



Guide for Patients and Treatment Diary

Starting and staying on course with Kisqali® (ribociclib) + an aromatase inhibitor

This guide 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 with your cancer care team or refer to the PIL which is included in the Kisqali pack.

How to report side effects can be found on page 34 of this booklet.

^{*}Kisqali can only be obtained with a prescription and treatment should be started by a doctor experienced in the use of cancer treatments.

Introduction

This guide is intended for use by patients who have been prescribed Kisqali (kis-KAH-lee) in combination with an **aromatase inhibitor** (AI) (such as letrozole, anastrozole or exemestane).

If you have not gone through the **menopause** you must also receive a **luteinising hormone-releasing hormone** (**LHRH**) **agonist** as part of your treatment combination (e.g. goserelin).

Kisqali is sometimes called by its active substance: 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 guide will help inform you about starting Kisqali and keeping your treatment on course. It was created with help from nursing professionals and has been reviewed by a patient reading group.

guide, please ask your doctor or nurse.

Be open with them about any

concerns you have about

your treatment or your health.

Communicating with your

doctor or nurse can help

you to better understand

your treatment.

If you have any questions after reading this

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Not sure what something means? The glossary can help. It has definitions for many of the terms used in this booklet. On the following pages, glossary words are **in bold** the first time they appear.

Who is this treatment for?

You have been prescribed Kisqali because:

- You have locally advanced or metastatic breast cancer (sometimes also called advanced or secondary breast cancer)
- Your breast cancer is a type called
 HR-positive/HER2-negative (HR+/HER2-)
- 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 through the menopause
- If you have not gone through the menopause you must also receive a luteinising hormone-releasing hormone (LHRH) agonist as part of your treatment combination. This is usually given as a monthly injection
- The advice contained in this booklet is for both pre- and postmenopausal women. Throughout this booklet you will see advice that is specific to premenopausal women in boxes like this

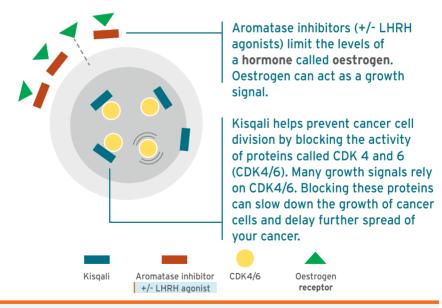


How does this treatment work?

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, and that can lead to cancer.

One goal of treatment is to slow down how quickly cancer cells divide. Kisqali is a targeted treatment called a CDK4/6 inhibitor that helps prevent cancer cell division. It does this by blocking the activity of a **protein** called CDK4/6. Kisqali can be taken in combination with an aromatase inhibitor. Aromatase inhibitors are a type of treatment called **hormone therapy** or **endocrine therapy**.

Kisqali works in combination with endocrine therapies



This combination works hand-in-hand to delay the growth of cancer

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 agonist – is required for women who have not gone through the menopause



You may have concerns about **side effects**, these are discussed further on page 12. In a large clinical trial, the side effects from taking Kisqali in combination with an aromatase inhibitor were mostly mild to moderate and could usually be managed. In some patients some serious side effects also occurred



You will have some medical tests to check if you are ready to start treatment

Remind your doctor or nurse if you:

- Have a fever, sore throat, or mouth ulcers due to infections (signs 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 rhythms
- Have or have had low levels of potassium, magnesium, calcium, or phosphorus in your blood
- Are allergic to peanuts or soya
- Are taking any other medicines or supplements



How do I take my 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 3 weeks, followed by a break of 1 week when you do not take these tablets. An aromatase inhibitor is a pill you take every day. These are treatments you continue to take until your doctor or nurse advises you to stop

RECOMMENDED 4-WEEK DOSING SCHEDULE (28-DAY CYCLE)

	WEEK 1	WEEK 2	WEEK 3	WEEK 4
Kisqali 600 mg (3 tablets of 200				
mg) once daily 21 consecutive days of treatment, followed by 7 days off treatment	$\langle \rangle$	$\langle \rangle$	$\langle \rangle$	X
Aromatase inhibitor Once daily, every day	\bigcirc	\bigcirc	\bigcirc	\bigcirc
LHRH agonist - only for women who have not gone through the menopause At the beginning of each cycle	⊘	×	×	×

- Your doctor or nurse 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 doctor or nurse
- Your doctor or nurse will regularly monitor your condition to check that the treatment is having the desired effect

Track your treatment on the Kisqali package

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

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	*	2			000	000	1000		
1-week break.		1	000	060	000	000	000	(10)	
ake your dose once a day or 3 weeks followed by	-	*							
aka uaur daga anga a dau				_		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

For premenopausal women who require an LHRH agonist, this is usually given as an injection once in every 28-day cycle



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 your doctor or nurse for advice if this happens



Avoid grapefruits and grapefruit juice while taking your treatment as these foods may alter the effectiveness of the treatment



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 your doctor or nurse, acute oncology department or any emergency phone number for advice straight away

What tests will I have?

Your doctor or nurse 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 doctor or nurse check for side effects. Tests most often occur during the first 6 months of treatment. These will include:



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



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

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

Appointment dates

The recommended test schedule during your first 2 cycles of treatment is below.

BEFORE TREATMENT	BLOOD TEST	ECG
You will receive these tests before starting treatment	\bigcirc	\bigcirc
CYCLE 1	BLOOD TEST	ECG ECG
Around day 14 of the 1st 28-day cycle	\bigcirc	\bigcirc
CYCLE 2	BLOOD TEST	ECG ECG
Around day 1 of the 2nd 28-day cycle	\bigcirc	\bigcirc
Around day 14 of the 2nd 28-day cycle	⊘	If your doctor or nurse requires

Blood tests are also recommended at the start of cycles 3, 4, 5 and 6. If your doctor or nurse 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 I experience?

The most common side effects of this treatment combination are:

- Low white blood cell counts
- Diarrhoea

- Nausea
- Fatigue

For women who have not gone through the menopause who are also taking an LHRH agonist (e.g. goserelin), this medication will stop your ovaries from making oestrogen. This means that you may have certain symptoms often associated with menopause, such as:

- Hot flushes
- Night sweats
- Vaginal dryness

- Mood changes
- Decreased sex drive

Some of these symptoms may improve over time.

For the full list of Kisqali side effects, please see the Patient Information Leaflet (PIL) provided in your box of tablets



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.

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

- Low white blood cell counts (neutropenia) can occur and your doctor will
 monitor for this with blood tests. It is important to tell your nurse or doctor
 straight away if you feel feverish or have chills or if you are experiencing
 frequent signs of infections, such as sore throat or mouth ulcers
- Liver problems can occur. It is important to tell your nurse or doctor straight away if you get itchy, yellow skin or yellowing of the whites of your eyes; nausea or vomiting; loss of appetite; pain in the upper right side of your stomach area (abdomen); dark or brown urine; and bleeding or bruising more easily than normal
- QT interval prolongation, which can affect the heart rhythm, does not usually cause symptoms. It can cause people to faint or feel faint, particularly if exercising or if stressed. If you experience this it is important to tell your nurse or doctor straight away
- Severe rash, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, or enlarged lymph nodes can occur. If you experience any of these it is important that you tell your nurse or doctor straight away
- Interstitial lung disease (ILD)/pneumonitis. This has been reported rarely
 with Kisqali and other drugs in the same class, and may require your
 treatment to be interrupted, reduced, or discontinued. Please contact your
 healthcare professional if you develop a cough/wheeze, pain on breathing,
 shortness of breath, or lightheadedness.

If you have side effects of any kind, it is important to tell your doctor or nurse straight away, as they may be able to help you manage them

Tips to help you manage side effects



Tips to help if you have nausea and vomiting

- Try taking your medicine with food and not on an empty stomach
- Eat frequent, small meals and have a snack at bedtime
- Drink clear fluids (preferably served cold) to prevent dehydration and avoid alcohol
- Avoid certain foods that may make nausea worse, such as spicy and fatty foods, and those high in sugar
- Food or drink containing ginger or peppermint can help reduce nausea; try ginger tea, ginger biscuits, peppermints 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, poultry, well-cooked eggs, white bread, pasta or rice
 - Eat less fibre (cereals, raw fruits and vegetables) until the diarrhoea improves
 - Avoid greasy, fatty foods such as chips and beefburgers, and spicy foods like chilli peppers
- As diarrhoea starts to improve, add foods low in fibre to your diet, such as bananas, rice and dry toast
- 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
- Pace yourself in the best way that suits you
- Get plenty of sleep each night, and if you feel the need, take short naps during the day
- Make sure you continue eating a healthy diet
- If you have children, explain that you're feeling tired. Plan activities where you can sit down while spending time with them



Tips to help if you have hair thinning or loss

- Be gentle when brushing and washing your hair; hair loss might be somewhat reduced by avoiding too much brushing or pulling
- You may wish to wear a hat to protect your scalp from the sun
- Use gentle hair products and avoid colouring, perming or relaxing
- Avoid using hairdryers, straighteners or hot rollers

If you have side effects of any kind, it is important to tell your doctor or nurse right away, so they can help you manage these and get the most out of your treatment

Dose interruptions and modifications

As with other cancer treatments, your doctor or nurse may adjust your Kisqali dose during treatment. This is to help find the dose that is effective but limits the number and severity of side effects. 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 and get the best from your treatment.

Dose modifications are typically done in one of two ways

Do not adjust your dose or stop taking your medication unless directed by your doctor or nurse.

A dose interruption:

 This is when your doctor or nurse asks you to stop taking Kisqali for a period of time. You will still take your aromatase inhibitor each day unless your doctor or nurse asks you not to

A dose reduction:

 This is when your doctor or nurse asks you to take fewer tablets of Kisqali each day

Before you restart Kisqali after an interruption, ask your doctor or nurse:

- 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 doctor or nurse can adjust your dose simply by changing the number of tablets you take each day. If your doctor or nurse lowers your dose, you will be able to continue treatment with the treatment 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 ensure you get the best out of your treatment with Kisqali.

Your doctor or nurse will explain the reasons for any schedule change



Your appointment tracker

Your doctor or nurse 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 doctor or nurse 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 and an ECG around day 14	Date: Time:	Date: Time:
CYCLE 2	BLOOD TEST	ECG
You will have a blood test and an ECG around day 1	Date: Time:	Date: Time:
You will also have a blood test around day 14*	Date: Time:	Date: Time:

^{*}You will have an ECG on day 14 of cycle 2 if your doctor or nurse requires it

The above tests are recommended for all patients starting on Kisqali + an aromatase inhibitor. However, if your doctor or nurse thinks it's needed, you may continue to have blood tests and ECGs throughout treatment.

Your treatment diary

The recommended starting dose of Kisqali is 600 mg every day (3 tablets of 200 mg). Your doctor or nurse will also prescribe an aromatase inhibitor (such as letrozole, anastrozole or exemestane) 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 premenopausal, you will also receive an injection of an LHRH agonist (e.g. goserelin) once every cycle

Using your diary

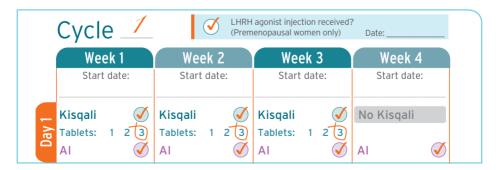
- Fill in the relevant cycle number
- If you are premenopausal and taking an LHRH agonist, for each cycle tick the box and fill in the date when you received this

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 doctor or nurse.

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LHRH agonist injection received? (Premenopausal women only)

Date: _____

	We	ek	1	Week 2			Week 3			Week 4	
	Start	te:	Start date:			Start date:			Start date:		
Day 1	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 2	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets:	1	2 3	No Kisqali Al	
Day 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 4	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 5	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 6	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 7	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	

Remember to take your aromatase inhibitor every day as directed by your doctor or nurse, even on days you do not take Kisqali unless you have been advised to stop both treatments.



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 doctor or nurse.

Questions about dosing	
Questions about side effects	
Questions about tests	
Other questions	



Eating well, drinking plenty of fluids, exercising regularly and sleeping as much as you need can maintain your immune system and improve your well-being and quality of life

Cycle	\bigcirc	LHRH agonist injection received? (Premenopausal women only)	Date:
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	We	ek	1	Wee	ek i	2	Wee	ek :	3	Week 4	
	Start	te:	Start date:			Start date:			Start date:		
Day 1	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
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Questions about dosing	
Questions about side effects	
Questions about tests	
Other questions	



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

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LHRH agonist injection received? (Premenopausal women only)

Date: _____

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	Start	da	te:	Start date:			Start date:			Start date:	
Day 1	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
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Questions about dosing	
Questions about side effects	
Questions about tests	
Other questions	
	_



Your emotional health can be as important as your physical health; talk to your doctor or nurse if you feel that you need support

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	LHRH agonist injection received?
\cup	(Premenopausal women only)

Date: _____

	We	ek	1	Wee	ek i	2	Wee	ek :	3	Week 4	
	Start	: da	te:	Start	dat	e:	Start	dat	e:	Start 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 doctor or nurse.

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Questions about side effects	
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Other questions	



Only you can decide when to share information with others. Some people find chatrooms or meeting others with similar experiences useful. Your doctor or nurse may be able to direct you to your local support groups

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	LHRH agonist injection received?
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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 doctor or nurse.

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Questions about tests	
Other questions	
	_



It is important that you are confident in taking your treatment. Your doctor or nurse 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	\bigcirc	LHRH agonist injection received? (Premenopausal women only)	Date:

	We	ek	1	Wee	ek i	2	Wee	ek :	3	Week 4	
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Day 5	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 6	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 7	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	

Remember to take your aromatase inhibitor every day as directed by your doctor or nurse, even on days you do not take Kisqali unless you have been advised to stop both treatments.



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 doctor or nurse.

Questions about dosing	
Questions about side effects	
Questions about tests	
Other questions	



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

Glossary

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.

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.

Fatique

A feeling of extreme tiredness 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.

Locally advanced or metastatic breast cancer

Cancer that has spread from the original tumour to other parts of the body. Sometimes, you may also hear this called advanced breast cancer or secondary breast cancer.

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.

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.

Reporting of side effects

If you think you may be getting any 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. Kisqali 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.

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at:

http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000.

E: postlicensing.medicinesauthority@gov.mt

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