

Medication Information Sheet

alpelisib (AL-peh-LIH-sib)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Piqray®

Appearance: Tablet in various strengths and colours

What is this medication for?

- For treating certain types of hormone sensitive breast cancer. It is usually given together with another medication.

What should I do before I have this medication?

- Tell your health care team if you have or had significant medical condition(s), especially if you have / had:
 - ◊ heart problems
 - ◊ diabetes or if you are pre-diabetic (high blood sugar levels)
 - ◊ serious skin problems
 - ◊ osteonecrosis of the jaw (exposed jawbone) or
 - ◊ any allergies
- To lower the chances of getting skin reactions, you may be given an oral antihistamine take for a few days when you start alpelisib treatment.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

You will have a blood test to check for hepatitis B before starting treatment. See the [Hepatitis B and Cancer Medications](#) pamphlet for more information.

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is **any** chance of pregnancy happening, you and your partner together must use **2 effective forms of birth control** at the same time until at least **1 week** after your last dose. Talk to your health care team about which birth control options are best for you.
- Do not use hormonal birth control (such as birth control pills), unless your health care team told you that they are safe. Talk to your health care team about the safest birth control for you.
- Do not breastfeed while on this medication and for at least **1 week** after your last dose.

How is this medication given?

- This medication is usually taken once a day by mouth right after food. Talk to your health care team about how and when to take your medication.
- Take the dose at about the same time each day.
- Swallow the tablets whole. Do not chew, crush or split the tablets.
- Do not take tablets that are broken, cracked or look damaged.
- If you miss a dose and 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 miss a dose and are more than 9 hours late, skip the dose for that day. Wait until the regular time on the next day for your next dose.
- Do not take two doses to make up for a missed dose.
- If you vomit (throw up) after taking a dose, do not take another dose on that day. Take your next dose at your regular time on the next day.
- If you take too much of your medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017.

To Prevent Skin Rash

You may be given a medication to take when you start alpelisib to prevent skin rashes.

- These medications are antihistamines such as cetirizine or Reactine®, or others.

What else do I need to know while on this medication?

- **Will this medication interact with other medications or natural health products?**
 - This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
 - Tell your health care team about all of your:
 - prescription and over-the-counter (non-prescription) medications and all other drugs, such as cannabis/marijuana (medical or recreational)
 - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
 - Check with your health care team before starting or stopping any of them.
- If you take medications to help with your blood sugar, your health care team may need extra blood tests and may change your dose.

What should I do if I feel unwell, have pain, a headache or a fever?

- **Always** check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- You have a fever if your temperature taken in your mouth (oral temperature) is:
 - 38.3°C (100.9°F) or higher at any time

OR

 - 38.0°C (100.4°F) or higher for at least one hour.

If you do have a fever:

- **Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.**
- Ask your health care team for the [Fever](#) pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

- Ask your health care team about the right medication for you. **Acetaminophen (Tylenol®)** is a safe choice for most people.
- **Talk to your health care team before you start taking** Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.
- Talk to your health care team if you already take **low dose aspirin** for a medical condition (such as a heart problem). It may still be safe to take.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- DO check your blood sugars regularly if you have diabetes. Your health care team may monitor your blood levels closely and may change the dose of your diabetic medications.

What NOT to DO while on this medication:

- DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.

How should I safely store this medication?

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- **How to safely touch oral anti-cancer medications**

If you are a patient:

- ◊ Wash your hands before and after touching your oral anti-cancer medication.
- ◊ Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

- ◊ Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- ◊ Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- ◊ Throw out your gloves after each use. Do not re-use gloves.
- ◊ Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.

- **What to do if oral anti-cancer medication gets on your skin or in your eyes**

If medication gets on your skin:

- ◊ Wash your skin with a lot of soap and water.
- ◊ If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

- ◊ Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this medication?

The following table lists side effects that you may have when getting alpelisib. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on alpelisib.

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p>High blood sugar</p> <p>(May be severe)</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may feel thirsty. You may pee more often than usual. You may feel tired or sleepy. <p>What to do?</p> <ul style="list-style-type: none"> Your health care team may do a blood test to check your blood sugar level. You may be told to change your diet or given medication to lower your blood sugar. If you have diabetes, check your blood sugar regularly. Your health care team may ask you to check it more often than usual. 	<p>Talk to your health care team as soon as possible.</p>
<p>Diarrhea</p> <p>(May be severe)</p> <p>What to look for?</p> <ul style="list-style-type: none"> Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. <p>What to do?</p> <p>If you have diarrhea:</p> <ul style="list-style-type: none"> Take anti-diarrhea medication if your health care team prescribed it or told you to take it. 	<p>Talk to your health care team if no improvement after 24 hours of taking diarrhea medication or if severe (more than 7 times in one day).</p>

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol, until your diarrhea has stopped. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. <p>Ask your health care team for the Diarrhea pamphlet for more information.</p>	
<p>Rash; dry, itchy skin</p> <p>(May be severe)</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may have cracked, rough, flaking or peeling areas of the skin. Your skin may look red and feel warm, like a sunburn. Your skin may itch, burn, sting or feel very tender when touched. <p>What to do?</p> <p>To prevent and treat dry skin:</p> <ul style="list-style-type: none"> Use fragrance-free skin moisturizer. Protect your skin from the sun and the cold. Use sunscreen with UVA and UVB protection and a SPF of at least 30. Avoid perfumed products and lotions that contain alcohol. Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less. <p>Rash may be severe in some rare cases and cause your skin to blister or peel, more marks may appear as "bulls-eyes". If this happens, get emergency medical help right away.</p>	<p>Talk to your health care team if it does not improve or if it is severe.</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Nausea and vomiting</p> <p>(Generally mild)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Nausea is feeling like you need to throw up. You may also feel light-headed. • You may feel nausea within hours to days after your treatment. <p>What to do?</p> <p>To help prevent nausea:</p> <ul style="list-style-type: none"> • It is easier to prevent nausea than to treat it once it happens. • If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (like coffee, tea) and avoid alcohol. <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take your rescue (as-needed) anti-nausea medication(s) as prescribed. • Ask your health care team for the Nausea & Vomiting pamphlet for more information. • Talk to your health care team if: <ul style="list-style-type: none"> ◦ nausea lasts more than 48 hours ◦ vomiting lasts more than 24 hours or if it is severe 	<p>Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if it is severe.</p>
<p>Fatigue</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. <p>What to do?</p> <ul style="list-style-type: none"> • Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. 	<p>Talk to your health care team if it does not improve or if it is severe.</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> • Check with your health care team before starting any new exercise. • Pace yourself, do not rush. Put off less important activities. Rest when you need to. • Ask family or friends to help you with things like housework, shopping, and child or pet care. • Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). • Avoid driving or using machinery if you are feeling tired. <p>Ask your health care team for the Fatigue pamphlet for more information.</p>	
<p>Low appetite, weight Loss</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loss of interest in food or not feeling hungry. • Weight loss. <p>What to do?</p> <ul style="list-style-type: none"> • Try to eat your favourite foods. • Eat small meals throughout the day. • You may need to take meal supplements to help keep your weight up. • Talk to your health care team if you have no appetite. <p>Ask your health care team for the Loss of Appetite pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe.</p>
<p>Mouth sores</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Round, painful, white or gray sores inside your mouth that can occur on the tongue, lips, gums, or inside your cheeks. • In more severe cases they may make it hard to swallow, eat or brush your teeth. • They may last for 3 days or longer. <p>What to do?</p> <p>To help prevent mouth sores:</p> <ul style="list-style-type: none"> • Take care of your mouth by gently brushing and flossing regularly. • Rinse your mouth often with a homemade mouthwash. 	<p>Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow.</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> To make a homemade mouthwash, mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water. Do not use store-bought mouthwashes, especially those with alcohol, because they may irritate your mouth. <p>If you have mouth sores:</p> <ul style="list-style-type: none"> Avoid hot, spicy, acidic, hard or crunchy foods. Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection. Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow. <p>Ask your health care team for the Oral Care (Mouth Care) pamphlet for more information.</p>	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Hair thinning or loss</p> <p>What to look for?</p> <ul style="list-style-type: none"> Your hair may begin to become thin or fall out during or after treatment. In most cases, your hair will grow back after treatment, but the texture or colour may change. In very rare cases, hair loss may be permanent. <p>What to do?</p> <ul style="list-style-type: none"> Use a gentle soft brush. Do not use hair sprays, bleaches, dyes and perms. 	<p>Talk to your health care team if this bothers you.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Dry mouth</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may have a dry or sticky feeling in your mouth or throat, Your saliva may be thick and stringy. You may have cracks in your lips or at the corners of your mouth You may have difficulty chewing, tasting, swallowing or talking <p>What to do?</p> <ul style="list-style-type: none"> Use sugar-free gum or lozenges (e.g. those that contain xylitol) to help keep your mouth moist. Suck on ice chips or sugarless popsicles to help relieve dry mouth. Rinse your mouth often (every 1 to 2 hours) with a homemade mouthwash. To make a homemade mouthwash, mix 1 teaspoon of baking soda and 1 teaspoon of salt in 4 cups (1L) of water Do not use store-bought mouthwashes, especially those with alcohol because they may irritate dry your mouth Spray your mouth with water or artificial saliva products (e.g., Moi-Stir Spray®, Biotene® products) as needed to keep it moist. Apply mouth lubricant (like Biotene Oral balance gel®) after you brush your teeth, at bedtime, and as needed. Use a steam vaporizer at night to relieve nighttime dry mouth Speak to your health care team about the right product for you. <p>See our Mouth Care pamphlet for more information.</p> <p>Talk to your health care team if your dry mouth does not improve or if it is severe.</p>	<p>Talk to your health care team if it does not improve or if it is severe.</p>
<p>Taste changes</p> <p>What to look for?</p> <ul style="list-style-type: none"> Food and drinks may taste different than usual. <p>What to do?</p> <ul style="list-style-type: none"> Eat foods that are easy to chew, such as scrambled eggs, pasta, soups, cooked vegetables. Taste foods at different temperatures, since the flavour may change. Try different forms of foods, like fresh, frozen or canned. Experiment with non-spicy foods, spices and seasonings. 	<p>Talk to your health care team if it does not improve or if it is severe.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Headache, mild joint, muscle pain or cramps</p> <p>What to look for?</p> <ul style="list-style-type: none"> New pain in your muscles or joints, muscle cramps, or feeling achy. <p>What to do?</p> <ul style="list-style-type: none"> Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. Read the above section: "What should I do if I feel unwell, have pain, a headache or a fever?" before taking acetaminophen (Tylenol®), ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding. Rest often and try light exercise (such as walking) as it may help. <p>Ask your health care team for the Pain pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe.</p>
<p>Mild swelling</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe. <p>What to do?</p> <p>To help prevent swelling:</p> <ul style="list-style-type: none"> Eat a low-salt diet. <p>If you have swelling:</p> <ul style="list-style-type: none"> Wear loose-fitting clothing. For swollen legs or feet, keep your feet up when sitting. 	<p>Talk to your health care team if it does not improve or if it is severe.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Liver problems</p> <p>Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe. <p>What to do?</p> <p>If you have any symptoms of liver problems, get emergency medical help right away.</p>	<p>Get emergency medical help right away.</p>
<p>Heartburn; stomach upset; bloating</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Pain or burning in the middle or top part of your chest. It may get worse when you are lying down or bending over or when you swallow. • A bitter or acidic taste in your mouth. <p>What to do?</p> <ul style="list-style-type: none"> • Drink clear liquids and eat small meals. • Do not eat acidic, fatty or spicy foods. • Limit caffeine (like coffee, tea) and avoid alcohol. • Avoid smoking or being around tobacco. • Sit up or stand after eating. Do not lie down. • Raise the head of your bed six to eight inches. You may need to use extra pillows to do this. 	<p>Talk to your health care team if it does not improve or if it is severe.</p>
<p>Anemia (low red blood cells)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may feel more tired or weaker than normal. • Pale skin and cold hands and feet. • You may feel short of breath, dizzy or lightheaded. • This may occur in days to weeks after your treatment starts. 	<p>Talk to your health care team if it does not improve or if it is severe.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>What to do?</p> <p>If your health care team has told you that you have anemia (low red blood cells):</p> <ul style="list-style-type: none"> • Rest often and eat well. • Light exercise, such as walking may help. • You may need medication or a blood transfusion. • If it is very bad, your doctor may need to make changes to your treatment regimen. 	
<p>Kidney problems</p> <p>Your health care team may check for proteins in your urine (pee) and your kidney function regularly with a blood test. You may have blood in your urine.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Swelling in your hands, ankles, feet or other areas of your body. • Weight gain that is not normal for you. • Pain in your lower back. • Muscle twitches and cramps or itchiness that won't go away. • Nausea (feeling like you need to throw up) and vomiting. • Changes in urination (peeing) such as less urine than usual. <p>What to do?</p> <ul style="list-style-type: none"> • If you have any of these signs, talk to your health care team or go to your closest emergency department. <p>To prevent kidney infections:</p> <ul style="list-style-type: none"> • Drink at least 6 to 8 cups (2 litres) of water or other liquids per day unless your health care team has told you to drink more or less. • When you feel the need to pee, go as soon as possible. Do not wait or hold in the pee. 	<p>Get emergency medical help right away.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Low neutrophils (white blood cells) in the blood (neutropenia)</p> <p>When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the Neutropenia (Low white blood cell count) pamphlet for more information.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. • Do not take medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen). • Do not eat or drink anything hot or cold right before taking your temperature. <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> • 38.3°C (100.9°F) or higher at any time OR • 38.0°C (100.4°F) or higher for at least one hour. <p>What to do?</p> <p>If your health care team has told you that you have low neutrophils:</p> <ul style="list-style-type: none"> • Wash your hands often to prevent infection. • Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist. • Keep a digital thermometer at home so you can easily check for a fever. <p>If you have a fever:</p> <p>If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.</p>	<p>If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you MUST get emergency medical help right away.</p>

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- signs of an allergic reaction: swollen lips, face or tongue, chest and throat tightness
- severe headache, accompanied by confusion and blurred vision
- new jaw, teeth or mouth problems: pain and swelling, poor healing of mouth sores, unusual discharge from gums, loosening of teeth or feeling of numbness or heaviness in the jaw
- severe rash with blistering or peeling of your skin or any unusual changes in your skin; may also have fever and swollen glands
- breathing problems, chest pain or coughing up blood
- any severe abdominal pain
- unusual bleeding or bruising

Who do I contact if I have questions or need help?

My cancer health care provider is: _____

During the day I should contact: _____

Evenings, weekends and holidays: _____

Other Notes:

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For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.