**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.

Foodsmart is a registered trademark of Zipongo, Inc.
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, swelling of the face or throat, 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 may 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, urinating more often than usual or having a higher amount of urine than normal, increased appetite with weight loss, confusion, nausea, vomiting, fruity odor on breath, difficulty breathing, or dry or flushed skin.

- **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 or colitis (inflammation of your intestines):** Diarrhea is common with PIQRAY and may be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney injury. Tell your health care provider right away, if you develop diarrhea, stomach-area (abdominal) pain, or see mucus or blood in your stool during treatment with PIQRAY. Your health care provider may tell you to drink more fluids or take medicines to treat diarrhea or colitis.

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 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 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

**Please see full Prescribing Information, including Patient Information.**