry eyes, eye redness, eye irritation, corneal ulcers, blurred vision, and severe vision loss. **Tell your healthcare provider if you develop new or worsening vision changes or eye problems during treatment with TIVDAK.**

- Your healthcare provider will send you to an eye specialist to check your eyes before you start treatment with TIVDAK, before each infusion for your first 9 infusions of TIVDAK, and as needed for any new or worsening signs or symptoms of eye problems.
- Your healthcare provider will ask if you have any signs or symptoms of eye problems before each infusion. You will be referred to an eye specialist for any new or worsening signs or symptoms of eye problems.
- Your healthcare provider will prescribe 3 different types of eye drops before you start treatment with TIVDAK. **Bring the eye drops with you to each infusion and use them as directed by your healthcare provider to reduce your risk of eye problems:**
 - Use 1 drop of steroid eye drops in each eye before each infusion and continue to use your eye drops 3 times a day for 3 days after each infusion.
 - Use vasoconstrictor eye drops right before each infusion.
 - Use lubricating eye drops throughout treatment and for 30 days after your last dose of TIVDAK.
- **Do not** wear contact lenses throughout your treatment with TIVDAK unless you are told to use them by your eye specialist.

See **“What are the possible side effects of TIVDAK?”** for more information about side effects.

What is TIVDAK?

TIVDAK is a prescription medicine used to treat adults with cervical cancer:

- that has returned or has spread to other parts of the body, **and**
- who have received chemotherapy that did not work or is no longer working.

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

Before receiving TIVDAK, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of vision or eye problems
- have numbness or tingling in your hands or feet
- have bleeding problems
- have liver problems
- are pregnant or plan to become pregnant. TIVDAK can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with TIVDAK.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with TIVDAK.
- You should use an effective birth control during treatment and for 2 months after your last dose of TIVDAK.

Males with female partners who are able to become pregnant:

- You should use an effective birth control during treatment and for 4 months after your last dose of TIVDAK.
- are breastfeeding or plan to breastfeed. It is not known if TIVDAK passes into your breast milk. Do not breastfeed during treatment and for 3 weeks after your last dose of TIVDAK.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking TIVDAK with certain other medicines may cause side effects.

How will I receive TIVDAK?

- TIVDAK will be given to you by intravenous (IV) infusion into your vein over 30 minutes.
- TIVDAK is usually given every 3 weeks.
- Your healthcare provider will decide how many infusions you need.
- Your healthcare provider will put cold packs on your eyes during each infusion.
- Your healthcare provider may decrease your dose, temporarily stop, or completely stop treatment with TIVDAK if you have side effects.

What are the possible side effects of TIVDAK?

TIVDAK can cause serious side effects, including:

- See **“What is the most important information I should know about TIVDAK?”**

- **Peripheral neuropathy.** Nerve problems called peripheral neuropathy are common with TIVDAK, and can also be serious. Tell your healthcare provider right away if you get numbness or tingling in your hands or feet or muscle weakness.
- **Bleeding (hemorrhage).** Bleeding problems are common with TIVDAK, and can also be serious. Tell your healthcare provider or get medical help right away if you get signs or symptoms of bleeding during treatment with TIVDAK, including:
 - blood in your stools or black stools (looks like tar)
 - blood in your urine
 - cough up or vomit blood
 - unusual vaginal bleeding
 - any unusual or heavy bleeding
- **Lung problems.** TIVDAK may cause severe or life-threatening inflammation of the lungs that can lead to death. Tell your healthcare provider right away if you get new or worsening symptoms, including trouble breathing, shortness of breath, or cough.
- **Severe skin reactions.** TIVDAK may cause severe or life-threatening skin reactions that can lead to death. Tell your healthcare provider or get medical help right away if you get signs or symptoms of a severe skin reaction during treatment with TIVDAK, including:
 - skin reactions that look like rings (target lesions)
 - rash or itching that continues to get worse
 - blistering or peeling of the skin
 - painful sores or ulcers in your mouth, nose, throat, or genital area
 - fever or flu-like symptoms
 - swollen lymph nodes

The most common side effects of TIVDAK include:

- decreased red blood cell counts
- numbness or tingling in your hands or feet
- eye problems (conjunctival disorders)
- nausea
- tiredness
- changes in liver function blood tests
- nosebleed
- hair loss (alopecia)
- bleeding (hemorrhage)

TIVDAK may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of TIVDAK.

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 TIVDAK.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about TIVDAK, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about TIVDAK that is written for healthcare professionals.

What are the ingredients in TIVDAK?

Active ingredient: tisotumab vedotin-tftv

Inactive ingredients: d-mannitol, l-histidine, l-histidine monohydrochloride, and sucrose.

Manufactured by: Seagen Inc., Bothell, WA 98021

Marketed by: Seagen Inc., Bothell, WA 98021 and Genmab US, Inc., Plainsboro, NJ 08536

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For more information, go to www.tivdak.com or call 1-855-4SEAGEN

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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