

Eye Care Guide for Patients

Caring for your eyes to
help reduce the risk of
eye problems

Not an actual patient.

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.**

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.

Eye problems (continued)

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:

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

Please see additional Important Safety Information on pages 1 and 3 and read the Important Facts about TIVDAK, including **IMPORTANT WARNING, at the end of this document.**

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 or call 1-800-FDA-1088.

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

Please see additional Important Safety Information on pages 1-2 and read the Important Facts about TIVDAK, including IMPORTANT WARNING, at the end of this document.

What's inside?

Caring for your eyes is always encouraged, and during treatment with Tivdak[®], eye care is especially important. Eye problems are common with Tivdak, and can also be serious. But there are steps you can take to help reduce the risk of eye problems.

This brochure will take you through those steps which we call Tivdak Required Eye Care.



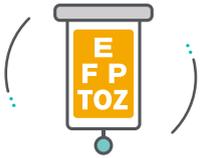
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Please see Important Safety Information on pages 1-3 and read the Important Facts about TIVDAK, including **IMPORTANT WARNING, at the end of this document.**

Exams

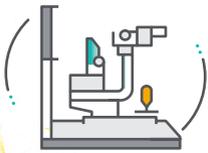
As part of Tivdak Required Eye Care, your care team will send you to an eye specialist to check your eyes. These eye exams will occur before you start treatment with Tivdak, before each infusion of Tivdak, and as needed.

Your eye specialist will perform 2 exams during an appointment, a visual acuity exam and a slit lamp exam. They will also monitor for any new or worsening signs and symptoms of eye problems.



Visual acuity exam

- ▶ Visual acuity measures how sharp your vision is at a distance. It is usually tested by reading an eye chart



Slit lamp exam

- ▶ A slit lamp is simply a microscope with a bright light used during an eye exam
- ▶ It helps to determine the health of your eyes and detect eye problems

Eye exams will occur before you start treatment with Tivdak, before each infusion of Tivdak, and as needed.

Eye drops

Either your oncologist or eye specialist will prescribe 3 different types of eye drops. These eye drops may help reduce the risk of eye problems. Bring all 3 of the eye drops with you to each infusion and use them as directed by your care team. The first prescription of steroid drops and all following prescription renewals will only be made after a slit lamp exam with an eye specialist.

	Why	When ^a	How many ^a
 Steroid drops	May help protect against redness, swelling, and itchiness	<p>~10 minutes before your infusion</p> <p>For 72 hours post infusion</p>	<p>1 drop per eye^b</p> <p>1 drop per eye, 2x a day (Day 1/infusion day)</p> <p>1 drop per eye, 3x a day (Days 2 and 3)</p>
 Vasoconstrictor drops	May help keep Tivdak [®] from affecting your eyes by reducing blood flow in the eyes	Right before your infusion	3 drops per eye ^b
 Lubricating drops^c	May help reduce and relieve dryness and discomfort	Duration of treatment and for 30 days after your last dose of Tivdak ^a	As needed

^aOr as instructed by your care team.

^bA nurse may help you apply drops at your infusion appointment.

^cThese drops may be purchased over the counter.

Don't forget to **bring all 3 eye drops to each infusion**

Check your eyes daily

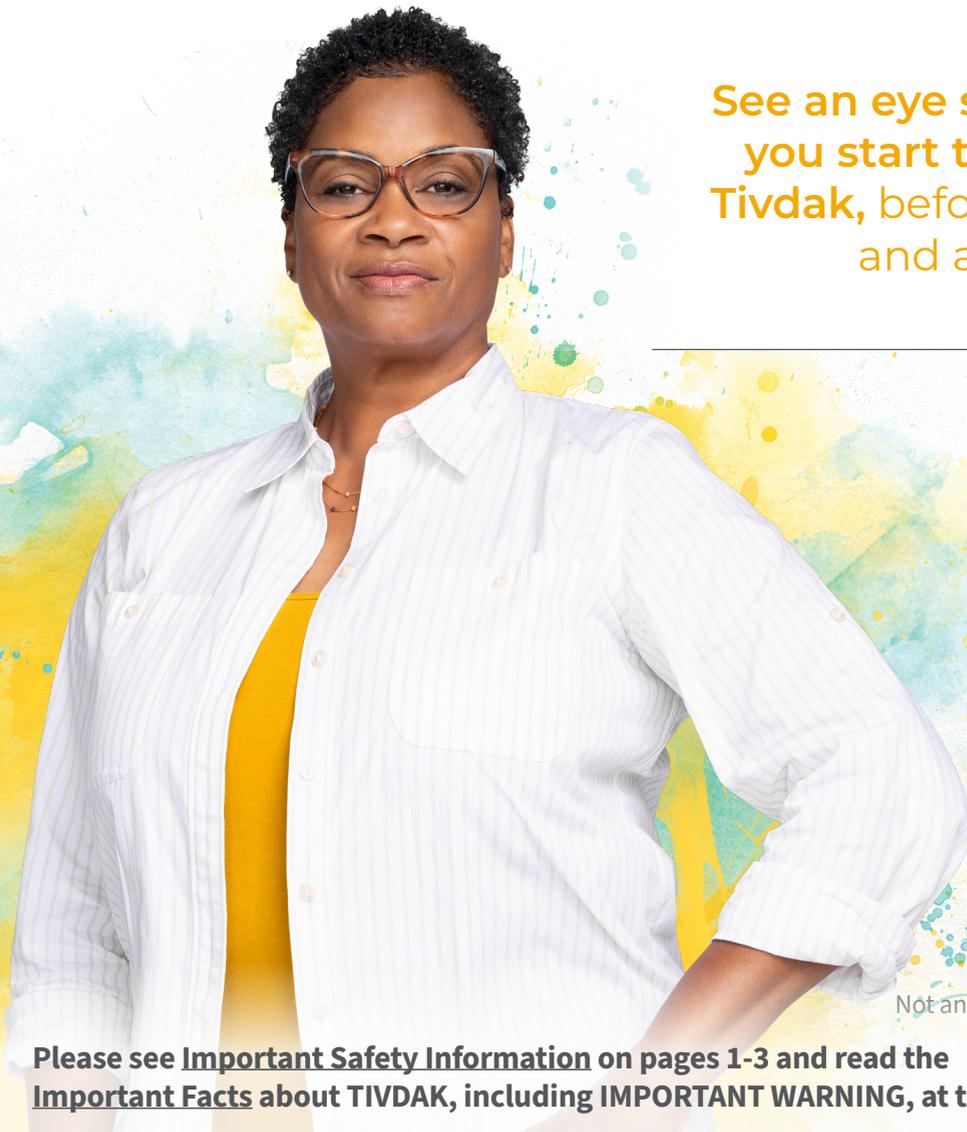
Make sure to check your eyes daily for any new or worsening eye problems, such as:



- Dry eyes
- Eye irritation
- Blurred vision
- Eye redness
- Light sensitivity
- Vision loss or impairment

If you experience new or worsening eye problems, call your care team right away. Your care team is there to help.

See an eye specialist before you start treatment with Tivdak, before each infusion, and as needed



Not an actual patient.

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.

Helpful tips and reminders

Things to keep in mind



Infusion Day

- Bring all of your eye drops to every infusion appointment. If you forget your drops, your infusion might get delayed



Throughout Treatment

- Take your eye drops as prescribed
- Avoid contact lenses and things that may irritate your eyes unless otherwise instructed by your care team

Keep track of your drops so you don't run out

Sign up for TivdakTexts

TivdakTexts is a text message support program designed to assist you throughout treatment

Some benefits of TivdakTexts include:



Infusion reminders



Eye drop reminders



Encouraging messages

Learn more about TivdakTexts and discover additional resources at tivdak.com/resources

Tivdak[®] Eye Drop Tracker

During your Tivdak treatment, it's important to follow steps to reduce the risk of eye problems. Remember to always speak with your healthcare team if you have any questions regarding your eye care.

This calendar will help you keep track of your eye drop schedule.^a
See instructions below:

1 Fill in the date for each day.

3 3 vasoconstrictor drops will be applied once, right before your infusion, with the help of your care team, if needed.

4 Continue to apply steroid eye drops for 72 hours post infusion. **1 drop per eye, 2x a day on Day 1 (infusion day) and 3x a day on Days 2 and 3.**

INFUSION CYCLE	Day 1	Day 2	Day 3
Date	INFUSION DAY <i>6/21</i>	<i>6/22</i>	<i>6/23</i>
Steroid Drops			
Vasoconstrictor Drops		—	—
Lubricating Drops	Remember to take your lubricating drops for the duration of treatment and for 30 days after your last dose.		
Notes: <i>Add notes here</i>			

2 Apply your first steroid drop in each eye at your infusion appointment. Your care team may do this for you.

5 Take notes on any new or worsening eye problems, or other side effects.

^aApply eye drops as outlined above unless otherwise directed by your care team.

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

Mark each circle with an X once the drops are applied.

Always use your eye drops as directed by your care team.

INFUSION CYCLE	Day 1	Day 2	Day 3
Date	INFUSION DAY		
Steroid Drops	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>
Vasoconstrictor Drops	<input type="radio"/>	—	—
Lubricating Drops	Remember to take your lubricating drops for the duration of treatment and for 30 days after your last dose.		
Notes:			

INFUSION CYCLE	Day 1	Day 2	Day 3
Date	INFUSION DAY		
Steroid Drops	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>
Vasoconstrictor Drops	<input type="radio"/>	—	—
Lubricating Drops	Remember to take your lubricating drops for the duration of treatment and for 30 days after your last dose.		
Notes:			

INFUSION CYCLE	Day 1	Day 2	Day 3
Date	INFUSION DAY		
Steroid Drops	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>
Vasoconstrictor Drops	<input type="radio"/>	—	—
Lubricating Drops	Remember to take your lubricating drops for the duration of treatment and for 30 days after your last dose.		
Notes:			

**Bring this Eye Drop Tracker with you
to your infusion appointments**

Learn more about Tivdak and find these additional resources at tivdak.com



Patient Brochure

An overview of Tivdak and what to expect from treatment



Tivdak Discussion Guide

FAQs and topics to review with your care team



TivdakTexts

A text message support program designed to assist you throughout treatment



Caring for your eyes while on Tivdak

Watch a nurse practitioner give an overview of Tivdak Required Eye Care at tivdak.com/caring-for-your-eyes



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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.

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
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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 to learn more or call 1-855-4SEAGEN.