

PIQ KNOWLEDGE



PIQRAY<sup>®</sup>  
(alpelisib) tablets  
50 mg • 150 mg • 200 mg

WHAT YOU NEED TO KNOW  
ABOUT TREATMENT

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.





# WELCOME

## INDICATION

PIQRAY® (alpelisib) tablets is a prescription medicine used in combination with the medicine fulvestrant to treat adults who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer with an abnormal phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA) gene that has progressed or spread to other parts of the body (metastatic) while 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.

**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

**If you’ve progressed on or after endocrine (hormone) therapy and have HR+, HER2- metastatic breast cancer (mBC) with a PIK3CA gene mutation, PIQRAY may be right for you.**

Get to know a first-of-its-kind treatment option specifically for PIK3CA mutations—which are common and linked to cancer growth—in HR+, HER2- mBC.

If you test positive for a PIK3CA gene mutation, you and your doctor can choose PIQRAY® (alpelisib) tablets, a treatment specifically for your type of mBC.

**Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.**





*I didn't choose a PIK3CA mutation. But I did*

# PIQ

HOPE

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.

## ABOUT PIQRAY® (alpelisib) TABLETS

*by knowing there's a treatment specifically for my type of mBC.*

### IMPORTANT SAFETY INFORMATION (CONT)

#### PIQRAY may cause serious side effects, including: (cont)

- **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





## Who is **PIQRAY** for?

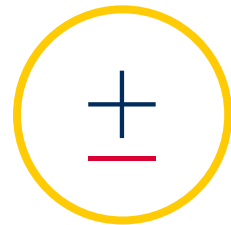
PIQRAY® (alpelisib) tablets is a biomarker-driven treatment approach, which means that your health care provider will test your metastatic breast cancer for an abnormal PIK3CA gene to make sure that PIQRAY is right for you. PIK3CA mutations have been linked to cancer growth. PIQRAY is the first and only treatment option specifically for people with a PIK3CA mutation in HR+, HER2- mBC, whose disease has progressed on or after hormone therapy.

PIQRAY is for adults, who:

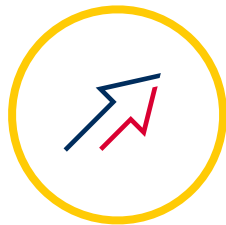


Test positive for a mutation, or abnormality, in a gene called PIK3CA

It is not known if PIQRAY is safe and effective in children.



Have HR+, HER2- advanced or metastatic breast cancer



Have progressed on or after hormone therapy

### IMPORTANT SAFETY INFORMATION (CONT)

**PIQRAY may cause serious side effects, including: (cont)**

- **High blood sugar levels (hyperglycemia):** Hyperglycemia is common with PIQRAY and may be severe. Your health care provider will check your blood sugar levels and may give you a medicine called metformin before you start treatment with PIQRAY. Your health care provider will monitor your blood sugar levels during treatment and 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.

## How common are **PIK3CA** mutations?

If you have a PIK3CA mutation, that means you have an abnormal (or mutated) PIK3CA gene, which can create proteins that may cause cancer cells to grow and spread. PIK3CA is the most common mutation that affects people with HR+, HER2- metastatic breast cancer.

~155k

people in the US are currently living with mBC.

~70%

of all people with breast cancer are HR+, HER2-.

~40%

of people with HR+, HER2- mBC have a **PIK3CA** mutation.



PIK3CA mutations are sporadic, meaning they occur at random and aren't passed down from parent to child. PIK3CA mutations can only be detected through a specific genomic test ordered by your doctor, so even if you've had genetic testing done before, ask about getting tested specifically for a PIK3CA mutation.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.



## How **PIQRAY** works



**PIQRAY® (alpelisib) tablets works by specifically targeting proteins made from a mutated PIK3CA gene.\***

\*PIQRAY affects cancer cells, but can also affect healthy cells. Although PIQRAY has been studied in patients with HR+, HER2- metastatic breast cancer (mBC), how PIQRAY works has only been demonstrated in laboratory studies.

### IMPORTANT SAFETY INFORMATION (CONT)

#### PIQRAY may cause serious side effects, including: (cont)

- **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 or high levels of sugar in your blood
- have a history of skin rash, redness of skin, blistering of the lips, eyes or mouth, or skin peeling

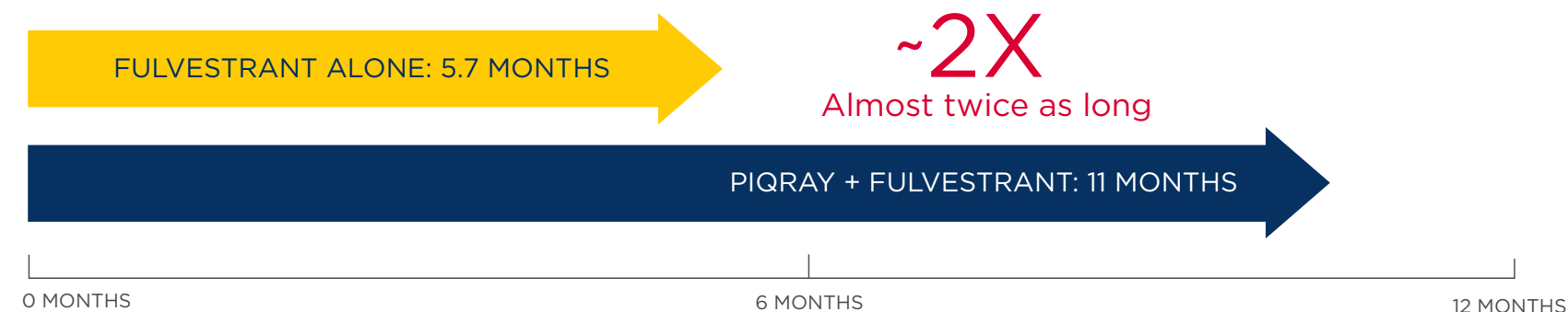
## How **PIQRAY** can help

PIQRAY was studied in a clinical trial that included 572 postmenopausal women, or men, with HR+, HER2- mBC who had progressed on or after an aromatase inhibitor (a hormone therapy). Of the 341 people who tested positive for the PIK3CA mutation, 169 took PIQRAY + fulvestrant (hormone therapy), while 172 took fulvestrant alone.

### Proven more time without disease progression

People who tested positive for a PIK3CA mutation and took PIQRAY + fulvestrant had more time without disease progression—almost twice as long as those who took fulvestrant alone.

Median time people with a **PIK3CA mutation** were progression-free from the start of treatment

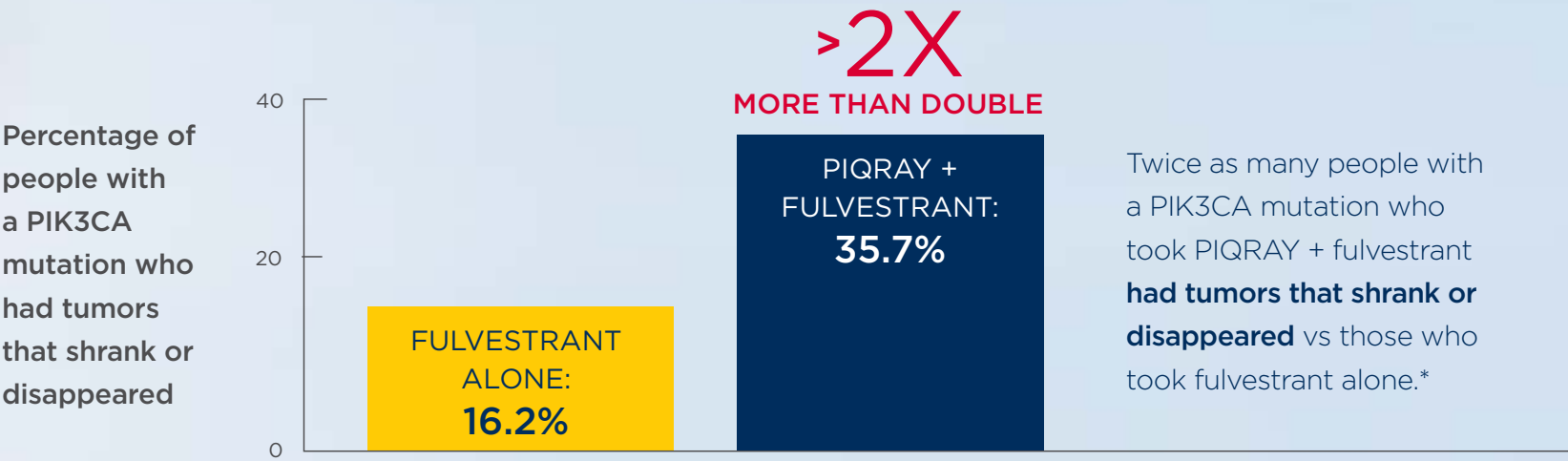
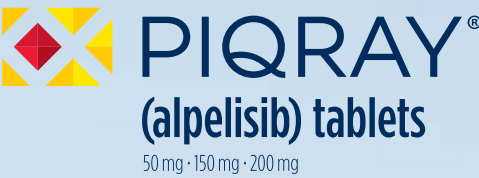


Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.



# Proven to shrink tumors

Additional results of the trial showed that PIQRAY<sup>®</sup> (alpelisib) tablets and fulvestrant worked together to shrink tumors in people with a PIK3CA mutation who had tumors large enough to measure. Of the 262 people with measurable disease, 126 took PIQRAY + fulvestrant and 136 took fulvestrant alone.



\*34.9% of people with a PIK3CA mutation who had tumors large enough to measure who took PIQRAY + fulvestrant saw their tumors shrink in size vs 14.7% of those who took fulvestrant without PIQRAY. And 0.8% of people with a PIK3CA mutation who had tumors large enough to measure who took PIQRAY + fulvestrant had their tumors completely disappear vs 1.5% of those who took fulvestrant without PIQRAY.

## IMPORTANT SAFETY INFORMATION (CONT)

Before you take PIQRAY, tell your health care provider about all of your medical conditions, including if you (cont):

- 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

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.





*Treatment is a part of my daily life, so I*

# PIQRAY<sup>®</sup>

## CLARITY

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.

## TAKING PIQRAY

*by understanding how to take PIQRAY<sup>®</sup> (alpelisib) tablets.*

### IMPORTANT SAFETY INFORMATION (CONT)

Before you take PIQRAY, tell your health care provider about all of your medical conditions, including if you (cont):

#### **Males with female partners who are able to become pregnant:**

- You 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. Talk to your health care provider about the best way to feed your baby during treatment.

You should also read the full Prescribing Information of fulvestrant for important pregnancy, contraception, infertility, and lactation information





## Q&A for taking **PIQRAY**

PIQRAY® (alpelisib) tablets is a once-daily oral tablet that is prescribed with fulvestrant. Fulvestrant is an injectable hormone therapy administered by your health care provider. It is important to always follow your doctor's directions on how to take PIQRAY.



### How should I take PIQRAY?

Take PIQRAY exactly as your health care provider tells you. Take it once a day at about the same time, with food.



### Can I change my dose of PIQRAY?

Do not change your dose or stop taking PIQRAY unless your health care provider tells you.

### IMPORTANT SAFETY INFORMATION (CONT)

**Tell your health care provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking PIQRAY with other medicines may affect the way PIQRAY works and may cause 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.



### What if I miss my dose of PIQRAY?

If you miss a dose of PIQRAY, you may still take it with food up to 9 hours after the time you usually take it. If it has been over 9 hours after you usually take your dose:

- ▶ Skip the dose for that day.
- ▶ Take the dose at your usual time the next day.
- ▶ Do not take 2 doses to make up for a missed dose.
- ▶ **If you vomit after taking PIQRAY**, do not take another dose that day. Take your next dose at your usual time.



### Can I chew or crush my PIQRAY tablets?

Swallow PIQRAY tablets whole. Do not chew, crush, or split them. Do not take any tablets that are broken, cracked, or that look damaged.



### What if I take too much PIQRAY?

If you take too much PIQRAY, call your health care provider or go to the nearest hospital emergency room right away.

**Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.**





# Recommended dosing schedule

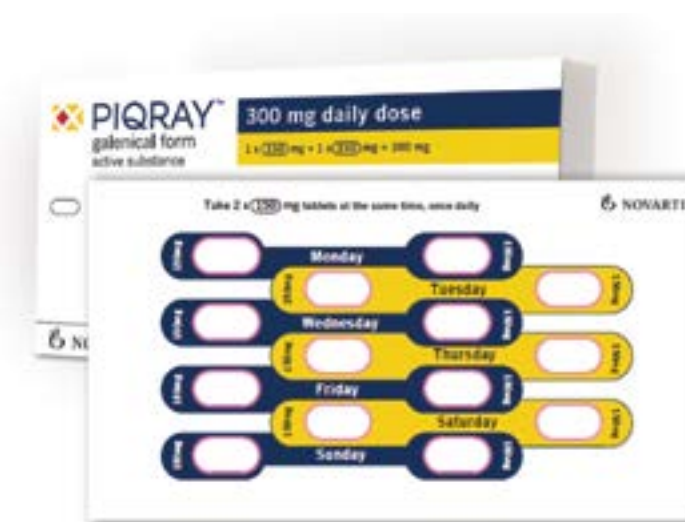
The recommended dose of PIQRAY® (alpelisib) tablets is 300 mg (two 150-mg film-coated tablets), taken orally, once daily, with food.

When given with PIQRAY, the recommended dose of fulvestrant is 500 mg administered as an injection by your doctor on days 1, 15, and 29, and once monthly thereafter. Ask your doctor for additional dosing information for fulvestrant.

DRUG	FIRST MONTH OF TREATMENT			FOLLOWING MONTHS
PIQRAY 300 mg (two 150-mg tablets) once daily	ONCE DAILY			
Fulvestrant 500-mg dose on days 1, 15, and 29 during the first month of treatment, and 500-mg dose once monthly thereafter	✓ DAY 1	✓ DAY 15	✓ DAY 29	✓ 1X MONTHLY

# PIQRAY packaging

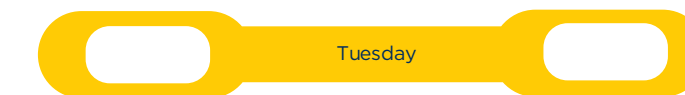
The PIQRAY blister pack is designed to help you stay on track with treatment. The pack is color-coded to help you take the right dose on the right day.



300 mg (Two 150-mg tablets once daily)



For example, you would take the tablets within the **blue** “Monday” strip on Monday.



On Tuesday, you would take the tablets within the **yellow** “Tuesday” strip.

## IMPORTANT SAFETY INFORMATION (CONT)

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





*When managing my metastatic breast cancer (mBC) treatment, I*

# PIQ ACTION

*by asking my doctor what to expect.*

## IMPORTANT SAFETY INFORMATION (CONT)

Tell your health care provider right away if you develop any changes in your vision, eye pain, sensitivity to light, or if your eyes look different.

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.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.

## SIDE EFFECTS



# Understanding side effects

With any new treatment option, it's natural to have concerns about the potential side effects. PIQRAY® (alpelisib) tablets may cause side effects that you may not be familiar with. Your health care provider may decrease your dose, have you take a break from treatment, or tell you to completely stop taking PIQRAY if you develop certain serious side effects.



The **serious side effects** of PIQRAY include:



**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 a severe rash or a 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 check your blood sugar levels and may give you a medicine called metformin before you start treatment with PIQRAY. Your health care provider will monitor your blood sugar levels during treatment and 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
- more frequent urination than usual or a higher amount of urine than normal
- increased appetite with weight loss
- confusion
- nausea
- vomiting
- fruity odor on breath
- difficulty breathing
- 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
- 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.

**INDICATION**  
PIQRAY® (alpelisib) tablets is a prescription medicine used in combination with the medicine fulvestrant to treat adults who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer with an abnormal phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA) gene that has progressed or spread to other parts of the body (metastatic) while 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 (Cont)

**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, swelling of the face or throat, flushing, rash, fever, or fast heart rate during treatment with PIQRAY



# Common side effects

The most common side effects of PIQRAY® (alpelisib) tablets when used with fulvestrant include:

	Rash		Decreased appetite		Weight loss
	Nausea		Mouth sores		Hair loss
	Tiredness and weakness		Vomiting		Changes in certain blood tests

Tell your health care provider right away if you develop any changes in your vision, eye pain, sensitivity to light, or if your eyes look different.

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.

Tell your health care provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of PIQRAY. Call your doctor for medical advice about side effects. You are encouraged to report side effects to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.





## Understanding **high blood sugar** (hyperglycemia)

High blood sugar is common with PIQRAY® (alpelisib) tablets and may be severe. It's important to understand the difference between hyperglycemia and diabetes.

- ▶ **Hyperglycemia** is high blood sugar due to any cause, and also a characteristic of diabetes.
- ▶ **Type 1 Diabetes** is a condition where your body stops making the insulin it needs to allow blood sugar to enter the cells of the body.
- ▶ **Type 2 Diabetes** is a condition where your body either doesn't make enough insulin or is unable to use it correctly.

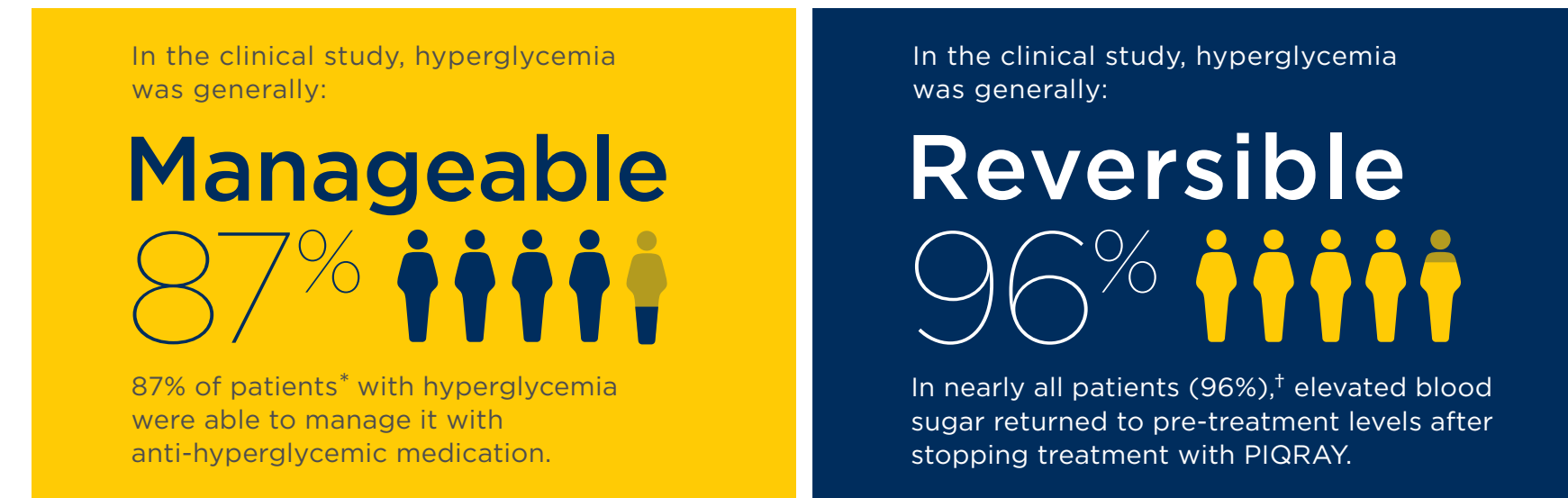
The safety of PIQRAY in patients with type 1 and uncontrolled type 2 diabetes has not been established. If you have a history of diabetes, talk to your doctor about how that could affect your experience with PIQRAY.

### IMPORTANT SAFETY INFORMATION (CONT)

#### PIQRAY may cause serious side effects, including: (cont)

- **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 check your blood sugar levels and may give you a medicine called metformin before you start treatment with PIQRAY. Your health care provider will monitor your blood sugar levels during treatment and 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.

In general, hyperglycemia that may be caused by PIQRAY is not diabetes. If you experience hyperglycemia while taking PIQRAY, remember:



\*Of the 187 patients with hyperglycemia, 163 were managed with anti-hyperglycemic medication.

<sup>†</sup>Of the 54 patients with elevated blood sugar levels, 52 had levels that returned to baseline after discontinuing PIQRAY.

If you experience hyperglycemia, your doctor may prescribe a medication (such as metformin), along with suggested lifestyle changes, and may require dose interruption, reduction, or discontinuation based on the severity of hyperglycemia. Always talk to your doctor before making any changes to your diet or exercise routine.

### IMPORTANT SAFETY INFORMATION (CONT)

- **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

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.



# Monitoring blood sugar

Your doctor will monitor your blood sugar levels before starting and while taking PIQRAY® (alpelisib) tablets. Your doctor may also have you monitor your blood sugar levels at home, which you should do in the morning, before eating or drinking. Your doctor may monitor your blood sugar levels more often if you have a history of type 2 diabetes. Your doctor may also monitor more frequently for the first few weeks during treatment if you have risk factors for high blood sugar. The chart below shows a recommended monitoring schedule.

## Monitoring to check for hyperglycemia

**FPG\***  
(Fasting Plasma Glucose)  
Measures glucose levels.

- 1X once before starting PIQRAY
- 1X at least once a week for the first 2 weeks of taking PIQRAY
- 1X after the first 2 weeks, at least once every 4 weeks while taking PIQRAY and as your doctor feels is necessary

**HbA1c**  
(Hemoglobin A1c)  
Measures glycosylated hemoglobin levels.

- 1X once before starting PIQRAY
- 1X once every 3 months while taking PIQRAY and as your doctor feels is necessary

## Monitoring if you develop hyperglycemia

**Fasting glucose**  
(FPG or fasting blood glucose)  
Measures glucose levels.

- 2X as your doctor feels is necessary and at least twice a week until levels return to normal
- While taking anti-hyperglycemia medication**
  - 1X at least once a week for 8 weeks
  - 1X after 8 weeks, once every two weeks and as your doctor feels is necessary

\*After starting treatment, fasting glucose (FPG or fasting blood glucose) can be monitored.



## Signs of high blood sugar include:

- excessive thirst
- dry mouth
- more frequent urination than usual or a higher amount of urine than normal
- increased appetite with weight loss
- confusion
- nausea
- vomiting
- fruity odor on breath
- difficulty breathing
- dry or flushed skin

Contact your doctor immediately if you experience any signs and symptoms of hyperglycemia. Your doctor may require dose interruption, reduction, or discontinuation based on the severity of hyperglycemia.

**IMPORTANT SAFETY INFORMATION (CONT)**  
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.







# Tips for managing diarrhea or colitis (inflammation of your intestines)

Diarrhea is common with PIQRAY® (alpelisib) tablets, and may be severe. Follow your health care provider’s instructions for how to manage diarrhea.



Diarrhea and colitis are serious side effects of PIQRAY. Notify your doctor immediately if you develop diarrhea, stomach-area (abdominal) pain or see mucus or blood in your stool while taking PIQRAY. Your doctor may suggest that you drink more fluids or have an antidiarrheal medicine on hand to help manage your diarrhea. For colitis, your doctor may tell you to drink more fluids or take additional treatment, such as enteric-acting and/or systemic steroids. Use these medicines only as directed by your doctor.



Talk to your doctor if antidiarrheal medicine does not help with your diarrhea. If you have diarrhea or colitis, your doctor may need to interrupt, reduce your dose of, or discontinue PIQRAY.



Help manage diarrhea or colitis by watching what you eat and drink.

- ▶ Diarrhea or colitis can cause you to lose more fluid than you’re taking in, so it’s important to stay hydrated.
- ▶ Try the BRAT Diet: Bananas, Rice, Applesauce, and Toast.
- ▶ Drink at least 8 glasses of clear liquids per day (such as water, broth, or sports drinks).
- ▶ Avoid milk and dairy products.
- ▶ Eat frequent, small meals and bland, easily digestible foods.
- ▶ Eat food high in protein, such as chicken, turkey, eggs, and fish.
- ▶ Avoid spicy and/or greasy foods, alcohol, coffee, tea, and soda with caffeine.

## IMPORTANT SAFETY INFORMATION (CONT)

**Before you take PIQRAY, tell your health care provider about all of your medical conditions, including if you:**

- have a history of diabetes or high levels of sugar in your blood
- have a history of skin rash, redness of skin, blistering of the lips, eyes or mouth, or skin peeling

**Talk to your doctor before making any changes to your diet.**

**Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.**





## Tips for managing a rash

Rash is one of the most common side effects of PIQRAY® (alpelisib) tablets when used with fulvestrant, and can appear within 2 weeks. Your doctor may require dose interruption, reduction, or discontinuation based on the severity of the rash.

### Antihistamines & PIQRAY

Ask your doctor about starting them at the same time.

**Before a rash appears:** Your doctor may prescribe an antihistamine to help reduce the chances of a rash developing. Taking antihistamines before a rash appears may decrease the chances of rash and severity of rash, based on the clinical trial.

**If a rash occurs:** Your doctor may prescribe one or more of the following types of medication (shown at right) to help with the symptoms, depending on their severity.

**Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.**



#### Topical corticosteroids:

Creams applied directly to the skin that may reduce swelling and redness



#### Oral antihistamines:

Medicines taken by mouth that may relieve itching



#### Systemic corticosteroids:

Medicines taken by mouth or injection that may reduce swelling

Here are some tips for taking care of a rash at home:

- ▶ Wear loose clothing.
- ▶ When outside, wear sunscreen or long sleeves and pants.
- ▶ Take cool or lukewarm showers.
- ▶ Use mild soap and unscented detergent.
- ▶ Gently pat your skin dry after bathing.

**Ask your doctor for clarification on any medication you're not familiar with.**

### IMPORTANT SAFETY INFORMATION (CONT)

**Before you take PIQRAY, tell your health care provider about all of your medical conditions, including if you (cont):**

- 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





*Finding the assistance I need lets me*

# PIQ

SUPPORT

*throughout my treatment experience.*

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.

## PATIENT SUPPORT

### IMPORTANT SAFETY INFORMATION (CONT)

**Before you take PIQRAY, tell your health care provider about all of your medical conditions, including if you (cont):**

**Males with female partners who are able to become pregnant:**

- You 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. Talk to your health care provider about the best way to feed your baby during treatment



## Financial resources and access for **PIQRAY**

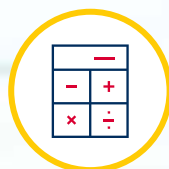
Our Patient Assistance Now Oncology (PANO) program was created to assist you with accessing your Novartis medicine(s)—from insurance verification to financial assistance—all through a knowledgeable and supportive call center.

### Novartis Oncology Universal Co-pay Program

You may be eligible for immediate co-pay savings on your next prescription of PIQRAY<sup>®</sup> (alpelisib) tablets:



Eligible patients with private insurance may pay \$0 per month



Novartis will pay the remaining co-pay, up to \$15,000 per calendar year, per product\*

To find out if you are eligible for the Novartis Oncology Universal Co-pay Program, call **1-877-577-7756** or visit [Copoly.NovartisOncology.com](https://Copoly.NovartisOncology.com).

\*Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit [Copoly.NovartisOncology.com](https://Copoly.NovartisOncology.com) or call 1-877-577-7756.

### Free Trial and Access Program

With the Free Trial and Access Program, you can receive a free supply of PIQRAY for a US Food and Drug Administration-approved indication. The supply can be shipped directly to your home or another convenient location so you can start treatment immediately. Program rules may vary by product.

Ask your health care professional to help you apply for the PANO Free Trial and Access Program.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 36-39.





## Summary of Important Information

### What is PIQRAY?

PIQRAY® (alpelisib) tablets is a prescription medicine used in combination with the medicine fulvestrant to treat adults who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer with an abnormal phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA) gene that has progressed or spread to other parts of the body (metastatic) while 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.

### Who should not take PIQRAY?

**Do not take PIQRAY** if you have had a severe allergic reaction to PIQRAY or are allergic to any of the ingredients in PIQRAY.

### What should I tell my health care provider before taking PIQRAY?

**Before you take PIQRAY, tell your health care provider about all of your medical conditions, including if you:**

- have a history of diabetes or high levels of sugar in your blood
- 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:**

- You 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. Talk to your health care provider about the best way to feed your baby during treatment

You should also read the full Prescribing Information of fulvestrant for important pregnancy, contraception, infertility, and lactation information.

### What other medications might interact with PIQRAY?

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking PIQRAY with other medicines may affect the way PIQRAY works and may cause 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.

### What are the possible side effects of 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, 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 check your blood sugar levels and may give you a medicine called metformin before your start treatment





## Summary of Important Information (Cont)

with PIQRAY. Your health care provider will monitor your blood sugar levels during treatment and 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.

### The most common side effects of PIQRAY when used with fulvestrant include:

- |                          |                      |                                  |
|--------------------------|----------------------|----------------------------------|
| • rash                   | • decreased appetite | • weight loss                    |
| • nausea                 | • mouth sores        | • hair loss                      |
| • tiredness and weakness | • vomiting           | • changes in certain blood tests |

Tell your health care provider right away if you develop any changes in your vision, eye pain, sensitivity to light, or if your eyes look different.

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.

### What laboratory monitoring tests do I need when taking PIQRAY?

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.

### General information about the safe and effective use of PIQRAY

Medicines are sometimes prescribed for purposes other than those listed. Do not use PIQRAY for a condition for which it was not prescribed. Do not give PIQRAY to other people, even if they have the same symptoms you have. It may harm them. You can ask your health care provider or pharmacist for more information about PIQRAY that is written for health professionals.

For more information about PIQRAY, talk with your doctor or pharmacist or call 1-833-4-PIQRAY (1-833-474-7729). For the FDA-approved product labeling or full Prescribing Information, please click [here](#).





FOR MORE INFORMATION,  
SPEAK WITH YOUR HEALTH CARE PROVIDER

Please see Important Safety Information throughout, and the  
Summary of Important Information on pages 36-39.

