

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**PIQRAY**[®]

Alpelisib tablets

Read this carefully before you start taking **PIQRAY**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your health professional about your medical condition and treatment and ask if there is any new information about **PIQRAY**.

Your breast cancer will be treated with **PIQRAY** in combination with another drug called fulvestrant. Read the Patient Medication Information leaflets for the other drug as well as this one.

Serious Warnings and Precautions

PIQRAY can cause:

- **Serious allergic reactions** (anaphylactic reactions) like face swelling, trouble breathing, flushing, rash, fever, or fast heart rate.
- **Serious skin reactions**
 - **Stevens-Johnson syndrome (SJS)** (a type of severe skin rash)
 - **Drug reaction with eosinophilia and systemic symptoms (DRESS)** a type of severe skin reaction that may affect one or more organs
 - **Erythema multiforme (EM)** (an allergic skin reaction)
- **High levels of:** blood acids (**diabetic ketoacidosis**), blood sugar (**hyperglycemia**) and its complications (**hyperglycemic hyperosmolar non-ketotic syndrome [HHNKS]**). Ketoacidosis can cause death. You will have regular blood tests done before and during treatment with **PIQRAY** to determine your blood sugar levels which may require treatment.
- **Lung problems (pneumonitis):** an inflammation of lung tissue.

The symptoms are listed in the 'Serious side effects and what to do about them' table. It is found later in this leaflet.

What is **PIQRAY** used for?

PIQRAY is used to treat breast cancer, which has spread to other parts of the body, in post-menopausal women and in men. The breast cancer must be hormone receptor-positive and with a specific gene mutation (PIK3CA). **PIQRAY** is used:

- with another drug for breast cancer called fulvestrant. This is used when the cancer gets worse after other therapies.

How does **PIQRAY** work?

Alpelisib, the medicinal ingredient in **PIQRAY**, is a type of drug called a kinase inhibitor. It works by stopping certain cancer cells from dividing and growing. When given together with fulvestrant, **PIQRAY** may slow down the growth and spread of certain breast cancer cells.

What are the ingredients in PIQRAY?

Medicinal ingredients: alpelisib

Non-medicinal ingredients: hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, iron oxide black, iron oxide red, macrogol / polyethylene glycol (PEG), talc, titanium dioxide.

PIQRAY comes in the following dosage forms:

Tablets, 50 mg, 150 mg and 200 mg

Do not use PIQRAY if:

- you are allergic to alpelisib or to any of the other ingredients in this drug or the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PIQRAY. Talk about any health conditions or problems you may have, including if you:

- have or ever had diabetes or if you are pre-diabetic (high blood sugar levels)
- have or ever had serious skin problems like:
 - Stevens-Johnson syndrome (SJS), a type of severe skin rash
 - Drug reaction with eosinophilia and systemic symptoms (DRESS), a type of serious skin reaction that may affect one or more organs
 - Erythema multiforme (EM), allergic skin reaction
- have or ever had osteonecrosis of the jaw (exposed jaw bone)

Other warnings you should know about:

PIQRAY can cause serious side effects including:

- **Severe diarrhea, nausea and vomiting:** Your healthcare professional will monitor your health. They might give you medicine to treat these symptoms.
- **Colitis**, which is when your colon (large intestine) becomes inflamed. If you experience abdominal pain and mucous or blood in your stool, you may have colitis. Contact your healthcare professional as soon as possible.
- **Osteonecrosis of the jaw** (exposed jaw bone): PIQRAY can cause osteonecrosis of the jaw. You might have a dental check-up before starting your treatment to determine your jaw health.

See the “Serious side effects and what to do about them” table, below, for more information on these and other serious side effects.

Pregnancy and breast-feeding:

Female patients

- Do not use PIQRAY if you are pregnant or if you are still able to get pregnant and are not using highly effective birth control.
- Use highly effective birth control if you can get pregnant while taking PIQRAY and for at least 1 week after your last dose.
- Avoid becoming pregnant while taking PIQRAY. It may harm your unborn baby.
- Tell your health professional right away if you become pregnant or think you are pregnant during treatment with PIQRAY.
- If you can get pregnant, your health provider should do a pregnancy test before you start treatment with PIQRAY.
- It is not known if PIQRAY passes into breast milk. Do not breastfeed during treatment with

PIQRAY and for at least 1 week after the final dose. Talk to your health professional about the best way to feed your baby during this time.

Male patients

- Use highly effective birth control while you are on PIQRAY and for at least 1 week after your last dose if:
 - your partner is pregnant, might be pregnant or can get pregnant
- Do not donate or store semen while you are on PIQRAY and for at least 1 week after your last dose.

Fertility – Male and Female patients: PIQRAY may affect your ability to have a child in the future.

Other patient groups:

- **Children under 18 years old** should not be given PIQRAY.
- **Adults 65 years and older** might get more certain side effects:
 - diarrhea, nausea, weight loss, shortness of breath, low potassium and high blood sugar levels.
- **Asians** might get more certain side effects:
 - severe skin and allergic reactions, rash.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PIQRAY:

- eltrombopag - used to treat low blood platelet count
- lapatinib - used to treat certain types of breast cancers
- pantoprazole - used to reduce the amount of acid produced in your stomach or heart burn
- ranitidine – used to treat heartburn
- cyclosporine – used to prevent organ transplant rejection
- warfarin - used to treat blood clots
- medicines called strong CYP3A4 inducers, including but not limited to:
 - rifampin - used to treat lung disease
 - apalutamide, enzalutamide and mitotane – used to treat types of cancer
 - carbamazepine and phenytoin – used to treat seizures
 - St. John's wort – an herbal remedy often used to treat depression
- medicines that can increase QT interval (a heart rhythm condition) including, but not limited to:
 - ondansetron – used to prevent nausea and vomiting
 - erythromycin, clarithromycin, azithromycin, moxifloxacin, levofloxacin, ciprofloxacin – used to treat bacterial infections (antibiotics)
- medicines used to treat diabetes. Always follow your healthcare professional's instructions on how to take these medicines with PIQRAY.

Ask your health professional if you are not sure whether your drug is listed above.

Tell your health professional if you are prescribed any new drugs during PIQRAY treatment.

How to take PIQRAY:

- Take PIQRAY only under the care of a doctor who knows how to use anti-cancer drugs.

- Take PIQRAY exactly as your healthcare professional tells you. Another drug called fulvestrant is also given to you while you are taking PIQRAY.
- Take PIQRAY once a day, at the same time, immediately following food.
- Swallow PIQRAY tablets whole. Do not chew, crush or split the tablets.
- Do not take PIQRAY tablets that are broken, cracked or look damaged.
- If you vomit after taking a dose of PIQRAY, do not take another dose on that day. Take your next dose at your regular time.
- Do not take more than the recommended dose prescribed by your healthcare professional.
- Do not change the PIQRAY dose or schedule unless your healthcare professional tells you to.
- Your healthcare professional will monitor your health. They may reduce, interrupt, or stop your PIQRAY dose. This may occur based on your current health, if you take certain other medications, or if you have certain side effects.

Recommended daily dose

Adults:

- **300 mg starting dose:** Two 150 mg tablets once daily

Reduced recommended daily dose

Adults:

- **250 mg daily dose:** One 200 mg tablet and one 50 mg tablet, once daily
- **200 mg daily dose:** One 200 mg tablet once daily

Overdose:

If you think you, or a person you are caring for, have taken too much PIQRAY, contact a health professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Show the PIQRAY packet. Medical treatment may be necessary.

Missed dose:

- If you are less than 9 hours late, take the missed dose, after food, as soon as you remember. Take the next dose at your regular time.
- If you are more than 9 hours late, skip the dose for that day. Wait until the regular time for your next dose.
- Do not take two doses to make up for a missed dose.

What are possible side effects from using PIQRAY?

These are not all the possible side effects you may feel when taking PIQRAY. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Headache
- Tiredness, difficulty to sleep
- Changes in the way food tastes
- Decreased appetite
- Indigestion
- Toothache, gum pain
- Cracked, chapped lips
- Dry, cracked skin

- Blurred vision, dry eyes
- Muscle pain
- Hair loss

PIQRAY can cause abnormal blood test results. Your health professional will order some tests before and during your treatment. These include blood tests to monitor the blood sugar level and electrolytes (potassium, calcium) in your body. More frequent blood tests might be needed. Your health professional will tell you if your test results are abnormal and if you need treatment to correct these side effects.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Acute Kidney Injury (severe kidney problems): urinating less than usual or a lower amount of urine than usual, swelling in legs, ankles, and around the eyes, tiredness, confusion, nausea, seizure, chest pain			√
Anemia: (low levels of red blood cells): tiredness, weakness, fatigue, pale skin	√		
Gastrointestinal disorders: diarrhea, nausea, vomiting, stomach pain, decreased appetite, heartburn, swelling or bloating of the abdomen, indigestion	√		
Hyperglycemia (high blood sugar): increased thirst, frequent urination, larger amounts of urine, increased appetite with weight loss		√	
Stomatitis (mouth sores, inflammation of the mouth) or Mucosal Inflammation (inflammation of the moist body surfaces): red, sore or swollen mouth, lips, gums	√		
Urinary Tract Infection (infection in the urinary system): painful and frequent urination, pelvic pain, strong smelling urine, cloudy urine		√	
COMMON			
Dehydration (when there is not enough water in the body): thirst; reduced sweating and urine; dry mouth	√		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Erythema Multiforme (allergic skin reaction): raised red or purple skin patches, possibly with blister or crust in the centre, possibly with mild itching or burning; possibly swollen lips			√
Hypertension (high blood pressure): headache, fatigue, dizziness, tinnitus, cold swelling, nosebleed, racing pulse or heart palpitations, shortness of breath	√		
Hypocalcaemia (low levels of calcium in blood): cramps	√		
Hypokalaemia (low levels of potassium in blood): muscle weakness and spasms, irregular heartbeats	√		
Lymphopenia (low white blood cells): fever; cough; runny nose; enlarged lymph nodes; painful joints; rash; night sweats; weight loss	√		
Osteonecrosis of the Jaw (exposed jaw bone): pain, swelling, numbness or heavy feeling of the jaw, or loosening of a tooth		√	
Palmar-plantar erythrodysesthesia syndrome (also called Hand-Foot Syndrome: reddening and/or swelling, peeling on the palms and soles, tingling sensation and burning pain of the feet		√	
Non-infectious Pneumonitis and Pneumonia (lung inflammation): new or changing respiratory problems including difficult or painful breathing, cough, rapid breathing, pain in chest while breathing, blue discoloration of the lips, tongue or skin, or hiccups			√
Serious Allergic Reactions: rash with red bumps, fever, itching, general swelling (including face), shortness of breath, irregular heartbeat			√
Thrombocytopenia (low platelet count): spontaneous bleeding or bruising		√	
UNCOMMON			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Ketoacidosis (high level of acids in the blood): difficulty breathing, nausea, vomiting			√
Pancreatitis (inflamed pancreas): severe upper stomach pain			√
Stevens Johnson Syndrome or erythema multiforme (EM), or toxic epidermal necrolysis (TEN) : (severe skin reaction): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by hives fever, chills, headache, cough, body aches or swollen glands			√
UNKNOWN			
Angioedema (a type of hypersensitivity reaction where the tissue under the skin swells): swollen face, throat, hands, feet or genitals; difficult breathing			√
Colitis (inflammation of your intestine): diarrhea, severe abdominal pain, stool with mucus or blood			√
Drug reaction with eosinophilia and systemic symptoms (DRESS) (serious skin reaction that may affect more than one or more organs): fever, severe rash, swollen lymph glands, flu-like feeling, swelling of the face; possibly yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinate less often, less urine			√
Hyperglycemic Hyperosmolar non-ketotic Syndrome (HHNKS, a complication of high blood sugar) : Confusion, dry mouth, dry or flushed skin, nausea, vomiting, tiredness, need to pass urine frequently, thirst.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your health professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Do not store above 30°C
- Do not take this medicine after the expiry date, which is stated on the box.
- Keep in the original package. Protect from moisture.
- Keep out of reach and sight of children.

Ask your pharmacist how to dispose of medicines you no longer use.

If you want more information about PIQRAY:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for health professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.novartis.ca), or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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