



Your guide to treatment

Starting and staying on track with PIQRAY® ▼ + fulvestrant

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See <https://yellowcard.mhra.gov.uk/> for how to report side effects.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/>. By reporting side effects you can help provide more information on the safety of this medicine.

This booklet is not a substitute for the Patient Information Leaflet (PIL) which is provided with the medicine – for further information on symptoms/side effects, please speak to your cancer care team or refer to the PIL which is included in the PIQRAY® pack.

PIQRAY® is sometimes called by its generic name, alpelisib. Your doctor, nurse, or pharmacist may have used the name alpelisib when talking to you about your medication. PIQRAY® and alpelisib are different names for the same medicine.

About this booklet

This booklet is intended for patients who have been prescribed PIQRAY® + fulvestrant and is designed to help you get the most out of your treatment by giving you:

- ▶ Information you need to help you manage your treatment with PIQRAY® + fulvestrant
- ▶ Tips for talking to your healthcare team

To find out more about your treatment with PIQRAY® + fulvestrant, such as how it works and the side effects you might experience, please visit **www.illuminatingabc.co.uk** or scan the QR code and use password: **connect@illuminatingABC**.



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**Before starting
treatment**

Who is this treatment for?

PIQRAY® is used:¹



- For the treatment of postmenopausal women and men with a type of breast cancer called advanced hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer
- In combination with fulvestrant (a hormonal anticancer therapy), in patients whose cancer has not responded to other hormonal treatments and who have certain changes (mutations) in a gene called PIK3CA

Glossary

Locally advanced or metastatic breast cancer

Cancer that started in your breast but has now moved to other parts of your body.²

Hormone receptor-positive (HR+)

Cancer cells that use hormones like *oestrogen* or *progesterone* to grow.³

Human epidermal growth factor receptor-negative (HER2-)

Cancer cells with normal amounts and types of HER2, a protein that can cause breast cancer cells to grow and spread.³

PIK3CA mutation

Cancer cells with a mutation (or abnormality) in a certain part of the DNA known as the *PIK3CA* gene. This mutation may cause cancer cells to grow and spread.^{4,5}

Progression

When cancer grows or gets worse.⁶ It is common for metastatic breast cancer to progress after some time, even if it is being treated. This is sometimes called becoming *resistant* to that treatment.⁷

How PIQRAY® works

You are one of the approximately ~30–40% of patients with a *PIK3CA* mutation and HR+, HER2- locally advanced or metastatic breast cancer.^{8–15}



Your doctor prescribed PIQRAY® + fulvestrant because of your specific type of cancer.

- PIQRAY® inhibits the activity of a protein, produced by the *PIK3CA* gene, which is involved in the growth of breast cancer¹
- Fulvestrant is a type of treatment called endocrine or hormone therapy that can limit the action of oestrogen. Oestrogen is a hormone that can act as a growth signal for breast cancer¹⁶
- PIQRAY® in combination with fulvestrant may slow down breast cancer cell growth¹

Before you start treatment, tell your doctor or pharmacist if you:¹



- ✓ Have or have ever had high levels of sugar in your blood or diabetes (or signs of increased sugar levels, such as excessive thirst and dry mouth, needing to pass urine more often than usual, producing greater amounts of urine than usual, tiredness, nausea, or increased appetite with weight loss)
- ✓ Are allergic to PIQRAY® or fulvestrant or any of their ingredients
- ✓ Have a history of severe skin reactions or rashes, including Stevens–Johnson syndrome (SJS), erythema multiforme (EM), drug reaction with eosinophilia and systemic symptoms (DRESS) or toxic epidermal necrolysis (TEN; possible symptoms include red skin, blistering of the lips, eyes or mouth, skin peeling, with or without fever, rash)
- ✓ Have a severe bone disease that affects the jaw (osteonecrosis of the jaw)

Blood tests before and during your treatment¹



Your doctor will carry out blood tests before and regularly during treatment to monitor your blood sugar.

Based on the results, your doctor will take any necessary actions, such as prescribing medicine to lower blood sugar levels. If necessary, your doctor may decide to temporarily interrupt treatment or reduce your PIQRAY[®] dose to allow your blood sugar to decrease. Your doctor may also decide to stop treatment permanently.

Write down any questions you may have for your healthcare team here











**While taking
your treatment**

How do I take my treatment?

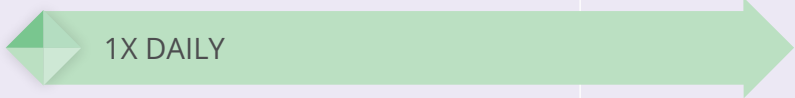




The usual starting dose of PIQRAY® is 300 mg once daily. Your doctor will decide on the right dose for you.¹

You should take PIQRAY®:¹

-  Once each day at about the same time
-  Immediately following food
-  By mouth, with a glass of water
-  Swallow whole. Do not chew, crush, or split the tablets

Fulvestrant is a slow injection into the buttock given by your healthcare team. Your doctor will tell you how often you need to get this injection.¹⁶

The recommended schedule is:
500 mg (two 250 mg/5 ml injections) given once a month, with an additional 500 mg dose given 2 weeks after the initial dose.¹⁶

| Drug | First month of treatment | | | Following months |
|--|--|---|---|---|
| PIQRAY® 300 mg (two 150 mg tablets) once daily ¹ |  | | | |
| Fulvestrant 500 mg (two 250 mg/5 ml injections) given once a month, with an additional 500 mg dose given 2 weeks after the initial dose. ¹⁶ |  DAY 1 |  DAY 15 |  DAY 29 |  1X MONTHLY |

DO NOT



- Take any tablets that are broken, cracked, or look damaged¹
- Change your dose or stop taking PIQRAY® unless your doctor tells you to¹

How should I store my medicine?



This medicine does not require any special storage conditions.¹
Remember to keep this medicine out of the sight and reach of children.¹

What if I miss a dose?

▶ **If it has been less than 9 hours from your regularly scheduled dose:¹**

- **Take your missed dose immediately following food**

For example: if you typically take PIQRAY® at breakfast and realise at lunch you have not yet taken your dose, you can take your missed dose.

▶ **If it has been more than 9 hours from your regularly scheduled dose:¹**

- **Do not take your missed dose**

For example: if you typically take PIQRAY® at breakfast and realise at dinner you have not taken your dose, skip the dose for that day. The next day, take the dose at your usual time. Do not take a double dose to make up for the one that you missed.

▶ **If you vomit after taking the dose:¹**

- **Do not take an additional dose on that day**

Start taking the usual dose the next day at the usual time.

If you accidentally take too many PIQRAY® tablets, please contact your doctor or nurse, acute oncology department or any emergency phone number for advice straight away. Medical treatment may be necessary¹

Dose interruptions and modifications



Depending on how your body responds to the treatment with PIQRAY®, your doctor may want to adjust your PIQRAY® dose. It is very important to follow your doctor's instructions. If you have certain side effects, your doctor may ask you to change to a lower dose, to interrupt treatment for a time, or to stop treatment.¹

Dose modifications are typically done in one of two ways

A dose interruption:¹

- This is when your doctor asks you to stop taking PIQRAY® for a period of time. Your doctor will advise you as to whether or not you will continue treatment with fulvestrant during this time

A dose reduction:¹

- This is when your doctor asks you to take a lower dose of PIQRAY® each day

Before you restart PIQRAY® after an interruption, ask your doctor or nurse:¹

- When you should start taking PIQRAY® again
- Whether you should finish your current pack or start a new one
- How many PIQRAY® tablets you should take each day

If side effects do not go away after interrupting or reducing the dose, your healthcare professional may need to stop treatment with PIQRAY® permanently. Stopping your treatment with PIQRAY® may cause your condition to become worse. Do not stop taking PIQRAY® unless your doctor tells you to stop.¹

What are some of the most common side effects?¹

Hyperglycaemia

(high blood sugar)



Diarrhoea



Mouth sores



Rash



Weight loss



Nausea, vomiting



Decreased appetite



Abnormal blood tests*



Fatigue†



Hair loss



If you have side effects of any kind, it's important to tell your healthcare team right away so they can help you manage them. Your doctor may suggest a dose reduction or interruption or prescribe additional medications to take alongside your treatment to help manage these side effects.¹

For more information on PIQRAY® side effects, please see the Patient Information Leaflet included in your box of tablets.

*Abnormal blood tests may indicate high blood levels of the following enzymes: gamma glutamyl transferase, alanine aminotransferase, lipase; high blood level of sugar; high blood level of creatinine and/or calcium; low blood level of lymphocytes, platelets, sugar, haemoglobin and/or albumin; increase in a measurement of blood clotting ability called activated partial thromboplastin time; high blood level of glycosylated haemoglobin (a marker of blood sugar level over the last 8 to 12 weeks).¹ For more information on side effects, please see the Patient Information Leaflet.

†Treatment with PIQRAY® may lead to tiredness. You should therefore be cautious when driving or using machines during your treatment with PIQRAY®.¹

Some side effects may be more serious:

Some side effects during treatment with PIQRAY® + fulvestrant may be more serious. If any of the following apply to you during your treatment with PIQRAY®, tell your doctor or pharmacist immediately:¹

- Feeling thirsty and dry mouth, passing urine more often than usual, tiredness, increased appetite with weight loss, confusion, nausea, vomiting, fruity odour on breath, difficulty breathing and dry or flushed skin, which may be signs of increased blood sugar levels (hyperglycaemia) and its complications
- Rash, itching, hives, breathlessness, difficulty breathing, wheezing, cough, light-headedness, dizziness, changes in levels of consciousness, low blood pressure, reddening of the skin, swelling of the face or throat, blue discolouration of the lips, tongue or skin (possible signs of severe allergic reactions)
- Fever, cough, runny nose, enlarged lymph nodes, painful joints, rash, night sweats, weight loss (possible signs of a low level of lymphocytes, a type of white blood cell)
- Breathing problems, such as difficult or painful breathing, cough, rapid breathing, blue discolouration of the lips, tongue or skin, hiccups (possible signs of non-infectious pneumonitis or pneumonia)
- Rash, reddening of the skin, blistering of the lips, eyes or mouth, skin peeling, sometimes with fever (possible signs of skin conditions called SJS, EM, DRESS or TEN)
- Passing urine less often than usual or passing smaller amounts of urine than usual, swelling in legs, ankles and around the eyes, tiredness, confusion, nausea, seizure, chest pain (possible symptoms of acute kidney failure)
- New or worsening symptoms affecting your mouth (such as loose teeth, pain or swelling, non healing of mouth sores, or discharge)
- Severe diarrhoea

Pregnancy, breastfeeding and fertility

PIQRAY® must not be used by women who are, or may be, pregnant or breastfeeding.¹ PIQRAY® may harm an unborn baby. If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Women should not breastfeed during treatment and for at least 1 week after the last dose of PIQRAY®. Your doctor will discuss with you the potential risks of taking PIQRAY® during pregnancy or breastfeeding.¹

If you are a woman who could become pregnant, your doctor will rule out an existing pregnancy before starting you on treatment with PIQRAY®. This may include having a pregnancy test.¹

Women who could become pregnant should use an effective method of birth control during treatment and for at least 1 week after stopping PIQRAY®. Ask your doctor about suitable methods. If you think you may be pregnant after starting treatment with PIQRAY®, tell your doctor immediately.¹

During treatment and for at least 1 week after stopping treatment, male patients should use a condom for intercourse with female partners who could become pregnant. If the partner of a male patient suspects that she has become pregnant during this time, she should inform a doctor immediately.¹



Hyperglycaemia (high blood sugar) can be a side effect of taking PIQRAY®.

What is hyperglycaemia?

- Hyperglycaemia occurs when the level of glucose (sugar) in the blood is higher than it should be¹⁸
- Hyperglycaemia can become serious if not managed¹⁷

Your blood sugar levels will be tested regularly before you start treatment, during treatment and after you stop treatment with PIQRAY®¹

Make sure that you regularly test your blood sugar before you start treatment, during treatment and after you stop treatment with PIQRAY®¹

- Your doctor will tell you exactly when and where to have the blood tests. Treatment with PIQRAY® may only be started if tests show that you have the right levels of sugar in your blood. This is because PIQRAY® can cause hyperglycaemia, which could be serious and need treatment. Only regular fasting blood tests can tell the doctor if you are developing hyperglycaemia
- Your doctor will tell you exactly when and where to test your blood sugar. This will be required more frequently in the first 4 weeks of treatment and especially in the first 2 weeks of treatment with PIQRAY®. Afterwards, blood tests will be needed at least once a month, depending on your blood sugar levels

Know the signs of hyperglycaemia so you can talk to your doctor about how to manage it

Signs and symptoms of hyperglycaemia¹⁸

- Feeling very thirsty
- Passing urine more often than usual
- Passing greater amounts of urine than usual
- Increased appetite with weight loss
- Increased tiredness or nausea



Hyperglycaemia can become serious if it is not properly managed. Call your healthcare team right away if you have any of these symptoms.

Managing hyperglycaemia

Here are things you can do to help manage your hyperglycaemia:¹⁷



Follow your doctor's instructions for monitoring your blood glucose, and any changes to the dose of your medicine(s)



Make lifestyle changes, such as keeping to a healthy weight, eating a balanced diet and being more physically active



Your doctor may prescribe a medicine, or a combination of medicines, to help control your blood sugar



Severe hyperglycaemia (high blood sugar) is considered serious, particularly if accompanied by symptoms such as confusion, dry mouth, dry or flushed skin, nausea, vomiting, tiredness, need to pass urine frequently, or thirst. These could be symptoms of hyperglycaemic hyperosmolar nonketotic syndrome (HHNKS). Contact your healthcare team immediately if you have any of these symptoms.¹⁷



Diarrhoea

Diarrhoea can be a side effect of taking PIQRAY®.

What is diarrhoea?

- Diarrhoea is loose or watery bowel movements that may happen more often than normal¹⁸
- Diarrhoea can be painful and can get in the way of your everyday life¹⁸

Know the signs and symptoms of diarrhoea so you can talk to your doctor about how to manage it

Signs and symptoms of severe diarrhoea¹⁸⁻²⁰

- More than 4 to 6 episodes of diarrhoea a day
- Blood in your stool or rectal area
- Weight loss due to diarrhoea
- Fever of 39°C (102°F)
- Diarrhoea that lasts more than 2 days
- Diarrhoea along with dizziness



Call your healthcare team right away if you experience any of these symptoms.

Managing diarrhoea

Here are things you can do to help control your diarrhoea:



Medicine: Ask your doctor about antidiarrhoea medicines and rehydration solutions^{18,21}

Ask your doctor before taking any medicine and be sure to follow their instructions about how to take the medicine.



Diet: Changing when and what you eat and drink may help reduce the severity of diarrhoea:²²

- Drink plenty of liquids (at least 2 litres or 3.5 pints a day) to replace the lost fluid
- Avoid drinking alcohol and coffee
- Eat small, frequent meals made from light and plain foods, such as white fish, poultry, well-cooked eggs, white bread, pasta or rice
- Eat your meals slowly
- Eat less fibre (such as cereals, raw fruits and vegetables) until the diarrhoea improves
- Avoid greasy, fatty foods such as chips or beef burgers, and spicy foods like chilli peppers



Stomatitis

Stomatitis, mouth ulcers, and oral mucositis have all been observed in patients treated with PIQRAY®.¹

What is stomatitis?

- Stomatitis is mouth sores or ulcers with gum inflammation²³
- The sore can be in the cheeks, gums, inside of the lips, or on the tongue²³

Know the signs of stomatitis so you can talk to your doctor about how to manage it

Signs and symptoms of stomatitis²³

- Redness of the lining of your mouth
- Patchy ulcers
- Ulcers joined together
- Bleeding from the mouth
- Difficulty eating or drinking



Stomatitis can become serious if it is not properly managed. Call your healthcare team right away if you have any of these symptoms.

Managing stomatitis

Here are some of the things you can do to help manage the symptoms of stomatitis:²³⁻²⁶



Avoid painful foods. Acidic and spicy foods can further irritate the mouth, as can sharp and crunchy foods, such as crisps and biscuits. Very hot or cold foods and beverages should also be avoided, as should drinks containing caffeine or alcohol.



Eat and drink carefully. Small meals eaten more frequently may be easier to manage, especially if food is cut into small pieces and eaten slowly. Using a straw for drinks keeps the liquid away from sore areas in the mouth.



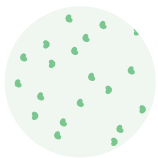
Continue cleaning your mouth. Although it can be uncomfortable, it's important that you maintain your oral hygiene to prevent the ulceration getting worse. A toothbrush with softer bristles may help, as well as rinsing out your mouth several times a day with a weak saltwater solution. Avoid alcohol-based mouthwashes.



Keep your mouth and lips moist. Rinse your mouth out regularly and apply moisturiser to your lips.



Topical treatments may help ease your discomfort and pain, but agents containing hydrogen peroxide, iodine, and thyme derivatives tend to worsen mouth ulcers, and should therefore be avoided. Antifungal agents must also be avoided unless a fungal infection is diagnosed.



Rash

Developing a rash can occur as a side effect of taking PIQRAY®.¹

What is a rash?

- A rash is a change in the texture or colour of your skin
- Your skin may look red, swollen (puffy) or bumpy, and it may feel dry or have sores (painful, broken patches of skin)
- A rash may feel painful, itchy, or hot

Know the signs of a rash so you can talk to your doctor about how to manage it

Signs of a rash²⁷

You may notice that your skin:

- Is red or warm
- Is swollen (larger than normal)
- Has sores (painful, broken patches of skin)
- Is irritated
- Is itchy



Rashes can become serious if not properly managed. Call your healthcare team right away if you have any of these symptoms.

Preventing a rash

Your doctor may advise you to take an antihistamine medicine to help prevent a rash.



Medicine: Ask your doctor about medicines to treat your rash. They may be able to prescribe a cream or oral medicine to help with your symptoms.

Tips for taking care of a rash at home:²⁷



- Wear loose clothing
- Avoid hot showers or baths; use cool or lukewarm water
- Use mild, unperfumed, soap-free cleansers
- Gently pat your skin dry after bathing
- Protect your skin from the sun with sunscreen or wear long, loose clothing
- If you have dry skin, use an unscented moisturiser at least twice a day on your face and body



A black and white photograph of two healthcare professionals in white lab coats. The woman in the foreground is smiling and looking towards the left. She has dark hair tied back. A purple rectangular box is overlaid on the right side of the image, containing the text 'Staying on track' in white. The background is slightly blurred, showing an indoor setting with plants and a window.

Staying on track

Managing appointments

Having open and honest communication with your healthcare team is an important part of managing locally advanced or metastatic breast cancer. It may be hard to talk about certain things, but remember that your doctor wants to help and give you the information you need.

Use the following tips to help with your appointments:



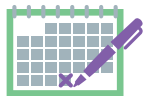
PREPARING for your appointments

- Write down your questions in order of importance
 - Keep a record of symptoms and emotions and bring it to your appointments
 - Ask someone to come with you to help ask questions and take notes
-



DURING your appointments

- Ask questions from your list
 - Ask your doctor to repeat any instructions that you don't understand
 - Ask if you can explain back to the doctor what you will do
 - Take notes
-



AFTER your appointments

- Follow up on instructions from your doctor, like making appointments or collecting prescriptions
- Share notes about your experience with friends or family members who support you

Finding support

Below are some breast cancer charities that may be able to help you with understanding and managing your condition. They offer both practical and emotional support.

Find local support



Breast Cancer Now

At Breast Cancer Now we're here for anyone affected by breast cancer. Our breast care nurses, expertly trained staff and volunteers, and award-winning information make sure you can get the support you need to help you live well with the physical and emotional impact of breast cancer.

For breast cancer care, support and information, call us free on **0808 800 6000** or visit **breastcancernow.org**



Macmillan Cancer Support

We're here to help everyone living with cancer live life as fully as they can, providing physical, financial and emotional support. So whatever cancer throws your way, we're right there with you.

For information, support or just someone to talk to, call **0808 808 00 00** or visit **macmillan.org.uk**

Asking for help

Living with advanced (or locally advanced and metastatic) breast cancer can be a challenge, but you are not alone. Let your healthcare team know if emotions are making it hard to carry out your day-to-day activities.

Asking questions

Your healthcare team is an important resource for you. Asking questions is the best way to get the information and support you need to manage your health.



Before starting or while on treatment, you may have lots of questions. Write them down here so that you can remember them for the next time you speak with your doctor or nurse.

Questions about dosing:

Questions about side effects:

Questions about tests:

Other questions:

Routine contact number for your doctor/nurse specialist:

Emergency contact numbers:

Treatment tracker

MONTH: _____

| Treatment tracker | | | | | | | | |
|--|--------|--------|--------|--------|--------|--------|--------|--------|
| Mark off each day's treatment when you take it | | | | | | | | |
| PIQRAY® | WEEK 1 | DAY 1 | DAY 2 | DAY 3 | DAY 4 | DAY 5 | DAY 6 | DAY 7 |
| | WEEK 2 | DAY 8 | DAY 9 | DAY 10 | DAY 11 | DAY 12 | DAY 13 | DAY 14 |
| | WEEK 3 | DAY 15 | DAY 16 | DAY 17 | DAY 18 | DAY 19 | DAY 20 | DAY 21 |
| | WEEK 4 | DAY 22 | DAY 23 | DAY 24 | DAY 25 | DAY 26 | DAY 27 | DAY 28 |

Fulvestrant

Note all injection dates in this cycle:

Day 1

Day 15

Day 29

Note: After Month 1, fulvestrant injection will be once a month.

Always follow your doctor's directions on how to take your medicine.

Notes

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To find out more about your treatment with PIQRAY® + fulvestrant, such as how it works and the side effects you might experience, please visit **www.illuminatingabc.co.uk** or scan the QR code and use password: **connect@illuminatingABC**.

This booklet is intended for use by Piqray patients based in GB (England, Scotland and Wales) only.

