

INTRAVENOUS CANCER TREATMENT EDUCATION



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TISOTUMAB VEDOTIN

Name of the regimen and cancer drugs

Tisotumab vedotin (ty-SOH-too-mab veh-DOH-tin): Tivdak

Common uses

This regimen is most commonly used for cervical cancer but may be used for other diagnoses.

Treatment schedule

Your treatment will be given into your vein through an intravenous (IV) line. This may be into a short, flexible temporary catheter in your arm, or through a central venous catheter. A central venous catheter, or central line is a long, flexible IV tube that empties into a very large vein next to the heart. Talk with your care team to see which will be best for you and your treatment.

Each tisotumab vedotin treatment is repeated every 21 days. This is known as one cycle. Your treatment may be given for a set number of cycles, or it will keep going until the drug stops working or you have side effects which stop you from continuing treatment.

- Tisotumab vedotin IV given on Day 1

Drug	Cycle 1	Day 1	2	3	4	5	6	7	8	9	10	11	...	21	Cycle 2 Day 1
Tisotumab vedotin															

Other medications

Other medications may be ordered for you to prevent or treat certain side effects. These include:

	Instructions:
Medications to prevent side effects	You will receive your medications to prevent side effects just before your chemotherapy. You may get prescriptions for other medications to take at home, as below: <hr/> <hr/> <hr/> <hr/>
Eye toxicity prevention	You will receive prescription eye drops to prevent eye toxicity. Bring these with you to your treatment appointment, and take before and after infusion, as directed

Possible drug interactions

- Tisotumab vedotin may interact with other drugs you are taking. Please inform your care providers of all prescription medicine, over-the-counter medications, vitamins, and herbal products that you take.
- Talk with your care provider or pharmacist before taking new medications, supplements, or receiving any vaccines.

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Common Side Effects

Common side effects that have been known to happen in patients receiving tisotumab vedotin are listed in the left side of this table. In some instances, the side effects may be reported less often but are still important to discuss. This table does not list all the known side effects for this therapy, only the ones that are experienced most often. Not every patient experiences every known side effect of a drug; even if you are taking the same drug as another patient, you may experience different side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be checked by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7 to 8 hours of sleep per night • Avoid operating heavy machinery if you feel too tired • Find a balance between “work” and “rest” • Stay as active as possible, but know that it is okay to rest as needed, too • You might notice that you are more pale than usual <p>Let your care team know right away if you have:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Fast or abnormal heartbeat
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an in-fec-tion. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe often for good personal hygiene. <p>Contact your care team if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning when peeing • Tiredness that is worse than normal • A sore that becomes red, is draining, or does not heal. <p>Check with your care team before taking any medicine for a fever or chills.</p>

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Possible Side Effect	Management
<p>Bleeding</p>	<p>You may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns • Blow your nose gently and do not pick your nose • Brush your teeth gently with a soft toothbrush and maintain good oral hygiene • When shaving use an electric razor instead of razor blades • Use a nail file instead of a nail clippers <p>Call your care team if you have bleeding that won't stop. Examples include:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than 5 minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed a lot when you floss or brush <p>Seek medical help right away if you have any severe headaches, blood in your urine or stool, coughing up blood, or bleeding that you cannot stop or lasts a long time.</p>
<p>Numbness or tingling in hands and feet.</p>	<p>Report changes in your sense of touch, such as a burning feeling, pain on the skin or weakness.</p> <p>Notify your care team as soon as these symptoms develop. Early intervention can limit or resolve these symptoms, but if not addressed these symptoms may become permanent.</p>
<p>Hair loss (alopecia)</p>	<ul style="list-style-type: none"> • Hair will likely grow back after treatment is completed, although the color and/or texture may be different. • It may take 3 to 6 months after therapy is completed to resume normal hair growth. • Some people choose to wear scarves, caps, or wigs. A short haircut prior to treatment may help with stress of hair loss. • Partial or complete hair loss is likely, usually 1-2 weeks after start of therapy. This hair loss can be all body hair. • Be sure to keep your head covered to protect it from the sun during the summer and cold during the winter. • If not covering your scalp during the summer months, be sure to use sunscreen when spending time outdoors.
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Possible Side Effect	Management
<p>Eye problems</p>	<p>This medication may cause blurred vision, dry eyes, or eye pain.</p> <ul style="list-style-type: none"> • Receive a thorough eye exam before your first dose and prior to each additional treatment • Use prescription eye drops as prescribed before and after treatment • Apply cooling pads to your eyes during infusion • Use lubricating eye drops for the duration of treatment and continue for 30 days after your last dose. • Avoid wearing contact lenses during treatment, unless specifically advised by your eye care professional <p>Report changes in eyesight to your care team</p>
<p>Nausea or vomiting</p>	<ul style="list-style-type: none"> • Take all medications as prescribed to help prevent and lessen symptoms of nausea and vomiting. • Eat and drink slowly. • Drink 8-10 (8-ounce) glasses of water and/or fluid (soup or broth) each day unless your care team has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid intense exercise immediately after eating. • Don't lay down right away after eating. • Wear loose fitting clothing for comfort. • Avoid strong odors. Consider getting fresh air and try deep breathing. <p>Let your care team know if you have nausea or vomiting. Your care team may prescribe medication to help with the symptoms.</p>
<p>Fatigue</p>	<ul style="list-style-type: none"> • You may be more tired than usual or have less energy • Stay as active as possible, but know it is okay to rest as needed • Try to do some type of moderate activity every day • Conserve your energy. Plan your activities and do them at a time of day when you feel a bit more energetic • Follow a healthy diet and stay hydrated • Accept help from family and friends • Find healthy ways to manage stress, such as meditation, journaling, yoga, and guided imagery • Develop good sleeping habits, limit napping during the day to help you sleep better at night • Avoid operating heavy machinery if you feel too tired • Contact your care team if you experience extreme fatigue that prevents you from doing your normal daily activities

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Rare but serious side effects

Tell your care provider if you experience any symptoms of these problems:

- This product may result in serious and fatal lung toxicity. When taking tisotumab vedotin, if you start to experience shortness of breath, fatigue, breathlessness, or discomfort/worsening of symptoms while lying on your back, please immediately contact your prescriber.

If you experience ANY new, worsening, or uncontrolled side effects, call your care team immediately.

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Some of the drugs you receive may be present in urine, stool, sweat, or vomit for many days after treatment. Many cancer drugs are toxic, your bodily waste may also be toxic and can be dangerous to come into contact with. Once you have started tisotumab vedotin, follow the instructions below for at least two days after your treatment. This is to keep you, your loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
- If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surface after every use before other people use the toilet.
- Wash hands with soap and water after using the toilet for at least 20 seconds.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

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Intimacy, sexual activity, contraception, and fertility

This treatment may cause changes that can affect intimacy and sexuality, including desire and body image. Maintaining physical closeness and/or intimacy with loved ones can be continued during treatment. Holding hands, hugging, and kissing can be done safely. It is recommended that you talk to your care team about any restrictions or questions you may have.

Some treatments can influence the ability to have children, also known as fertility. If you're interested in preserving fertility, talk to your care team before treatment. Ask your healthcare provider to determine when it is safe to become pregnant after your treatment. Patients of reproductive ability should not become pregnant or get their partners pregnant while receiving tisotumab vedotin. Some of the drugs you receive may be present in semen and vaginal secretion for many days after treatment. You should use barrier devices, such as condoms, during sexual activity to limit exposure to body fluids.

- Talk to your care team about birth control. Not all options may be right for your treatment or cancer. Effective contraception could include one or more of the following: barrier methods (e.g. condoms), hormone methods (e.g. birth control pills), or surgery.
- Tell your care team if you become pregnant or plan to breastfeed.

Additional resources

Product website: <https://www.tivdakhcp.com/>

Prescribing information link: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761208Orig1s000lbledt.pdf

Product resources: <https://www.tivdakhcp.com/eye-care/> and <https://www.tivdak.com/>

Additional instructions

Updated – July 1, 2022

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the therapy derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this therapy and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this therapy by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual receiving therapy. All decisions related to receiving this therapy should be made with the guidance and under the direction of a qualified healthcare professional.

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