



Eye Care Guide for Patients

This guide is designed to help you understand what eye care steps to take while on Tivdak, to reduce the risk of eye 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

TIVDAK was FDA-approved based on a clinical study that measured how many patients had a tumor response and how long that response lasted. There is another study with TIVDAK to confirm the clinical benefit.

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.**

Continue reading information about eye problems on pages 2-3.

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

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.

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:

Peripheral neuropathy (nerve problems) can occur 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 (hemorrhage) can occur with TIVDAK and can be serious. Tell your healthcare provider right away if you get signs or symptoms of bleeding during treatment with TIVDAK including blood in your stool or black stool (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.

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
- 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.

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 or call 1-800-FDA-1088.

Please see [Important Facts](#) about TIVDAK including **IMPORTANT WARNING** at the end of this document.

Tivdak Required Eye Care

Be sure to read through the Tivdak Important Facts. Talk to your care team if you have any questions. Tell your care team if you have any new or worsening eye problems while taking Tivdak.

1

Before each dose

You will visit an eye specialist for an exam before each dose of Tivdak.

2

Infusion day

A nurse will supervise administration of your vasoconstrictor and steroid eye drops, and cold packs.

3

After infusion

Use steroid and lubricating eye drops as directed and self-monitor eyes for any new or worsening eye problems.



You will need to get an exam from an eye specialist before every treatment.

Below is a guide to caring for your eyes while taking Tivdak.

1 BEFORE EACH DOSE OF TIVDAK

□ Eye appointment

Your healthcare provider will send you to an eye specialist to check your eyes before each dose with Tivdak

□ Eye drop prescriptions

You will be prescribed 3 different types of eye drops. Bring the eye drops with you to each infusion. Always take your eye drops as directed by your doctor.

Vasoconstrictor drops

Right before each infusion (3 drops per eye, or as directed, with nurse assistance)

Steroid drops

Day of infusion		For 2 days after each infusion
Just before each infusion	Remainder of the day	For 2 days after each infusion
		
1 drop per eye (or as directed)	1 drop per eye, 2x (or as directed)	1 drop per eye, 3x (or as directed)

Lubricating drops

Use multiple times every day throughout treatment as needed until 30 days after your last dose.

Please see [Important Safety Information](#) on pages 1-3 and read the [Important Facts](#) about TIVDAK, including **IMPORTANT WARNING** at the end of this document.

Tivdak Required Eye Care (continued)

2 INFUSION DAY (DAY 1): Prior to appointment



- Bring all eye drops**



- Avoid contact lenses**
Do not wear contact lenses throughout your treatment with Tivdak unless you are told to use them by your eye specialist.



- Avoid eye irritants**
Avoid putting things on or near your eyes that may irritate them during treatment. Consult your care team for further guidance.

2 INFUSION DAY (DAY 1): During and after the appointment

Eye drops

Just before your infusion begins, you will apply the following eye drops with the help of a nurse:

Vasoconstrictor drops

 **3 drops per eye**
(or as directed)

Steroid drops

 **1 drop per eye**
(or as directed)

Cold packs

You will receive a cold pack to place over your eyes before, during, and after the infusion. Cold packs will be kept on starting ~10 minutes before your infusion until ~20 minutes after.

For the remainder of the day

- Steroid drops: 1 drop per eye, 2x throughout day (or as directed)
- Lubricating drops: multiple drops as needed per eye, or more as needed



IMPORTANT: Don't forget your drops or your infusion may be delayed!

Please see [Important Safety Information](#) on pages 1-3 and read the [Important Facts](#) about TIVDAK, including **IMPORTANT WARNING** at the end of this document.

Tivdak Required Eye Care (continued)

3 AFTER INFUSION (DAYS 2-3)

Steroid drops

On days 2 and 3 take steroid eye drops as instructed by your care team:



1 drop per eye
3x daily
(or as directed)

Lubricating eye drops



Take your lubricating eye drops multiple times per day as needed or as directed

ONGOING

Eye drops

Lubricating drops

Every day throughout treatment as needed and for 30 days after your last dose of Tivdak

Check your eyes daily

Report any changes with your eyes or eye problems to your care team:

- | | |
|---|--|
| <input checked="" type="checkbox"/> Swelling | <input checked="" type="checkbox"/> Watery eyes |
| <input checked="" type="checkbox"/> Redness | <input checked="" type="checkbox"/> Dry eye |
| <input checked="" type="checkbox"/> Itchy eyes | <input checked="" type="checkbox"/> Light sensitivity |
| <input checked="" type="checkbox"/> Eye pain | <input checked="" type="checkbox"/> Severe vision loss |
| <input checked="" type="checkbox"/> Blurry vision | |

Refilling eye drop prescriptions

- Remember to keep track of your drops so you don't run out
- You will need to have an eye exam before you can renew your steroid eye drops

Avoid contact lenses and things that may irritate your eyes

Please see [Important Safety Information](#) on pages 1-3 and read the [Important Facts](#) about TIVDAK, including **IMPORTANT WARNING** at the end of this document.

tivdak[®]
tisotumab vedotin-tftv
for injection 40 mg

Please see [Important Safety Information](#) on pages 1-3 and read the [Important Facts](#) about TIVDAK, including **IMPORTANT WARNING** at the end of this document.



Tivdak and its logo are trademarks of Seagen Inc. Seagen and its logo are US registered trademarks of Seagen Inc. Genmab; the Y-shaped Genmab logo; and Genmab in combination with the Y-shaped Genmab logo are trademarks for Genmab A/S and/or its subsidiaries.

©2021 Seagen Inc. and Genmab US, Inc. All rights reserved. US-TVP-21-113-MT

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 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.

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

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 are the possible side effects of TIVDAK? (continued)

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.

Get more information

- This is only a summary of key information about TIVDAK
- Talk to your healthcare provider or pharmacist to learn more
- Go to tivdak.com or call 1-855-4SEAGEN
- If you need help paying for your medicine, visit SeagenSecure.com for program information

Visit tivdak.com to learn more or call 1-855-4SEAGEN.