

ORAL CHEMOTHERAPY EDUCATION



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DUVELISIB

Name of your medication

Generic name — Duvelisib (DOO-veh-LIH-sib)
Brand name — Copiktra™ (koo-PIK-truh)

Common uses

Duvelisib is used to treat adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Duvelisib may also be used for other treatments.

Dose and schedule

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

- Your dose may vary, but the usual dose of duvelisib is 25 milligrams (25 mg) to be taken by mouth at a scheduled time twice a day.
- Duvelisib can be taken with or without food, but at the same times each day.
- Duvelisib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow duvelisib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of duvelisib:
 - Only take the missed dose if it has been less than 6 hours since you were supposed to take it. Then 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.

Drug and food interactions

- Duvelisib has many drug interactions, so inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

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

- Store duvelisib at room temperature (68°F–77°F) in a dry location away from light.
- Keep duvelisib out of reach of children and pets.
- Leave duvelisib in the provided packaging until it is ready to be taken.
- Whenever possible, you should give duvelisib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the duvelisib to you, they also need to follow these steps.

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1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the duvelisib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. 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 duvelisib, **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 duvelisib.
 - If you are traveling, put your duvelisib's packaging in a sealed plastic bag. Ask your pharmacist if additional travel precautions are needed.

Side Effects of Duvelisib

The common side effects that have been known to happen in about one third or more of patients taking duvelisib are listed on the left side of this table. You **MAY NOT** experience these 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 regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>

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Possible Side Effect	Management
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed 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, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if either of the following occurs:</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 provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication. If your diarrhea is severe or anti-diarrhea medications did not work, you may need treatment with a steroid medicine for which your health care provider should determine if it is appropriate.</p>
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored 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 7–8 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. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Rash</p>	<p>Rashes and other skin reactions can be serious. Tell you health care provider if you have any new or worsening rash, or other skin reactions during treatment including:</p> <ul style="list-style-type: none"> • Painful sores or ulcers on your skin, lips, or in your mouth • Severe rash with blisters or peeling skin • Rash with itching • Rash with fever

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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 electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider 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 excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, notice blood in your urine or stool, cough up blood, or have prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or hold your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>
<p>Changes in liver function</p>	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • High lipase levels • High amylase levels • High potassium levels • Low phosphorus levels • Low sodium levels • Low albumin levels 	<p>Changes in some laboratory values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs and feet • Red- or brown-colored urine

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Serious side effects

- Serious infections may develop, so monitor for signs and symptoms of infection.
- Severe diarrhea has occurred with the use of duvelisib, so monitor for development of worsening diarrhea.
- Serious skin reactions can develop, so report this side effect to your healthcare provider.
- Lung side effects have been reported with the use of duvelisib, so monitor for shortness of breath, chest pain, or worsening cough.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since duvelisib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take duvelisib, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, 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 surfaces before other people use the toilet.
 - Wash hands with soap and water 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 or duvelisib 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

- Women should not become pregnant and men should not get a partner pregnant while taking duvelisib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 1 month after the last dose of duvelisib.
- Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking duvelisib and for 1 month after the last dose of duvelisib.
- Inform your care provider if you become pregnant.
- 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 provider.

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Obtaining medication

- Talk with your care provider about the process for obtaining your duvelisib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: www.copiktra.com

Product prescribing information: www.accessdata.fda.gov/drugsatfda_docs/label/2018/211155s000lbl.pdf;
<https://copiktra.com/pdf/COPIKTRA-PI-USCPR2007403.pdf>

Product resources: 1-833-570-2273; <https://copiktrahcp.com/cil-sll/support-resources>

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Additional instructions

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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