

ORAL CHEMOTHERAPY EDUCATION



UMBRALISIB

Name of your medication

Generic name — umbralisib (UM-brah-LIH-sib)
Brand name — Ukoniq® (yoo-KAH-nik)

Approved uses

Umbralisib is used to treat adults with marginal zone lymphoma or follicular lymphoma that relapsed (came back) or did not get better after treatment with other anticancer therapy. Umbralisib blocks certain proteins, which may help keep cancer cells from growing and may kill them.

Dose and schedule

Taking umbralisib 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 umbralisib is 800 milligrams (800 mg) to be taken by mouth at a scheduled time once a day.
- Umbralisib should be taken with food, at the same time each day.
- Umbralisib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow umbralisib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of umbralisib, only take the missed dose if it has been less than 12 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

- Umbralisib has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.
- Avoid live vaccines during treatment with umbralisib.

Storage and handling

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

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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 umbralisib, **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 umbralisib.
 - If you are traveling, put your umbralisib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Umbralisib

Below are common side effects that have been known to happen in about one third or more of patients taking umbralisib 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
Changes in kidney function	<p>Your kidney (renal) 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"> • Decreased amount of urination • Unusual swelling in your legs and feet
Diarrhea (loose and/or urgent bowel movements)	<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 because of some other health problem. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast). • Avoid high-fiber foods (e.g., raw vegetables, raw fruits, whole grains). • Avoid foods that cause gas (e.g., broccoli, beans). • Avoid lactose-containing foods (e.g., yogurt, 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.</p>

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Possible Side Effect	Management
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is OK to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.
Nausea or vomiting	<ul style="list-style-type: none"> • Eat and drink slowly. • 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 foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.</p>
Changes in liver function	<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 • Unusual bleeding or bruising
Decreased white blood cells (WBCs) and increased risk for infection	<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 such as:</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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Serious side effects of umbralisib

- Infections may occur while taking umbralisib. Seek medical attention right away if you experience any new or worsening signs or symptoms of infection, such as a fever above 100.4°F, chills, or weakness.
- Umbralisib can cause severe skin reactions. Check your skin regularly and tell your care team right away if you have a rash or red, dry, itchy, peeling, or cracked skin.
- Allergic reactions are a rare but serious side effect of umbralisib due to the inactive ingredient, FD&C Yellow No. 5. Immediately seek medical attention if you notice difficulty breathing, swelling of the mouth or tongue, or a serious rash.
- Umbralisib can cause serious birth defects. Do not take umbralisib if you are pregnant or think you might be pregnant.

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

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since umbralisib 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 umbralisib, it is important to know 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 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 umbralisib 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 umbralisib. Females of childbearing age and potential should use effective contraception during therapy and for a minimum of one month after the last dose of umbralisib. Males with female partners of reproductive potential should use effective contraception during therapy and for a minimum of one month after the last dose of umbralisib.

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- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking umbralisib and for one month after the last dose of umbralisib.
- Please 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.

Obtaining medication

Talk with your care provider about how to obtain your umbralisib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://ukoniq.com/>

Product prescribing information: <https://tgtherapeutics.com/prescribing-information/uspi-ukon.pdf>

Product resources: <https://ukoniq.com/patientsupport>

Updated — February 20, 2021

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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