



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

DOCTOR DISCUSSION GUIDE

Talking with your doctor about treatment options.

Taking an active role in your treatment decisions

An HR+, HER2- metastatic breast cancer diagnosis can be complicated and confusing. At this time, your doctor can be your most valuable resource.

Use this guide to get the most out of your appointments and to find out if PIQRAY could be an option for you.

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.

Please see Important Safety Information (ISI) in the last section, and [click here](#) for full Prescribing Information, including Patient Information.



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Before your appointment

▶ Get informed

1. Call your oncologist to see if you've already been tested for a PIK3CA ("pick-three-C-A") mutation
2. If you have been tested, ask for a copy of your results
3. Check your results to see if you tested positive for a PIK3CA mutation. If so, PIQRAY may be an option for you
4. If you were tested using a blood sample and no mutation was found, ask your doctor to test your tissue

▶ Get prepared

- If you want to ask about getting tested for a PIK3CA mutation, look into [mutation testing](#) so you can take an active part in the conversation
- Jot down any thoughts or questions you don't want to forget
- Phone a friend or family member who can go to the appointment with you

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At your appointment

- ▶ If you know you have a PIK3CA mutation, ask:
 1. Can we consider [PIQRAY as an option](#)?
 2. PIQRAY [specifically targets](#) PIK3CA mutations. How is that different from my other treatment options?
 3. What kind of [side effects](#) can I expect from PIQRAY?
 4. How would my [blood sugar be monitored](#) while on PIQRAY?
 5. What is the [dosing](#) like for PIQRAY?

- ▶ If you haven't been tested, ask:
 1. Can I get tested for a [PIK3CA mutation](#)?
 2. How is [this type of testing](#) done?
 3. Would I need a new biopsy or do I have previous biopsy tissue available for testing?
 4. If we can't use tissue, am I a candidate for plasma testing?

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After your appointment

▶ Follow up about results

- If you got tested for a PIK3CA mutation, call the office to see if your results show that you have a PIK3CA mutation
- If you have a PIK3CA mutation, ask to speak with your oncologist about PIQRAY as a treatment option

▶ See how PIQRAY may help

If you and your doctor discussed PIQRAY as an option:

1. Learn more about how [progression free survival](#) can mean more time before your cancer grows and spreads
2. Call your doctor's office with any other questions about treatment and your day-to-day life

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PIQRAY Patient Support

Treatment with PIQRAY goes beyond medicine. Once you get started, you'll get support at every step with services like:

- Co-pay Support if eligible
- Personal Patient Navigators
- Patient Starter Kit

[Learn More](#)

Keep this guide handy on your phone for your next appointment, and find [more resources](#) to help you get the most out of your care.

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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.

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 [click here](#) for full Prescribing Information, including Patient Information.



For more information,
visit [PIQRAY.com](https://www.piqray.com)

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 **NOVARTIS**

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9/20

PIQ-1233730