

IV AND ORAL CANCER TREATMENT EDUCATION



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TAFASITAMAB-CXIX + LENALIDOMIDE

Name of the regimen and anti-cancer drugs

- Oral Treatment
Generic name (pronunciation): lenalidomide (leh-nuh-LIH-doh-mide)
Brand name: Revlimid® (REV-lih-mid)

- Infusion Treatment
Generic name (pronunciation): tafasitamab-cxix (TA-fuh-SIH-tuh-mab)
Brand name: Monjuvi® (mon-JOO-vee)

Common uses

This regimen is most commonly used for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

Treatment dose and schedule

The first part of your treatment, tafasitamab-cxix, 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.

The second part of your treatment, lenalidomide, will be given orally. This medication will be ordered by your provider to take by mouth at home.

Each tafasitamab-cxix and lenalidomide treatment is repeated every 28 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, or drugs, stop working or you have side effects which stop you from continuing treatment.

- Your tafasitamab-cxix is given through your veins (IV) as follows:
 - Cycle 1: Days 1, 4, 8, 15 and 22 of the 28-day cycle
 - Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle
 - Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle
- Your lenalidomide should be taken by mouth once daily on days 1-21 of each 28-day treatment cycle

Taking lenalidomide as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose and schedule of lenalidomide will be determined by your overall health, diagnosis, and individual treatment needs.
- Lenalidomide is to be taken by mouth one time per day.
- Lenalidomide can be taken with or without food but at the same time each day.
- Lenalidomide should be taken whole and not opened, crushed, cut, or dissolved. If you are unable to swallow lenalidomide, talk to your care provider or pharmacist for possible options.
- If you miss a dose
 - Do not take the missed dose if it has been more than 12 hours since you should have taken it. Simply take the next dose at the regularly scheduled time.
 - Do not take two doses at one time.
 - Be sure to write down if you miss a dose and let your care provider know about any missed doses.

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Other medications

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

	Instructions
Medications to prevent allergic reactions	<p>You will receive medications to prevent infusion related reactions prior to starting your cancer treatment.</p> <hr/> <hr/> <hr/> <hr/>
Medications to prevent side effects	<p>You will receive your medications to prevent side effects just before your cancer treatment. You may get prescriptions for other medications to take at home, as below:</p> <hr/> <hr/> <hr/> <hr/>

Possible drug interactions

- Tafasitamab-cxix and lenalidomide 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 of tafasitamab-cxix + lenalidomide

Common side effects that have been known to happen in patients receiving **TAFASITAMAB-CXIX + LENALIDOMIDE** 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 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 infection. 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>
<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 • Headache

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Possible Side Effect	Management
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, 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>You may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care team or dentist before any scheduled procedures.</p>
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <p>If experiencing diarrhea, consider the following:</p> <ul style="list-style-type: none"> • Drink 8-10 (8-ounce) glasses of water or fluid each day unless your care team has asked you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • Avoid high fiber foods, such as raw vegetables and fruits and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid foods with lactose, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your care team if:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by 4 or more. • You feel dizzy or lightheaded. <p>Your care team may recommend an over-the-counter medication or prescribe something to help manage your symptoms.</p>

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Possible Side Effect	Management
<p>Fluid retention or swelling (edema)</p>	<ul style="list-style-type: none"> • Do not stand for long periods of time • Keep your legs elevated when sitting or lying down • Try to not eat salty foods, which can increase swelling • Avoid tight-fitting clothing and shoes • Weigh yourself daily • Take any medications as prescribed to decrease fluid retention <p>Contact your care team if you notice:</p> <ul style="list-style-type: none"> • Swelling in the hands, feet, or legs • You are short of breath • You have gained 5 pounds or more in one week
<p>Infusion reaction</p>	<p>During your treatment, let the nurse know right away if any of these symptoms happen:</p> <ul style="list-style-type: none"> • Chills or shaking • Dizziness • Fever • Itchiness or rash • Flushing • Difficulty breathing • Wheezing • Throat irritation • Cough • Congestion • Sudden back pain • Feeling faint
<p>Rash or itchy skin</p>	<ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness and wear loose fitting clothing. • Avoid using perfumes and cologne as these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Your provider may recommend an over-the-counter antihistamine or a topical cream. • Sunlight can make symptoms worse. <ul style="list-style-type: none"> <input type="checkbox"/> Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultra-violet) radiation occurs between the hours of 10am and 4pm. <input type="checkbox"/> Wear long-sleeved clothing, with UV protection if possible. <input type="checkbox"/> Wear broad-brimmed hats. <input type="checkbox"/> Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. <input type="checkbox"/> Use lip balm with at least SPF 30. <input type="checkbox"/> Avoid tanning beds. <p>If your rash or itching continues to worsen, contact your care team.</p>

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Rare but serious side effects

- ❑ If you experience ANY new, worsening, or uncontrolled side effects, call your care team immediately.
- ❑ Tafasitamab-cxix can cause infections like pneumonia and urinary tract infections. Let your provider know if you experience a new or worsening cough, pain when urinating or increased urinary frequency, especially in combination with a fever. Always let your provider know if you experience a temperature more than 100.4°F or 38°C.
- ❑ Lenalidomide may be harmful to your liver. Speak to your care provider to know when you need to have laboratory tests done to monitor your liver function. If you get this side effect, your doctor may change your dose or stop treatment for some time.
- ❑ Some patients taking tafasitamab + lenalidomide have experienced a condition called tumor lysis syndrome when starting treatment. This results from the rapid destruction of cancer cells in the body during the initial cycles of treatment. Your care team may do blood tests to check for this side effect.
- ❑ Lenalidomide can cause tumor flare reaction, which can cause a temporary worsening of symptoms related to the size or location of your cancer.
- ❑ Severe allergic reactions are a rare but serious side effect of lenalidomide. Immediately seek medical attention if you notice difficulty breathing, swelling of the mouth or tongue, or a serious rash.
- ❑ Lenalidomide can increase your risk of having a blood clot. Seek immediate medical attention if you have sudden swelling in an arm or leg, have chest pain, or have trouble breathing.
- ❑ Lenalidomide can cause serious birth defects or death of a baby if taken while pregnant. To receive this medication, your doctor must help you sign up for the Risk Evaluation and Mitigation Strategies (REMS) program. The REMS program requires females who can get pregnant to use two forms of birth control. It also requires men to always use a condom during any sexual contact with females who can get pregnant. Let your doctor know if you are pregnant, or if you think you might be pregnant.

(INSTITUTIONAL CONTACT INFO)

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Storage and handling of lenalidomide

Handle lenalidomide with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the others to the drug should be limited.

- Store lenalidomide at room temperature (68°F to 77°F) in a dry location away from light.
- Keep lenalidomide out of reach of children and pets.
- Leave lenalidomide in the provided packaging until it is ready to be taken.
- Whenever possible, you should give lenalidomide to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the lenalidomide to you, they also need to follow these steps:
 - Wash hands with soap and water.
 - Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 - Gently transfer the lenalidomide from its package to a small medicine or other disposable cup.
 - Administer the medicine immediately by mouth with water.
 - Remove gloves and do not use them for anything else.
 - Throw gloves and medicine cup in household trash.
 - Wash hands with soap and water.
- If a daily pill box or pill reminder will be used, contact your care team before using:
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.
- If you have any unused lenalidomide, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of lenalidomide.
- If you are traveling, put your lenalidomide's packaging in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

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 TAFASITAMAB-CXIX + LENALIDOMIDE, follow the instructions below during 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 your body fluids.
- Toilet and septic systems:
 - You may use the same toilet, septic tank, and/or sewer that you usually use. Close the lid and flush to ensure all waste has been discarded. If you have a low-flow toilet, close the lid and flush twice.

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- ❑ If the toilet or toilet seat is soiled with urine, stool, or vomit, clean the surface after every use before other people use the toilet.
- ❑ Wash hands with soap and water for at least 20 seconds after using the toilet
- ❑ 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.

Pregnancy, sexual activity, and contraception

- ❑ Patients of reproductive ability should not become pregnant or get their partners pregnant while receiving TAFASITAMAB-CXIX + LENALIDOMIDE. Patients of childbearing age and potential should use effective contraception during therapy and for a minimum of 3 months after the last dose of TAFASITAMAB-CXIX + LENALIDOMIDE.
- ❑ Women of childbearing age and potential must have 2 negative pregnancy tests prior to starting lenalidomide and will need to repeat this test with each cycle or sooner.
- ❑ Women of childbearing age and potential should go without having sex or use 2 forms of birth control beginning 4 weeks before starting treatment with lenalidomide, during treatment, and for at least 4 weeks after stopping treatment.
 - Effective contraception could include one or more of the following: barrier methods (e.g. condoms), hormone methods (e.g. birth control pills), or surgery.
- ❑ Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking lenalidomide, during treatment breaks, and for up to 4 weeks after discontinuing lenalidomide, even if they have undergone a successful vasectomy.
- ❑ Do not donate sperm while taking lenalidomide, during treatment breaks, and for 4 weeks after stopping this medication.
- ❑ Do not breastfeed while taking lenalidomide and for 4 weeks after the last dose of TAFASITAMAB-CXIX + LENALIDOMIDE
- ❑ Please inform your care provider if you become pregnant.
- ❑ 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.
- ❑ It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy and you are encouraged to ask your care team for assistance.

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Obtaining medication

- Talk with your care provider about how to obtain your lenalidomide.
- Lenalidomide is available only through a Risk Evaluation and Mitigation Strategy (REMS) program, and prescribers, patients, and pharmacies must be certified with this REMS program.
- Only a 28-day supply of medication can be obtained from the pharmacy at one time, and this medication is not eligible for automatic refills.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product websites:

Monjuvi®: <https://www.monjuvi.com>

Revlimid®: <https://www.revlimid.com/multiple-myeloma>

Prescribing information links:

Tafasitamab-cxix: <https://www.monjuvi.com/pi/monjuvi-pi.pdf>

Lenalidomide: https://packageinserts.bms.com/pi/pi_revlimid.pdf

Product resources:

Treatment calendar: <https://www.monjuvi.com/treatment-tracker>

Lenalidomide REMS: <https://www.lenalidomiderems.com/index.html>

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Additional instructions

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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 medication 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 medication 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 medication 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 consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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