

Your Guide to Treatment & Treatment Diary

Starting and staying on course with KISQALI® (ribociclib)



Guidance and support for your treatment journey

This booklet is not a substitute for the Patient Information Leaflets (PILs), which are provided with the medicines - for further information on symptoms/side effects, please speak with your cancer care team or refer to the PILs, which are included in the KISQALI® and aromatase inhibitor (AI) packs (and luteinising hormone-releasing hormone agonist pack, where applicable).

This booklet is intended for patients with HR+/HER2- early breast cancer with high risk of recurrence who have been prescribed KISQALI® + AI as adjuvant treatment.

REPORTING SIDE EFFECTS: If you get side effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the medication pack. You can also report side effects via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of your medication.

More details about how to report side effects can be found on page 45 of this booklet.

This booklet has been created and funded by Novartis Pharmaceuticals UK Ltd in conjunction with nursing and medical professionals and has been reviewed by patients and a mix of different healthcare professionals (i.e. nurses, pharmacists, and doctors). If you require further clarification or have any questions regarding any aspect of this document, please consult your Healthcare Professional. Where this document is available in any other languages than English, the English version shall prevail.

About this booklet

This booklet is intended for use by patients with **early breast cancer** with intermediate or high risk of recurrence who have been prescribed Kisqali (kis-KAH-lee) as **adjuvant treatment**.

Kisqali is sometimes called by its generic name: ribociclib. Your doctor, nurse or pharmacist may have used the name ribociclib when talking to you. Kisqali and ribociclib are different names for the same medicine.

This booklet will help inform you about starting Kisqali and keeping your treatment on course. It was created with help from healthcare professionals and has been reviewed by patients and a mix of different healthcare professionals (i.e. nurses, pharmacists, and doctors).

If you have any questions after reading this booklet, please ask a member of your care team. Be open with them about any concerns you have about your treatment or your health.

Communicating with your care team can help you to better understand your treatment.



You will take Kisqali with **endocrine therapy** for **3 years**



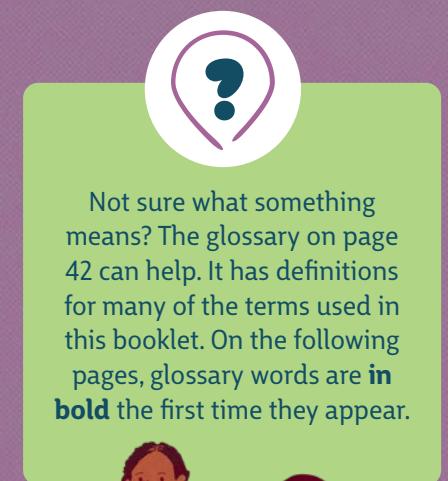
You'll start treatment with **fortnightly monitoring for the first 2 months**, followed by **monthly monitoring for 6 months**, then the clinic will review you as directed



Once you've finished Kisqali, you'll **continue on endocrine therapy** and check in with your care team as directed

Inside this booklet

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Who is this treatment for?

You have been prescribed Kisqali because:

- You have **early breast cancer**
- Your breast cancer is a type called **hormone receptor-positive/human epidermal growth receptor 2-negative** (HR+/HER2-)
- Your cancer has certain characteristics that increase the risk of the cancer returning

- Kisqali in combination with an aromatase inhibitor can be used in women who have not gone through the menopause as well as women who have gone, or are going through the menopause, and men
- The advice contained in this booklet is for both pre-/peri- and postmenopausal women and men. Throughout this booklet, you will see advice that is specific to **pre-/perimenopausal** women and men in boxes like this

If you have not gone through the menopause (premenopausal), are going through the menopause (perimenopausal), or are male, you must also receive a luteinising hormone-releasing hormone agonist (LHRH injection) as part of your treatment combination (e.g. goserelin).

In early breast cancer, Kisqali can be used to help prevent the cancer from coming back after surgery (treatment after surgery is called 'adjuvant therapy').

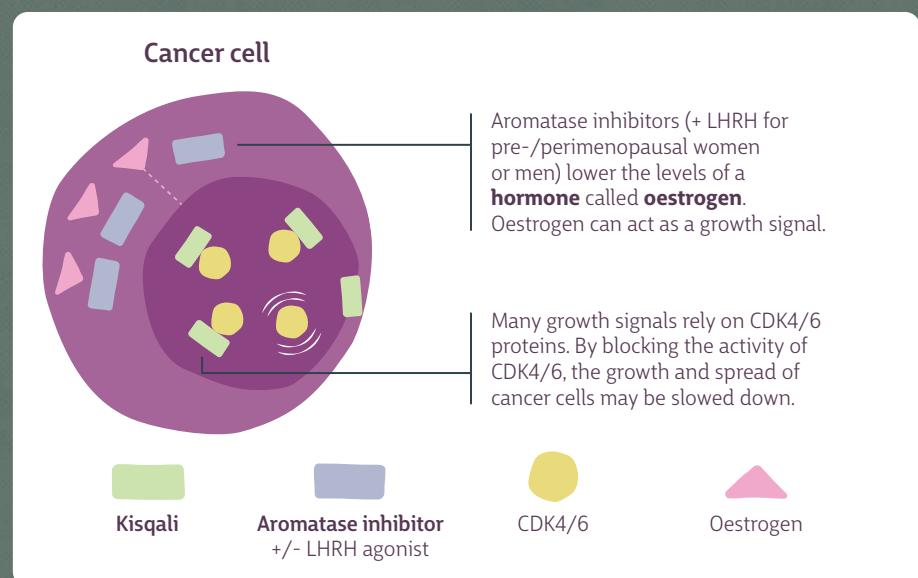


How does this treatment work?

It's normal for many kinds of cells in the body to divide or split. To do this, they rely on the body's own growth signals. Sometimes these signals tell cells to divide too quickly, which can lead to cancer.

One goal of treatment is to slow down how quickly cancer cells divide. Kisqali is one of the targeted treatments known as cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors that helps slow down the growth of cancer cells. It does this by blocking the activity of **proteins** called CDK4 and CDK6. Kisqali must be taken in combination with an aromatase inhibitor. Aromatase inhibitors are a type of treatment called **hormone therapy** or **endocrine therapy**. CDK4/6 inhibitors and hormone therapies work together to reduce cancer cell growth. If you have not gone through the menopause (premenopausal), are going through the menopause (perimenopausal), or are male, you must also receive an LHRH injection.

Kisqali works in combination with hormone therapies, such as aromatase inhibitors



Adapted from Tripathy D, et al. Clin Cancer Res 2017;23(13):3251-3262

About hormone therapy

Hormone therapy, also called **endocrine therapy**, is a type of treatment used to help reduce the growth of breast cancer after surgery for hormone sensitive or hormone receptor positive (HR+) breast cancer. You will be prescribed a hormone therapy treatment alongside KISQALI, either as a tablet or injection.

There are different types of hormone therapy, including:

- **Luteinising hormone-releasing hormone (LHRH) agonists, also called LHRH injections** – these stop hormone production in the ovaries or testicles
- **Aromatase inhibitors (AIs)** – these block oestrogen production outside of the ovaries

The type of hormone treatment you will be given depends on different factors, including:

- Whether or not you've gone through the **menopause**
- The risk of your cancer coming back
- How your body responds to other hormone therapies

While hormone therapy can be used on its own, adding Kisqali has been shown to further reduce the risk of your cancer returning.

Like many treatments, hormone therapy can cause side effects. Common ones include:

- Menopausal symptoms, such as hot flushes, night sweats, and joint pain
- Vaginal dryness and discomfort, which can sometimes lead to urinary symptoms or urinary tract infections (UTIs)

These symptoms may be more noticeable at the start of your treatment and may improve over time. It can be challenging, but it's important to continue taking your medication.

If you're struggling with any side effects, be sure to speak with your treatment team. They are here to help and there are ways they can help to make things easier, such as:

- Cognitive behavioural therapy (CBT) to help with hot flushes, anxiety, and sleep problems
- Non-hormonal vaginal moisturisers to help with dryness and discomfort
- Dietary supplements, such as calcium and vitamin D, to support bone health
- Switching to a different hormone therapy, if your treatment team think this is right for you



Your treatment team are there to help, so do not be afraid or embarrassed to speak to them about any symptoms you may be experiencing. It's important not to suffer in silence and remember that they have most likely heard similar (or worse!) symptoms from others.

**Dr Rebecca Bowen,
Consultant Medical Oncologist**

Getting regular exercise, eating a balanced diet, and avoiding alcohol and caffeine late at night can also help you manage your symptoms and improve sleep quality.

What is breast cancer recurrence?

Recurrence is the term used to describe cancer coming back.

Most breast cancers do not come back after treatment. However, there is a chance that breast cancer may come back months or years after your diagnosis and treatment.

Breast cancer treatments aim to remove all cancer cells from your body, but some cells might remain, and these may grow into a new breast tumour or spread to other parts of the body.

You may be prescribed further treatments after surgery to reduce the risk of breast cancer coming back, like the regimen that you are about to start. It's important that you take these medicines as directed by your care team to reduce the risk of cancer returning. Maintaining a healthy lifestyle is also important to keep your body well and help manage the risk of recurrence.

Being well-informed about your risk of recurrence and the role of adjuvant, or endocrine, therapy in reducing your risk will help you understand the importance of your prescribed treatment(s). Below is a list of questions to ask your doctor, but you may also have other questions of your own.

- What does risk of recurrence mean?
- Is it possible to determine my own individual risk of my cancer coming back?
- Is there anything I can do, like lifestyle changes, to lower my risk?
- How does my prescribed treatment reduce the risk of recurrence?



Before you start your Kisqali treatment

Things you should know

- Kisqali is an oral tablet. It is taken with another type of oral medicine called an aromatase inhibitor. A third medication – an LHRH injection – is required for women who have not gone through, or are going through, the menopause, and men
- You may have concerns about **side effects**, these are discussed further from page 18
- You will have some medical tests to check if you are ready to start treatment

Do not take Kisqali:

- If you are allergic to ribociclib, peanut, soya or any of the other ingredients of this medicine

If you think you might be allergic, ask someone on your care team for advice.

Before taking Kisqali, tell a member of your care team if you:

- Have a fever, sore throat, or mouth ulcers due to infections (may be a sign of a low level of **white blood cells**)
- Have any problems with your liver or kidneys, or have previously had any type of liver disease or kidney disorder
- Have or have had heart disorders or heart rhythm disorders, such as an irregular heartbeat. This includes **QT interval prolongation**, where the heart takes longer than normal to recharge its electrical system between heart beats. This can cause abnormal heart rhythm
- Have or have had low levels of potassium, magnesium, calcium, or phosphorus in your blood

Please see the Patient Information Leaflet (PIL) for information on which medicines may influence the effect of Kisqali.

If you experience any of the symptoms below, tell your healthcare professional right away:

- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes (signs of a severe skin reaction; frequency not known). In case of a severe skin reaction, your doctor will ask you to immediately stop treatment with Kisqali
- Trouble breathing, cough and shortness of breath (may be signs of lung or breathing problems). If necessary, your doctor may interrupt or reduce your dose of Kisqali or decide to stop treatment with Kisqali permanently.

Pregnancy and breastfeeding

If you are breastfeeding or think you may be pregnant, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the potential risks of taking Kisqali during pregnancy.

- You should not breastfeed while taking Kisqali and for at least 21 days after the last dose
- Kisqali should not be used during pregnancy since it may harm your unborn baby. If you are a woman of childbearing potential, you should have a negative pregnancy test before starting treatment with Kisqali
- You should use effective contraception (e.g. double-barrier contraception such as condom and diaphragm) while taking Kisqali and for at least 21 days after the last dose. Ask your care team about options for effective contraception



This is not an exhaustive list of precautions for before you start your treatment. Please refer to the PIL for the full guidance.

Driving and using machines

Treatment with Kisqali may lead to tiredness, dizziness or spinning sensation. You should therefore be cautious when driving or using machines during your treatment with Kisqali.

Other medicines and Kisqali:

Before you take Kisqali, tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines including prescription and non-prescription medicines, herbal medicines or supplements, because these may influence the effect of Kisqali.

Always tell your doctor if you are prescribed a new medicine after you have started treatment with Kisqali.

This includes:

- Tamoxifen, another medicine for the treatment of breast cancer
- Some medicines used to treat fungal infections, such as ketoconazole, itraconazole, voriconazole or posaconazole
- Some medicines used to treat HIV/AIDS such as ritonavir, saquinavir, indinavir, lopinavir, nelfinavir, telaprevir and efavirenz
- Some medicines used to treat seizures or fits (anti-epileptics) such as carbamazepine and phenytoin
- St. John's Wort (also known as *Hypericum perforatum*) – a herbal product used to treat depression and other conditions
- Some medicines used to treat heart rhythm problems or high blood pressure such as amiodarone, disopyramide, procainamide, quinidine, sotalol and verapamil
- Antimalarials such as chloroquine
- Antibiotics such as clarithromycin, telithromycin, moxifloxacin, rifampicin, ciprofloxacin, levofloxacin and azithromycin
- Some medicines used for sedation or anaesthesia such as midazolam
- Some medicines used as antipsychotics such as haloperidol
- Medicines used to treat angina such as bepridil
- Methadone, used to treat pain or addiction to opioids
- Medicines like intravenous ondansetron, used to prevent nausea and vomiting caused by chemotherapy (treatment with cancer medicines)

Kisqali may increase or decrease the levels of some other medicines in your blood:

This includes:

- Medicines used to treat symptoms of benign prostatic hyperplasia such as alfuzosin
- Tamoxifen, another medicine used for the treatment of breast cancer
- Antiarrhythmics such as amiodarone or quinidine
- Antipsychotics such as pimozide or quetiapine
- Medicines used to improve blood fat levels such as simvastatin or lovastatin, pitavastatin, pravastatin or rosuvastatin
- Medicines used to treat high blood sugar levels (e.g. diabetes) such as metformin
- Medicines used to treat cardiac disorders such as digoxin
- Medicines used to treat pulmonary arterial hypertension and erectile dysfunction such as sildenafil
- Medicines used to treat low blood pressure or migraine such as ergotamine or dihydroergotamine
- Some medicines used to treat epileptic fits or that are used for sedation or anaesthesia such as midazolam
- Medicines used to treat sleep disorders such as triazolam
- Analgesics such as alfentanil and fentanyl
- Medicines used for the treatment of gastrointestinal disorders such as cisapride
- Medicines used to prevent the rejection of an organ transplant such as tacrolimus, sirolimus and ciclosporin (also used to treat inflammation in rheumatoid arthritis and psoriasis)
- Everolimus, used for several types of cancer and tuberous sclerosis (also used to prevent the rejection of an organ transplant)

Ask your doctor or pharmacist if you are not sure if your medicine is one of the medicines listed above.



How to take your treatment

Kisqali and an aromatase inhibitor are taken in a 28-day cycle. Kisqali is a tablet that is taken orally, once a day for 21 days, followed by a break of 7 days when you do not take these tablets. An aromatase inhibitor is a pill you take every day. These treatments are continued until your healthcare professional advises you to stop.

Recommended 4-week dosing schedule (28-day cycle)

	DAYS 1-7	DAYS 8-14	DAYS 15-21	DAYS 22-28
Kisqali 400 mg (2 tablets of 200 mg) once daily 21 consecutive days of treatment, followed by 7 days off treatment	✓	✓	✓	✗
Aromatase inhibitor Once daily, every day	✓	✓	✓	✓

Please refer to the PIL for your aromatase inhibitor and, if applicable, your LHRH injection treatment for dosing and how to take this medicine.

- A member of your care team will tell you the **doses** you should take for each of your treatments, and when you should take them
- Do not change your treatment dose or schedule without talking to your care team
- Your care team will regularly monitor your condition to check that the treatment is having the desired effect and to monitor possible side effects

Track your treatment on the Kisqali package

- Use the dosing calendar on the tablet box to keep track of your treatment each day

Kisqali + an aromatase inhibitor is taken in a 28-day cycle. Take Kisqali on days 1 to 21 of the 28-day cycle and the aromatase inhibitor for the entire 28-day cycle.

If you are a pre-/perimenopausal woman or a man who requires the LHRH injection, please refer to the PIL for your LHRH agonist treatment for dosing



Take your Kisqali tablets at the same time each day, preferably in the morning. You can take your treatment with or without food



Kisqali tablets should be swallowed whole (tablets should not be chewed, crushed, or split prior to swallowing). Do not take any tablet that is broken, cracked, or otherwise not intact; please contact a member of your care team for advice if this happens



Do not eat grapefruits or foods that contain grapefruit or drink juices that contain grapefruit during your treatment with Kisqali, as these foods may change how it is processed in your body and how much is in the bloodstream



If you vomit after taking a dose of Kisqali or forget a dose:

- Skip the missed dose that day
- Take the next dose at your usual time
- Do not take a double dose to make up for a forgotten dose



If you accidentally take too many tablets please contact a healthcare professional, acute oncology department, or any emergency phone number for advice straight away. Show the Kisqali packet. Medical treatment may be necessary

What tests will you have?

Your care team will do all they can to help you with your experience on this treatment. One way they do this is by using medical tests to monitor your health.

Tests to help you get the most out of treatment

You will have had certain tests before starting treatment. You will continue to have these tests during treatment to help your care team check for side effects.

These will include:



Blood tests, to check your kidney and liver function and to measure certain blood cells and **electrolytes** (e.g. potassium, magnesium, calcium, and phosphorus) in your blood



Electrocardiograms (ECGs), to check the electrical activity of your heart

If necessary, additional tests to evaluate your kidney function will be performed during treatment with Kisqali.



Monitoring can help identify possible side effects and keep your treatment on course.

Please see the Patient Information Leaflet (PIL) for information on monitoring during your treatment.

Appointment dates

The recommended test schedule during your first 6 cycles of treatment is below.

BEFORE TREATMENT	BLOOD TESTS	ECG
You will receive these tests before starting treatment	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
CYCLE 1	BLOOD TESTS	ECG
Around day 1 of the 1st 28-day cycle	<input checked="" type="checkbox"/>	
Around day 14 of the 1st 28-day cycle	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
CYCLE 2	BLOOD TESTS	ECG
Around day 1 of the 2nd 28-day cycle	<input checked="" type="checkbox"/>	If care team requires
Around day 14 of the 2nd 28-day cycle	<input checked="" type="checkbox"/>	If care team requires
CYCLES 3-6	BLOOD TESTS	ECG
Around day 1 of the 3rd-6th 28-day cycle	<input checked="" type="checkbox"/>	If care team requires

If your care team thinks it's needed, you may have more frequent testing or you may continue to have blood tests and ECGs throughout treatment.

What side effects might you experience?

Like for all medicines, you could experience some side effects, although not everybody gets them. If you do experience side effects, it's important to not suffer in silence. Your care team are there to help you and there are steps they can take to make your experience easier, so make sure you speak to them if you get any side effects.

Your doctor may decide to lower your dose of Kisqali to try and ease your symptoms. This is not a bad thing and it won't negatively affect your treatment. It may take some time for side effects to get better, but be sure to talk to your care team if you are struggling.

If you are experiencing side effects that are affecting your day-to-day life, contact your care team as soon as you can as they may be able to help you manage them.

Some side effects seen with Kisqali may be serious

The medical tests you will have can help your healthcare professional check for these side effects. Based on the results of these tests, your healthcare professional may interrupt or reduce your dose of Kisqali. This can allow your body to recover. If the side effect doesn't go away after interrupting or reducing the dose, your healthcare professional may also decide to stop treatment with Kisqali permanently.

Some serious side effects also have symptoms you can watch for. Tell your doctor immediately if you get any of the following symptoms during treatment with Kisqali:

Very common side effects (may affect more than 1 in 10 people)

- Fever, sweating or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhoea or stomach pain, or feeling very tired (signs or symptoms of infections)
- Abnormal results of blood tests that give information about the health of the liver (abnormal liver function tests)

Common side effects (may affect up to 1 in 10 people)

- Spontaneous bleeding or bruising (signs of a low level of blood platelets)
- Fever, chills, weakness and frequent infections with symptoms such as sore throat or mouth ulcers (signs of a low level of leukocytes or lymphocytes, which are types of white blood cells)
- Tiredness, itchy yellow skin or yellowing of the whites of your eyes, nausea or vomiting, loss of appetite, pain in the upper right side of the belly (abdomen), dark or brown urine, bleeding or bruising more easily than normal (these may be signs of a liver problem)
- Reduced level of potassium in the blood, which could lead to disturbances in heart rhythm
- Chest pain or discomfort, changes in heartbeat (fast or slow), palpitations, lightheadedness, fainting, dizziness, lips turning blue colour, shortness of breath, swelling (oedema) of your lower limbs or skin (these may be signs of heart problems)
- Inflammation of the lungs, which can cause dry cough, chest pain, fever, shortness of breath and breathing difficulty (these may be signs of interstitial lung disease/pneumonitis which, if severe, may be life-threatening)

Uncommon side effects (may affect up to 1 in 100 people)

- Sore throat or mouth ulcers with a single episode of fever of at least 38.3°C or fever above 38°C for more than one hour and/or with infection (febrile neutropenia)

Other side effects include those listed on the following page. If these side effects become severe, tell your doctor, pharmacist or nurse.

Very common side effects:

- Sore throat, runny nose, fever (signs of a respiratory tract infection)
- Painful and frequent urination (signs of a urinary tract infection)
- Nausea ('feeling sick')
- Headache
- Fatigue (tiredness)

- Asthenia (weakness)
- Alopecia (hair loss or hair thinning)
- Diarrhoea
- Constipation
- Cough
- Abdominal (belly) pain
- Pyrexia (fever)

Common side effects:

- Rash
- Dizziness or light headedness
- Tiredness, pale skin (potential sign of a low level of red blood cells, anaemia)
- Vomiting
- Pruritus (itching)
- Peripheral oedema (swollen hands, ankles or feet)
- Dyspnoea (shortness of breath, difficulty breathing)

- Stomatitis (mouth sores +/- gum inflammation)
- Oropharyngeal pain (sore throat)
- Reduced level of calcium in the blood, which may sometimes lead to cramps
- Reduced appetite
- Abnormal kidney blood test result (high level of creatinine in the blood)

For women who have not gone through the menopause who are also receiving an LHRH injection (e.g. goserelin), this medication will reduce the oestrogen produced by your body. This means that you may have certain side effects that are often associated with menopause, such as:

- Hot flushes
- Night sweats
- Vaginal dryness
- Decreased sex drive

This is not an exhaustive list of side effects associated with LHRH injections, and includes side effects of varying frequencies. Please refer to your LHRH injection PIL for all associated side effects.

For more information on side effects, please see the PIL provided in your box of tablets. For side effects associated with aromatase inhibitors and LHRH injections (if required), please see the aromatase inhibitor PIL.

Please ensure that you check the storage conditions for this medicine. These can be found on the packaging itself or within the PIL.



Tips to help you manage side effects

Tips to help if you have nausea and vomiting

- Eat frequent, small meals
- Drink clear fluids (preferably served cold) to prevent dehydration
- Avoid certain foods that may make nausea worse, such as fatty foods
- Food or drink containing ginger or peppermint can help reduce nausea; try ginger tea, ginger biscuits or peppermint tea
- Slowly sipping a fizzy drink is a popular remedy for feeling sick, try mineral water, ginger ale or lemonade

Tips to help if you have diarrhoea

- Eat frequent, small meals:
 - Made from light foods such as dairy produce, white fish, mashed potatoes, white bread, plain biscuits, low fibre cereals, white pasta or rice
- Eat less fibre (cereals, raw fruits and vegetables) until the diarrhoea improves
- Avoid greasy, fatty foods such as chips and beef burgers, and spicy foods like chilli peppers
- Drink up to two litres of clear fluids a day to prevent dehydration



Tips to help if you have fatigue

- Get lots of rest and regular exercise
 - If you feel like trying, ask your doctor how long you could exercise to get your heart rate up to a good level for you
 - Any exercise you do doesn't need to be high intensity, doing a little bit on a regular basis is better than nothing at all
 - Pace yourself in the best way that suits you
- Make sure you continue eating a healthy diet
- If you're going to be up and about for a long time, and make the most of it

Fatigue should not be life-limiting. If you're really struggling with fatigue and it's starting to affect your mental health, speak to your care team so they can take steps to help you.

Tips to help if you have hair thinning or loss

- Be gentle when brushing and washing your hair
- You may wish to wear a hat to protect your scalp from the sun
- Use gentle hair products and avoid hair processing techniques
- Avoid using hairdryers, straighteners or hot rollers

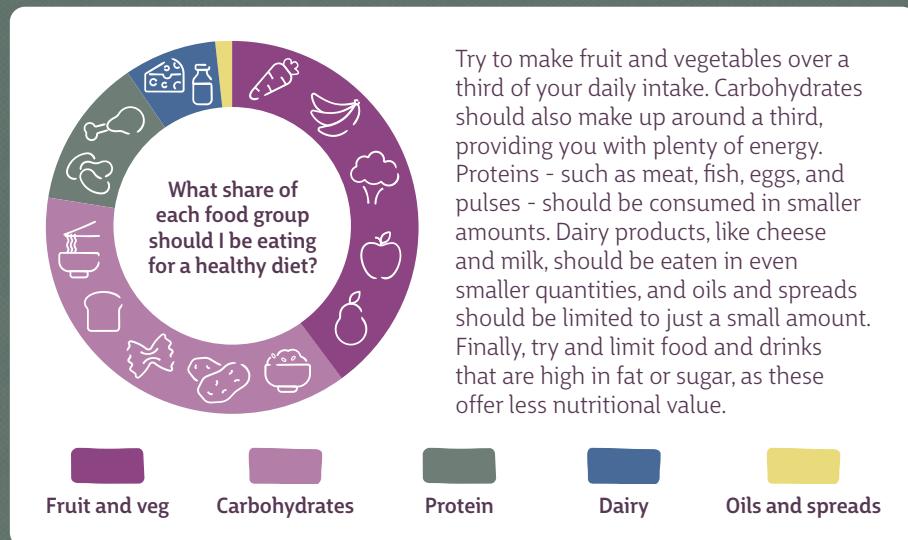
If you have side effects of any kind, it is important to tell a member of your care team right away, so they can help you manage them and get the most out of your treatment.

Tips for maintaining your health and wellbeing

After a cancer diagnosis, you may find that following a healthy lifestyle and looking after your mental wellbeing can help you maintain a sense of control. Here are some tips for eating a balanced diet, staying active, and looking after your mental health.

Healthy eating

A healthy, balanced diet contains a variety of foods, in the right amounts, to give you enough energy, protein, vitamins and minerals to stay healthy.



You don't need to get the balance right with every meal but try to get it right over a few days.

Staying active

There are lots of benefits to staying active during treatment. Not only is it great for your physical health, and can reduce fatigue, it may also help improve your mental wellbeing by raising your self-esteem and providing you with a sense of achievement when you set and reach your goals.

There is not a single activity that is best for everyone. The important thing is to choose something that fits in with your lifestyle and doesn't overexert you.

If you feel unfit or your treatment is making you feel very tired, then you could start gently, by trying to:

- Reduce the amount of time you spend sitting or lying down
- Do some light housework or gardening
- Go for a walk

Being active during cancer treatment is generally safe, but before starting any physical activity plan, it is important to talk to a healthcare professional.

Maintaining resilience

- Pay attention to your needs in the present moment:
 - Some people call this 'mindfulness', and it can help you to understand yourself better and enjoy life more
 - Mindfulness can positively change the way you feel about life and how you approach challenges
- Be kind to yourself
 - Understand that there will be days when motivation wanes due to the demands of life and the way your body is responding to treatment
 - Ask yourself what you would say to a friend in your circumstances and apply it to yourself
 - Make time for self-care. Include regular physical activity at a level and pace that is safe for you
- Keep talking
 - Bring up mental health during appointments with your healthcare team. They are trained for these discussions and can signpost you to support
 - If you have an existing mental health problem, discuss it early on with your cancer team. Tell them what you may need to feel supported
 - Talk about your mental health with someone you trust. They will be able to support you better if they understand how you feel

Dose interruptions and modifications

As with other cancer treatments, your prescribing healthcare professional may adjust your Kisqali dose during treatment. This is to help find a balance between the effectiveness of your treatment and any side effects you may experience. A change in dose most often happens during the first few months of treatment. It's really important to tell your team about side effects as soon as they occur, as they can be harder to manage over time. You can be completely honest with your healthcare team, who will be able to help you manage them. With any changes to your Kisqali dosage, you will continue to be prescribed your hormone treatment (such as an aromatase inhibitor), unless directed by your care team.

Dose modifications are typically done in one of two ways

Do not adjust your dose or stop taking your medication unless directed by your care team.

A dose interruption:

- This is when a member of your care team asks you to stop taking Kisqali for a period of time. You will still take your aromatase inhibitor each day unless your team asks you not to

A dose reduction:

- This is when a member of your care team asks you to take fewer tablets of Kisqali each day

Before you restart Kisqali after an interruption, ask your care team:

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

Kisqali tablets come in one strength

This means that your care team can adjust your dose simply by changing the number of tablets you take each day. If your prescribing healthcare professional lowers your dose, you will be able to continue treatment using the same pack you already have, rather than waiting for a new prescription.

Tracking your treatment

Use your appointment tracker and treatment diary to help you to stay on course with your treatment.

Your doctor may suggest a dose reduction or dose interruption to help with any side effects you may experience. Your care team will explain the reasons for any schedule change.



Your appointment tracker

Your care team may refer to your treatment in cycles. One cycle with Kisqali and aromatase inhibitor lasts for 28 days and involves taking Kisqali for the first 21 days of each cycle and the aromatase inhibitor for the entire 28 days.

The chart below can help you keep track of your test appointments during the first 2 months of your treatment. Fill in the date and time of each appointment with your care team to help you remember.

BEFORE TREATMENT	BLOOD TEST	ECG
You will receive these tests before starting treatment	Date: Time:	Date: Time:

CYCLE 1	BLOOD TEST	ECG
You will have a blood test around day 1	Date: Time:	
You will also have a blood test and an ECG around day 14	Date: Time:	Date: Time:

CYCLE 2	BLOOD TEST	ECG (IF REQUIRED)
You will have a blood test around day 1	Date: Time:	Date: Time:
You will also have a blood test around day 14	Date: Time:	Date: Time:

The above tests are recommended for all patients starting on Kisqali + an aromatase inhibitor. Blood tests must also be performed at the start of cycles 3, 4, 5 and 6. If your care team thinks it's needed, you may have more frequent testing, or you may continue to have blood tests and ECGs throughout treatment.

Your treatment diary

The recommended starting dose of Kisqali is 400 mg once daily (2 tablets of 200 mg). Your healthcare professional will also prescribe an aromatase inhibitor (AI) such as letrozole and anastrozole, that you should take in combination with Kisqali.

- Take Kisqali on days 1 to 21 of a 28-day cycle
- Take your aromatase inhibitor once daily throughout the 28-day cycle

- If you are pre-/perimenopausal or a man, you will also receive an LHRH injection (e.g. goserelin) as per the dosing detailed in its PIL

Using your diary

- Fill in the relevant cycle number

- If you are pre-/perimenopausal or a man and receiving an LHRH injection, for each cycle tick the box and fill in the date when you received this

On the days when you take Kisqali:

- Tick your Kisqali box to show you have taken your Kisqali dose that day
- Circle the number which represents the number of Kisqali tablets you have taken that day
- Tick your AI box to show you have taken your aromatase inhibitor daily dose

On the days when you do NOT take Kisqali:

- Tick your AI box to show you have taken your aromatase inhibitor daily dose



Do not adjust your dose or stop taking your medication unless directed by your care team.

Cycle



LHRH injection received?
(Pre-/perimenopausal women and men)

Date:

Remember to take your aromatase inhibitor (AI) every day as directed by your care team, even on days you do not take KISQALI unless you have been advised to stop both treatments.

	WEEK 1	WEEK 2	WEEK 3	WEEK 4
DAY 1	Start date: KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	Start date: KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	Start date: KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	Start date: No KISQALI® AI <input type="checkbox"/>
DAY 2	KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	No KISQALI® AI <input type="checkbox"/>
DAY 3	KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	No KISQALI® AI <input type="checkbox"/>
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DAY 7	KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	KISQALI® <input type="checkbox"/> Tablets: 1 2 AI <input type="checkbox"/>	No KISQALI® AI <input type="checkbox"/>



While on treatment, you may have questions. Write them down here so that you can remember them for the next time you speak with your care team.

Questions about dosing:

Questions about side effects:

Questions about tests:

Other questions:



TIP: Eating well, drinking plenty of fluids, exercising regularly and sleeping as much as you need can help maintain your immune system and improve your wellbeing and quality of life

Cycle



LHRH injection received?
(Pre-/perimenopausal women and men)

Date:

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Questions about dosing:

Questions about side effects:

Questions about tests:

Other questions:



TIP: Try to find something special in each day. Stay busy and engaged with the healthy part of your life

Cycle



LHRH injection received?
(Pre-/perimenopausal women and men)

Date:

Remember to take your aromatase inhibitor (AI) every day as directed by your care team, even on days you do not take KISQALI unless you have been advised to stop both treatments.

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Questions about dosing:

Questions about side effects:

Questions about tests:

Other questions:



TIP: Your emotional health can be as important as your physical health. Talk to your care team if you feel that you need support

Cycle



LHRH injection received?
(Pre-/perimenopausal women and men)

Date:

Remember to take your aromatase inhibitor (AI) every day as directed by your care team, even on days you do not take KISQALI unless you have been advised to stop both treatments.

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Questions about dosing:

Questions about side effects:

Questions about tests:

Other questions:



TIP: Only you can decide when to share information with others. Some people find chatrooms or meeting others with similar experiences useful. Your care team may be able to direct you to your local support groups. Please see the end of this booklet for information on patient support groups

Cycle



LHRH injection received?
(Pre-/perimenopausal women and men)

Date:

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While on treatment, you may have questions. Write them down here so that you can remember them for the next time you speak with your care team.

Questions about dosing:

Questions about side effects:

Questions about tests:

Other questions:



TIP: It is important that you are confident in taking your treatment. Your care team will welcome any question, however small. As soon as you think you may have a side effect or an adverse reaction, you must tell them.

Cycle



LHRH injection received?
(Pre-/perimenopausal women and men)

Date:

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While on treatment, you may have questions. Write them down here so that you can remember them for the next time you speak with your care team.

Questions about dosing:

Questions about side effects:

Questions about tests:

Other questions:



TIP: It is important to listen to your body; if you feel tired don't resist it, it is important to rest

Glossary

Adjuvant therapy

Treatment that is given in addition to the initial treatment.

Aromatase inhibitor (AI)

A treatment that decreases the amount of oestrogen made by the body, which helps slow the growth of hormone receptor-positive cancer.

Cycle

A course of treatment that is repeated on a regular schedule.

Dose

The amount of medicine taken at one time.

Early breast cancer

Cancer that is small and only found in the breast tissue or lymph nodes close to the breast.

Electrocardiogram (ECG)

A test that traces the electrical activity of the heart on a line graph. One heart abnormality that an ECG can test for is QT interval prolongation.

Electrolytes

Minerals in blood that carry an electric charge and affect a variety of body functions.

Fatigue

A feeling of extreme tiredness often for an extended period of time.

Hormone

A chemical in the body that controls the activity of cells or organs.

Hormone receptor-positive (HR+)

Having cancer cells with hormone receptors.

Hormone (endocrine) therapy

Treatment that lowers the level of hormones in the body or blocks their action.

Human epidermal growth factor receptor 2-negative (HER2-)

Testing negative for a certain protein (HER2) found on the surface of cancer cells. HER2 can send signals for the cancer to grow.

Luteinising hormone-releasing hormone (LHRH) agonist

A treatment that lowers the level of oestrogen in the body by reducing the amount of oestrogen that is made by the ovaries. An example of an LHRH agonist is goserelin, sometimes called Zoladex®.

Menopause

The end of menstruation; the time of life when a woman stops having periods. This may have been artificially induced or have taken place naturally.

Neutropenia

When the body has an abnormally low concentration of neutrophils, leading to an increased risk of infection.

Neutrophil

A type of white blood cell that helps the body fight infection.

Oestrogen

A hormone that all women normally have in their bodies that can sometimes make cancer cells grow.

Perimenopausal

This is when you have symptoms of menopause, but your periods have not stopped. It ends when you reach menopause.

Premenopausal

If you are premenopausal this means that you have not gone through the menopause and you still have regular menstrual periods.

Protein

A large molecule made up of a chain of small chemical compounds, called amino acids. Proteins make up the structure of all cells and control how they work.

QT interval prolongation

When your heart takes longer than normal to recharge its electrical system between heart beats.

Receptor

A protein inside or on the surface of a cell to which substances can attach.

Side effect

An unwanted symptom caused by a medical treatment.

White blood cell

A type of blood cell that helps the body fight infection.



Finding the support you need

Below are some breast cancer charities that may be able to help you with understanding and managing your condition.

Find local support:



When you have breast cancer, everything changes. At Breast Cancer Now, we understand the emotions, challenges and decisions you face every day, and we know that everyone's experience is different. That's why we offer support and information and campaign for better care.

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



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



Coping with cancer can be difficult. There is help and support available. Find out about the emotional, physical and practical effects of cancer and how to manage them at www.cancerresearchuk.org



The Centre for Building Resilience in Breast Cancer (BRiC)'s primary mission is empowering women in survivorship. We strive to create a supportive environment where women can thrive beyond their experiences, fostering resilience and well-being. For information, peer support, and empathy, visit briccentre.co.uk.



We Are Undefeatable supports people with a range of long-term health conditions, including cancer, to be active. Their website offers information, ideas and activity videos to help everyone find something that works for them. Find out more at weareundefeatable.co.uk

Reporting of side effects

If you get side effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack. You can report side effects via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of your medication.

You may wish to record some useful numbers here:

Routine contact number

Your doctor:

Your nurse specialist:

Your pharmacist:

In an emergency

Emergency/acute oncology:



Notes

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Handwriting practice area for the right page. It features a large, rounded rectangular frame with a thin black border. Inside the frame, there are 10 sets of horizontal grey lines for handwriting practice.



This booklet is intended for early breast cancer patients in the UK who have been prescribed Kisqali