

# Tivdak Discussion Guide

Questions and considerations  
when starting Tivdak

## 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

TIVDAK was FDA approved based on a clinical study that measured how many patients had a tumor response and how long that response lasted. Continued approval is dependent on the results of an ongoing study to confirm the benefit of TIVDAK.

## Select Important Safety Information

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

**Eye problems** are common with TIVDAK and can be serious. 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.**

Your healthcare provider will send you to an eye specialist to check your eyes before you start treatment with TIVDAK, before each dose of TIVDAK, and as needed for any new or worsening signs and symptoms of eye problems.

**Continue reading information about eye problems on page 2.**

Please see additional [Important Safety Information](#) on pages 2-3 and read the [Important Facts](#) about TIVDAK, including **IMPORTANT WARNING**, at the end of this document.

## Important Safety Information (continued)

### Eye problems (continued)

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:**

- You should use steroid eye drops before each infusion and as prescribed for 72 hours after each infusion
- You should use vasoconstrictor eye drops right before each infusion
- You should 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.

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

Serious side effects of TIVDAK may include:

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

**Nerve problems (peripheral neuropathy)** are common with TIVDAK and can be serious. Tell your healthcare provider right away if you have new or worsening numbness or tingling in your hands or feet or muscle weakness.

**Bleeding problems (hemorrhage)** are common with TIVDAK and can be serious. Tell your healthcare provider or get medical help right away if you have 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, or 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 have 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 have 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 and white blood cell counts
- Tiredness
- Nausea
- Numbness or tingling in your hands or feet, or muscle weakness (peripheral neuropathy)
- Hair loss (alopecia)
- Nosebleed (epistaxis)
- Eye problems (conjunctival disorders)
- Bleeding (hemorrhage)
- Changes in kidney function blood tests
- Dry eye
- Abnormal blood clotting test results
- Diarrhea
- Rash

Your healthcare provider may decrease your dose of TIVDAK, temporarily stop, or completely stop treatment if you have side effects.

### What should I tell my healthcare provider before receiving TIVDAK?

**Tell your healthcare provider about all 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
- are breastfeeding (nursing) or plan to breastfeed. It is not known if TIVDAK passes into your breast milk. Do not breastfeed during treatment and for at least 3 weeks after the last dose of 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 method of birth control during your treatment and for at least 2 months after the last dose of TIVDAK

#### Males with female partners who are able to become pregnant:

- You should use effective birth control during treatment and for 4 months after the 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.

These are not all the possible side effects of TIVDAK. Discuss side effects with your healthcare provider. You are encouraged to report side effects of prescription drugs to the FDA. Visit [www.fda.gov/Safety/MedWatch](http://www.fda.gov/Safety/MedWatch) or call 1-800-FDA-1088.

Please see **Important Facts** about TIVDAK including **IMPORTANT WARNING** at the end of this document.

# Common questions about Tivdak

There are a lot of questions when you're starting a new treatment. We're here to help you learn more about Tivdak and feel ready to get started. Take a look at some frequently asked questions below:

## About Tivdak

### What is Tivdak and why did my doctor prescribe it?

In up to 60% of women with cervical cancer, their disease will return or spread to other parts of the body within 2 years after initial treatment. When that happens, treatments you have taken before for your cervical cancer may not be right for you anymore. Your doctor prescribed Tivdak because it is a prescription medicine used to treat adults with cervical cancer who have cancer that has returned or has spread to other parts of the body, and have received chemotherapy that did not work or is no longer working.

### How Tivdak is thought to work

Tivdak is unlike any medicine you have taken before for your cervical cancer. It is not a chemotherapy.

Based on lab studies, Tivdak attaches to a special protein on the outside of the cancer cell called Tissue Factor and is absorbed into the cell. Once inside, Tivdak releases its cell-killing medicine.

The special protein, Tissue Factor, is also present on normal cells. So, Tivdak can still harm normal cells and cause side effects.

### How often will I need treatment?

Tivdak is a 30-minute intravenous infusion (or IV) given every 3 weeks. Your doctor will decide how many treatments you need.

### How long is each treatment?

Work with your care team to help plan your infusion day. The actual infusion will take approximately 30 minutes with chair time of 1 hour, which includes application of eye drops and cold packs. The full appointment may take more than an hour due to the pre-infusion check and paperwork.

## Side Effects

### What are the most common side effects of Tivdak?

The most common serious side effects were problems moving food and stool through your gut (ileus), bleeding, pneumonia, tingling or numbness in the hands and feet, sepsis, constipation, and fever.

The most common side effects of Tivdak were:

- Decreased red blood cell and white blood cell counts
- Tiredness
- Nausea
- Numbness or tingling in your hands or feet, or muscle weakness (peripheral neuropathy)
- Hair loss (alopecia)
- Nosebleed (epistaxis)
- Changes in kidney function blood tests
- Dry eye
- Eye problems (conjunctival disorders)
- Bleeding (hemorrhage)
- Abnormal blood clotting test results
- Diarrhea
- Rash

These are not all the possible side effects of Tivdak. For more information, see Important Facts about Tivdak at the end of this document.

### If I think I have a side effect, how will I know when it's time to call my care team?

If you notice any new or worsening side effects, tell your care team right away.

### Does a side effect mean I have to stop treatment?

Your care team may need to change, pause, or stop your treatment if you have certain side effects. If you notice any new or worsening side effects, tell your care team right away.

### Is there anything I can do to help reduce side effects?

Tivdak Required Eye Care may help reduce possible eye problems. Your care team may also recommend other medications to help combat possible side effects, such as nausea, constipation, and/or diarrhea. Talk to your care team about any discomfort or side effects you are experiencing.

## Eye Care

### What do I do if I experience any eye problems?

If you experience any new or worsening changes with your eyes or eye problems, call your care team. Your care team is there to help.

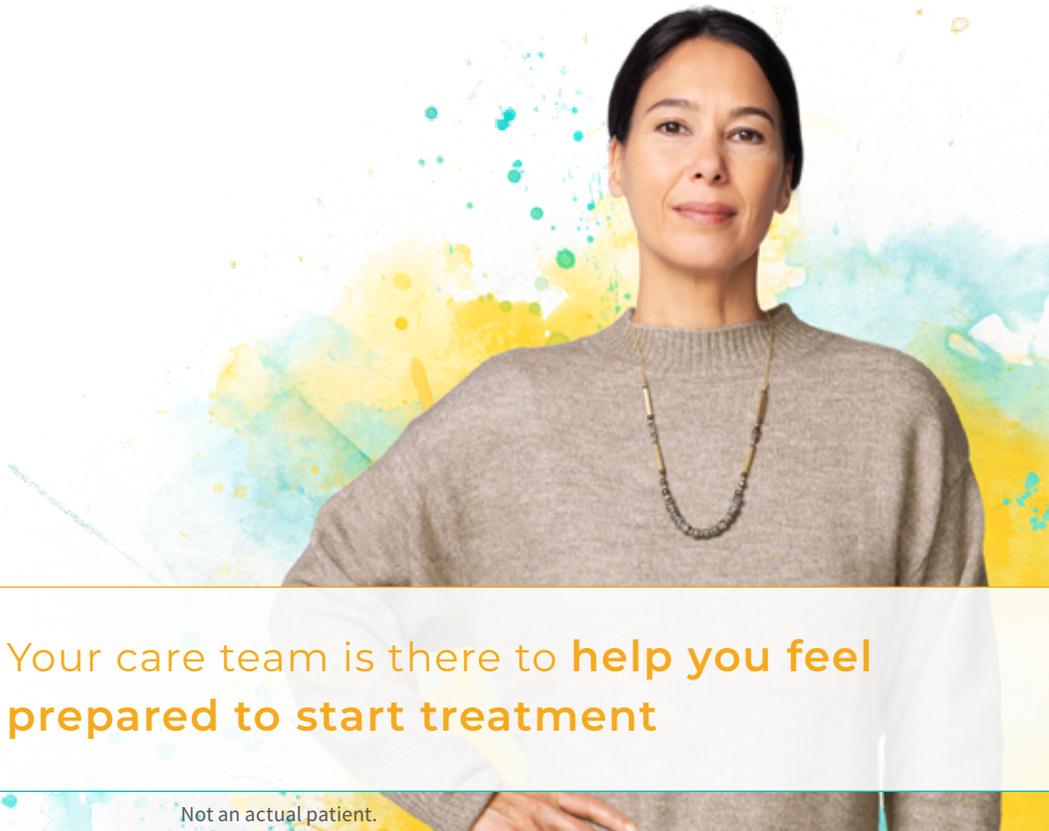
### What happens if I forget my eye drops on the day of infusion?

Forgetting your drops could delay your treatment. Remember to keep track of your drops so you don't run out. The best thing to do is to remember to bring all of your drops to your infusion appointment. Try setting a reminder or creating a checklist for yourself on the day of your appointment to help you remember.

### Can I buy my eye drops over the counter?

You will be prescribed 3 different types of eye drops. The vasoconstrictor and steroid drops will need to be filled by a pharmacist. You can purchase the lubricating drops over the counter. If the lubricating eye drops your care team recommended are not in stock, ask your pharmacist to recommend another.

**This is only an overview of important information, and an example of some of the questions you may have about Tivdak. Talk to your care team to learn more and ask any other questions you may have.**



Your care team is there to **help you feel prepared to start treatment**

Not an actual patient.

## Discussing Tivdak with your care team

It is important to ask your care team any questions you have about starting Tivdak. Learning about Tivdak can help you prepare for treatment.

### Here are some questions to help start a conversation about Tivdak

#### How is Tivdak different from chemotherapy?

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#### How will I know if Tivdak is working?

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#### When will I start treatment?

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#### What should I do to prepare for my first treatment?

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#### Is there anything I can do to help with potential side effects?

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#### How can I keep track of my eye drop schedule?

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# Important Facts

This is only a summary of important information about TIVDAK. Talk to your care team or pharmacist to learn more.

**tivdak**  
tisotumab vedotin-tftv  
for injection 40 mg

## 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 serious. 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 dose of TIVDAK, and as needed for any new or worsening signs and 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:**
  - You should use steroid eye drops before each infusion and as prescribed for 72 hours after each infusion.
  - You should use vasoconstrictor eye drops right before each infusion.
  - You should 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

# Important Facts

This is only a summary of important information about TIVDAK. Talk to your care team or pharmacist to learn more.

**tivdak**<sup>®</sup>  
tisotumab vedotin-tftv  
for injection 40 mg

## What are the possible side effects of TIVDAK? (continued)

- 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 and white blood cell counts
- tiredness
- nausea
- hair loss (alopecia)
- nosebleed
- changes in kidney function blood tests
- dry eye
- abnormal blood clotting test results
- diarrhea
- rash

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

These are not all 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.

Visit [tivdak.com](https://www.tivdak.com) to learn more or call 1-855-4SEAGEN.