

Patient Starter Kit

You will soon receive the PIQRAY® (alpelisib) tablets Patient Starter Kit. The kit includes the printed patient brochure, along with supportive tools and resources to help you manage day-to-day life and play an active role in your treatment. The kit is housed inside a travel pouch, which can be useful when carrying and organizing your treatment materials for visits with your health care team.

INSIDE THE POUCH, YOU'LL FIND:



Your Guide to PIQRAY:

Get answers to your questions about treatment, from taking PIQRAY to finding one-on-one support.



Antihistamine Sample:

Because rash is a common side effect of taking PIQRAY, talk to your doctor about how an antihistamine, such as the one included, may help.



Zipongo® Access Card:

Discover a digital nutrition platform to help with healthy eating and menu planning. Talk to your doctor before making any changes to your diet.



Collapsible Water Bottle:

Fill up on the go with this lightweight, collapsible water bottle.



Daily Journal:

Keep track of appointments, upcoming tests, experiences, and questions you may have for your doctor as you navigate your treatment journey.



Support for Every Day Booklet:

Learn about helpful resources, such as house cleaning and transportation, for those living with metastatic breast cancer.



Navigator Overview:

Learn about the one-on-one support Patient Navigators can provide through a series of personal pre-scheduled phone calls.



Learn more about taking PIQRAY by watching this onboarding video: www.starting-piqray.com

High blood sugar levels are common with PIQRAY and can be severe. Your doctor will monitor your blood sugar levels before you start and during treatment, and more often if you have a history of type 2 diabetes. Talk to your doctor about monitoring tools, such as a glucometer, to help you check your blood sugar levels at home during treatment.

To receive your Patient Starter Kit, talk to your doctor.

INDICATION

PIQRAY® (alpelisib) tablets is a prescription medicine used in combination with the medicine fulvestrant to treat women who have gone through menopause, and men:

- who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), with an abnormal phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA) gene, **and**
- whose disease has progressed on or after endocrine therapy

Your health care provider will test your cancer for an abnormal “PIK3CA” gene to make sure that PIQRAY is right for you.

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

Important Safety Information

Do not take PIQRAY if you have had a severe allergic reaction to PIQRAY or are allergic to any of the ingredients in PIQRAY.

Please see additional Important Safety Information on the next page. Please see full Prescribing Information including Patient Information.

 **PIQRAY®**
(alpelisib) tablets
50 mg • 150 mg • 200 mg

PIQRAY may cause serious side effects, including:

- **Severe allergic reactions:** Tell your health care provider or get medical help right away if you have trouble breathing, flushing, rash, fever, or fast heart rate during treatment with PIQRAY
- **Severe skin reactions:** Tell your health care provider or get medical help right away if you get severe rash or rash that keeps getting worse, reddened skin, flu-like symptoms, blistering of the lips, eyes or mouth, blisters on the skin or skin peeling, with or without fever
- **High blood sugar levels (hyperglycemia):** Hyperglycemia is common with PIQRAY and can be severe. Your health care provider will monitor your blood sugar levels before you start and during treatment with PIQRAY. Your health care provider may monitor your blood sugar levels more often if you have a history of Type 2 diabetes. Tell your health care provider right away if you develop symptoms of hyperglycemia, including excessive thirst, dry mouth, urinate more often than usual or have a higher amount of urine than normal, or increased appetite with weight loss
- **Lung problems (pneumonitis):** Tell your health care provider right away if you develop new or worsening symptoms of lung problems, including shortness of breath or trouble breathing, cough, or chest pain
- **Diarrhea:** Diarrhea is common with PIQRAY and can be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney problems. If you develop diarrhea during treatment with PIQRAY, tell your health care provider right away. Your health care provider may tell you to drink more fluids or take medicines to treat diarrhea

Your health care provider may tell you to decrease your dose, temporarily stop your treatment, or completely stop your treatment with PIQRAY if you get certain serious side effects.

Before you take PIQRAY, tell your health care provider about all of your medical conditions, including if you:

- have a history of diabetes
- have a history of skin rash, redness of skin, blistering of the lips, eyes or mouth, or skin peeling
- are pregnant or plan to become pregnant. PIQRAY can harm your unborn baby

Females who are able to become pregnant:

- Your health care provider will check to see if you are pregnant before you start treatment with PIQRAY
- You should use effective birth control during treatment with PIQRAY and for 1 week after the last dose. Talk to your health care provider about birth control methods that may be right for you during this time

- If you become pregnant or think you are pregnant, tell your health care provider right away

- Males** with female partners who are able to become pregnant should use condoms and effective birth control during treatment with PIQRAY and for 1 week after the last dose. If your female partner becomes pregnant, tell your health care provider right away.
- are breastfeeding or plan to breastfeed. It is not known if PIQRAY passes into your breast milk. Do not breastfeed during treatment with PIQRAY and for 1 week after the last dose

You should also read the Full Prescribing Information of fulvestrant for important pregnancy, contraception, infertility, and lactation information

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. PIQRAY and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your health care provider or pharmacist when you get a new medicine.

The most common side effects of PIQRAY when used with fulvestrant include:

- rash
- nausea
- tiredness and weakness
- decreased appetite
- mouth sores
- vomiting
- weight loss
- hair loss
- changes in certain blood tests

PIQRAY may affect fertility in males and in females who are able to become pregnant. Talk to your health care provider if this is a concern for you.

These are not all of the possible side effects of PIQRAY. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information, including Patient Information.

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