MEDICATION GUIDE
UKONIQ™ (you-KON-ik)
(umbralisib)
Tablets

What is the most important information I should know about UKONIQ?

UKONIQ can cause serious side effects, including:

- **Infections.** UKONIQ can cause serious infections that may lead to death. Tell your healthcare provider right away if you have fever, chills, weakness, flu-like symptoms, or any other signs of infection during treatment with UKONIQ.
- **Low white blood cell count (neutropenia).** Neutropenia is common with UKONIQ treatment and can sometimes be serious. Your healthcare provider will check your blood counts regularly during treatment with UKONIQ. Tell your healthcare provider right away if you have a fever or any signs of infection during treatment with UKONIQ.
- **Diarrhea or inflammation of your intestine (colitis).** Diarrhea is common during UKONIQ treatment and can sometimes be serious. Tell your healthcare provider right away if you have diarrhea that does not go away or worsening diarrhea, stool with mucus or blood, or if you have severe stomach area (abdominal) pain during treatment with UKONIQ. Drink plenty of fluids during treatment with UKONIQ to help prevent dehydration from diarrhea.
- **Liver problems.** Abnormal liver function blood test results are common and can sometimes be serious. Your healthcare provider will do blood tests before and during your treatment with UKONIQ to check for liver problems. Tell your healthcare provider right away if you have any of the following symptoms of liver problems:
  - yellowing of your skin or the white part of your eyes (jaundice)
  - dark or brown (tea colored) urine
  - pain in the upper right side of your stomach area (abdomen)
  - bleeding or bruising more easily than normal
- **Severe skin reactions.** Rashes and other skin reactions are common with UKONIQ treatment and can sometimes be severe and may lead to death. Tell your healthcare provider right away if you get a new or worsening skin rash or other signs of a severe skin reaction during treatment with UKONIQ, including:
  - painful sores or ulcers on your skin, lips, or in your mouth
  - rash with blisters or peeling skin
  - rash with itching
  - rash with fever

If you have any of the above serious side effects during treatment with UKONIQ, your doctor may completely stop your treatment, stop your treatment for a period of time, or change your dose of UKONIQ.

See **"What are the possible side effects of UKONIQ?"** for more information about side effects.

What is UKONIQ?

UKONIQ is a prescription medicine used to treat adults with:

- Marginal zone lymphoma (MZL) when the disease has come back or did not respond to treatment and who have received at least one certain type of prior treatment.
- Follicular lymphoma (FL) when the disease has come back or did not respond to treatment and who have received at least three prior treatments.

It is not known if UKONIQ is safe and effective in children.

Before taking UKONIQ, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- have abdominal or intestinal problems
- have liver problems
- are allergic to FD&C Yellow No. 5 (tartrazine) or aspirin. UKONIQ tablets contain FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain people, especially people who also have an allergy to aspirin.
- are pregnant or plan to become pregnant. UKONIQ can harm your unborn baby. If you are able to become pregnant, your healthcare provider will do a pregnancy test before starting treatment with UKONIQ.
  - **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with UKONIQ and for 1 month after the last dose of UKONIQ. Talk to your healthcare provider about birth control methods that may be right for you. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with UKONIQ.
  - **Males** with female partners who are able to become pregnant should use effective birth control (contraception) during treatment with UKONIQ and for 1 month after the last dose of UKONIQ.
- are breastfeeding or plan to breastfeed. It is not known if UKONIQ passes into your breast milk. Do not breastfeed during treatment with UKONIQ and for 1 month after the last dose of UKONIQ.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take UKONIQ?

- Take UKONIQ exactly as your healthcare provider tells you.
- Your healthcare provider may tell you to decrease your dose, temporarily stop, or completely stop taking UKONIQ, if you develop side effects. Do not change your dose or stop taking UKONIQ without talking to your healthcare provider first.
- Take UKONIQ tablets 1 time each day with food at about the same time each day.
- Swallow UKONIQ tablets whole. Do not crush, break, cut or chew the tablets.
- If you vomit after taking a dose of UKONIQ, do not take another dose on that day. Take your next dose at your usual time.
- If you miss a dose of UKONIQ, take it as soon as you remember on the same day. If it has been more than 12 hours, skip the missed dose and take your next dose on the next day at your usual time.

What are the possible side effects of UKONIQ?

UKONIQ can cause serious side effects. See "**What is the most important information I should know about UKONIQ?"**

The most common side effects of UKONIQ include:

- changes in certain kidney function blood tests
- tiredness
- nausea
- muscle or bone pain
- low red blood cell count (anemia)
- low platelet count
- upper respiratory tract infection
- vomiting
- abdominal pain
- decreased appetite

These are not all of the possible side effects of UKONIQ.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store UKONIQ?

- Store UKONIQ tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep UKONIQ and all medicines out of reach of children.

General information about the safe and effective use of UKONIQ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use UKONIQ for a condition for which it was not prescribed. Do not give UKONIQ to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about UKONIQ that is written for healthcare professionals.

What are the ingredients in UKONIQ?

Active ingredient: umbralisib tosylate

Inactive ingredients: croscarmellose sodium, hydroxypropyl betadex, hydroxypropyl cellulose, magnesium stearate and microcrystalline cellulose. The tablet coating film consists of FD&C Blue No. 1, FD&C Yellow No. 5 (tartrazine), ferric oxide yellow, hypromellose 2910, polydextrose, polyethylene glycol 8000, titanium dioxide and triacetin.

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For more information, go to www.ukoniq.com or call 1-877-848-9462.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: Month/Year