

Consumer Medicine Information

This leaflet provides important information about using PIQRAY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PIQRAY.**

Where to find information in this leaflet:

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2. What should I know before I use PIQRAY?
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1. Why am I using PIQRAY?

PIQRAY contains the active ingredient alpelisib. PIQRAY belongs to a class of medicines known as PI3K inhibitors.

PIQRAY is used with a medicine called fulvestrant to treat adult men and women with certain types of advanced breast cancer.

PIQRAY works by blocking the effects of specific enzymes (proteins) that signal cancer cells to grow and multiply. By blocking these enzymes, PIQRAY can decrease cancer cell growth and making new cancer cells, and can also destroy cancer cells.

2. What should I know before I use PIQRAY?

Warnings

Do not use PIQRAY if:

- you are allergic to alpelisib, fulvestrant or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

If you experience an allergic reaction, stop using the medicine and inform your doctor or pharmacist immediately.

Some of the symptoms of an allergic reaction may include:

- Severe itching of the skin, with a red rash, or raised bumps;
- Swelling of the face, lips, tongue, throat, or other parts of the body;
- Difficulty in breathing or swallowing;
- Dizziness.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have any questions about why this medicine has been prescribed for you
- have high levels of sugar in your blood or are having the following symptoms (increased thirst/dry mouth, more frequent wee, feeling tired or sick or increased appetite with weight loss).
- develop a rash, red skin, blistering of the lips, eyes or mouth or skin peeling; with

or without fever which may be possible signs of severe skin and tissue condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Genetic screening

Before you commence treatment, your tumour tissue or a blood sample will be tested for a particular mutation in a gene called PIK3CA. If the result is positive, PIQRAY is likely to help with your type of breast cancer.

Blood tests before and during your treatment with PIQRAY

Your doctor will carry out blood tests before and regularly during treatment with PIQRAY to monitor your blood sugar. Based on the results, your doctor will take any necessary actions, such as prescribing a medicine to lower blood sugar levels.

- Your doctor will tell you exactly when and where to have the blood tests. You can only start PIQRAY if the blood tests show that you have the right levels of sugar in your blood. This is because PIQRAY can increase sugar in your blood, which could be serious and need treatment. Only regular fasting blood tests can tell the doctor if you are developing high blood sugar levels.
- Your doctor will tell you exactly when and where to test your blood sugar. You will need to have blood sugar tests at least once a week for the first 2 weeks of treatment with Piqray. You will need to have your blood sugar levels checked closely for the first 4 weeks. Afterwards, you will need to have blood tests at least once a month, depending on your blood sugar levels.

Pregnancy and breastfeeding

If you are pregnant, ask your doctor or pharmacist for advice before taking this medicine. PIQRAY may harm an unborn baby and should not be used during pregnancy unless clearly necessary.

If you become pregnant or think you are pregnant, tell your doctor right away.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss with you the potential risks of taking PIQRAY during pregnancy or breast-feeding. It is not known if PIQRAY passes into your breast-milk.

Do not breast feed during treatment with Piqray and for at least 4 days after the last dose.

Contraception

If you are a woman of child-bearing age, your doctor will check that you are not pregnant, and may perform a pregnancy test if necessary before starting treatment with PIQRAY.

You should avoid becoming pregnant while using Piqray and for at least 4 days after you stop using it. If you are a male you should use a condom if with a female partner that could become pregnant. You should use a

condom for at least 4 days after you stop Piqray.

Ask your doctor or pharmacist for options of effective birth control.

Children and adolescents

- PIQRAY is not to be used in children or adolescents under 18 years of age. It is not known whether PIQRAY is safe and effective in children or adolescents.