



ENGLISCH



**METASTATIC BREAST CANCER**

Metastasierter Brustkrebs

Your treatment instructions

# Kisqali – understanding the treatment and applying it in everyday life

Only intended for patients who have already been prescribed Kisqali.

# Dear patient,

Your doctor has selected Kisqali® (ribociclib) for you to treat *advanced metastatic breast cancer*.

You will, of course, have some questions: What is Kisqali? How does it work, how do you take it and what can you expect from the treatment?

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## This brochure provides the answers

This brochure contains important information on these topics. It is intended to make it easier for you to deal with the medication and help you to implement your treatment as effectively as possible.

You may have further questions after reading it through. In this case, please discuss any concerns you may have about the treatment with your doctor.

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### Unclear medical terms?

The glossary at the end of the brochure may help. It explains many of the terms used in this brochure. Glossary terms appear in *italics* the first time they occur.



Open communication with your treatment team is an important pillar of your therapy.

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# About Kisqali

The news that you have advanced metastatic breast cancer changes your life. Information about treatment is an important first step in dealing with your diagnosis. The more you know, the better you can face the challenges with confidence and hope.

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## What is Kisqali and what is it used for?

The medication contains the active substance ribociclib, which belongs to a class of medicines called CDK4/6 inhibitors. It works by inhibiting the *proteins* CDK4 and CDK6, which regulate cell growth and division. By interfering with the activity of these proteins, ribociclib can slow the growth of cancer cells and delay the progression of your cancer.

Ribociclib is used in combination with an *aromatase inhibitor* (e.g. *letrozole*) or *fulvestrant* for the treatment of advanced metastatic breast cancer in women.

Women who have not yet reached menopause are also treated with an *LHRH agonist* (LHRH = luteinising hormone-releasing hormone).



Treatment with ribociclib and an aromatase inhibitor or fulvestrant is a targeted therapy for advanced metastatic breast cancer.

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# How does Kisqali work?

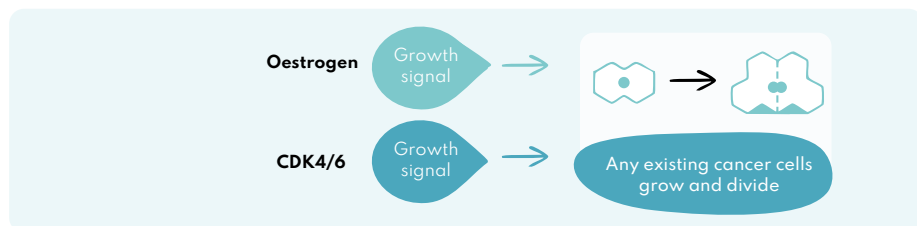
To stay healthy, the body's cells divide. For this process, they need growth signals from the body. Cancer cells use these growth signals to divide in an uncontrolled manner.

One of the goals of cancer therapy is to prevent the cancer cells from dividing uncontrollably, so that the cancer does not continue to grow.

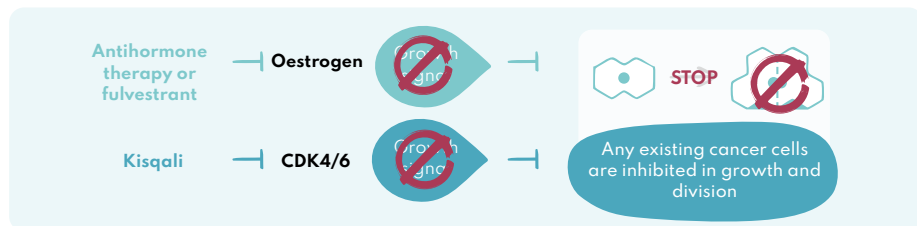
Ribociclib and aromatase inhibitors or fulvestrant work in different ways and inhibit the growth of tumour cells:

Aromatase inhibitors or fulvestrant inhibit the formation of *oestrogen*. CDK4/6 inhibitors disrupt the action of CDK4 and CDK6 proteins, preventing over-division of tumour cells.

In women before or during menopause, treatment with ribociclib and an aromatase inhibitor or fulvestrant should be combined with an LHRH agonist, which inhibits the release of oestrogen.



## Treatment with ribociclib and an aromatase inhibitor or fulvestrant



Ribociclib and the aromatase inhibitor or fulvestrant can delay the progression of cancer due to how their mechanisms of action interact.

Please contact your doctor if you have any questions about how the medication works. You can make notes for your medical consultation here.



A series of horizontal dotted lines for taking notes, arranged in a vertical column on the left side of the page.



# Starting treatment with Kisqali

## Before starting the treatment, inform your doctor

- if you have a fever (38°C or above), sore throat or mouth ulcers due to infection (deficiency of *white blood cells*).
- if you have problems with your liver or have previously been affected by a liver disease.
- if you currently have or have previously had heart problems or heart rhythm problems.
- if you are allergic to any of the ingredients in the medication, such as the active ingredient ribociclib, peanuts or soya – in this case you should not take Kisqali.



## Getting the most out of your treatment

Your treatment team will make every effort to ensure that the therapy has the optimal effect for you. To help with this, it is essential that you regularly attend your check-up appointments for medical tests.

- Your doctor will perform regular check-ups during the first six months after starting treatment. This is because possible *side effects* (changes in the blood count) are not always easy to detect.

The following routine test are carried out:



Blood tests to measure certain components in the blood, such as liver *enzymes* and *electrolytes* (salts)



*Electrocardiogram (ECG)* to measure the electrical activity of your heart

- Your treatment team can use the test results to identify possible side effects of your treatment.
- After six months, your doctor will decide whether and at what frequency further tests are necessary.



A medical check-up can reveal possible side effects and help you stay on track with your treatment.

# How to take Kisqali



## Taking ribociclib with an aromatase inhibitor

The recommended dose is three ribociclib tablets (600 mg total) 1× daily and one tablet of the aromatase inhibitor at the same time.

## Ribociclib can be taken with or without food



Avoid **grapefruit and its juice** when taking ribociclib.

## You are not yet in the menopause



In pre- or perimenopausal women, therapy should be combined with an LHRH agonist (LHRH = luteinising hormone-releasing hormone).



## Taking ribociclib with fulvestrant

The recommended dose is three ribociclib tablets 1× daily (600 mg total).

In addition, an intramuscular injection of fulvestrant is given on days 1, 15 and 29 of treatment, followed by 1× monthly.

## Take 1× daily, preferably in the morning



Ribociclib tablets must be swallowed whole: do not chew, crush or divide the tablets before swallowing!

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All information on storing the tablets can be found in the package leaflet.


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**Ribociclib is administered together with an aromatase inhibitor or fulvestrant in a 28-day cycle.**

28-day cycle	Week 1	Week 2	Week 3	Week 4
<b>Ribociclib</b> 600 mg 1× daily, 3 weeks taking it, 1 week break	✓	✓	✓	✗
<b>+ aromatase inhibitor</b> 1× daily taken continuously	✓	✓	✓	✓

**or**

28-day cycle	Week 1	Week 2	Week 3	Week 4
<b>Ribociclib</b> 600 mg 1× daily, 3 weeks taking it, 1 week break	✓	✓	✓	✗
	Day 1	Day 15	Day 29	1× monthly
<b>+ fulvestrant</b> IM injection 1× monthly plus 1× 14 days and 1× 29 days after first injection				

- ✓ The treatment is administered 1× daily during this week in the cycle.
- ✗ The treatment is not administered during this week in the cycle.
-  Fulvestrant is administered via an intramuscular injection on days 1, 15 and 29, and then 1× monthly.

In pre- or perimenopausal women, the therapy should be combined with an LHRH agonist.

Please always adhere to the treatment cycle prescribed by your doctor.



### What to do if ...

- **you have forgotten to take your tablets:**

Do not take a double *dose* to make up for a forgotten dose.

Instead, wait until it is time for your next dose and take the usual number of tablets.

- **you have accidentally taken too many tablets:**

Contact your doctor or a hospital immediately.

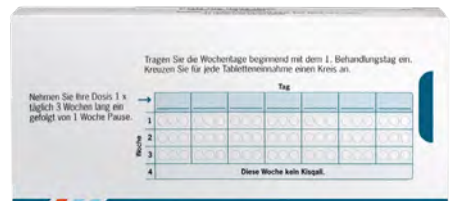


Do not change the Kisqali dose or treatment plan without consulting your doctor!

# Treatment plan

The Kisqali packaging is designed to make it easier for you to take the tablets correctly.

A dosing schedule on each pack helps you with taking it throughout the treatment cycle.



## Tips to make sure you don't forget to take your daily dose:



Write down when you take it each day in your logbook and/or on the pack.



Take the tablets as part of a daily activity such as breakfast, after brushing your teeth or when you do your morning exercise.



Ask family and friends to remind you to take it.



Set an alarm on your smartphone or alarm clock.

## Your logbook with dosing schedule

The dosing schedule in your logbook enables you to track what tablets you have taken. Simply tick as many circles each day as you have taken ribociclib tablets and aromatase inhibitor tablets or had fulvestrant administered.





# What are the possible side effects?

Ribociclib is taken with the medicine letrozole or another aromatase inhibitor or fulvestrant. Like all medicines, these two medicines can also cause side effects, although not everybody gets them.



Most side effects that occur with ribociclib + aromatase inhibitor<sup>a</sup> or fulvestrant are mild or moderate in nature.

This means that they can cause inconvenience, but they (should) have little effect on your everyday life.

**Some possible side effects** may be nausea and vomiting, diarrhoea, tiredness (fatigue) or hair thinning/loss. You can find more information about possible symptoms and side effects and how to deal with them on the following pages.

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## Please note

The symptoms mentioned in this brochure are not a complete list of all possible side effects. For this, please read the package leaflet of your medication.



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<sup>a</sup> Clinical trials were conducted with the aromatase inhibitor letrozole.

# Recommendations for managing side effects



## For nausea and vomiting

- Take the medication with food and not on an empty stomach.
- Eat more but smaller meals and a snack before going to bed.
- Drink clear fluids (ideally cold), e.g. water, ginger tea or herbal tea to prevent dehydration.
- Avoid foods that exacerbate nausea (e.g. spicy, high-fat or high-sugar foods).
- Choose easily digestible foods such as turkey, biscuits, porridge, pretzels, rice or plain soups.
- Exercise in the fresh air.



## For diarrhoea

- Eat several smaller meal throughout the day.
- Avoid dairy products, alcohol, tobacco, caffeinated drinks and spicy, high-fat (e.g. deep-fried or baked in fat) and fibre-rich (e.g. wholegrain products, pulses) foods.
- Avoid raw fruit and vegetables and acidic fruits or juices.
- Drink large amounts of clear fluids, such as ginger tea or herbal tea to prevent dehydration.



### For weakness and tiredness

- Spread your physical activities across the whole day.
- Make sure you have a regular sleep pattern.
- Lie down for short naps.
- Make sure you eat a balanced diet.
- Exercise in the fresh air.  
Just 15 minutes can boost your energy level considerably.
- Do not drive or operate machinery if you feel weak and dizzy.



### For hair thinning/loss

- Wash and brush your hair gently.
- Use a broad-spectrum sunscreen with SPF 30 or higher and wear a hat to protect your scalp from the sun.



Contact your treatment team if you notice any of the side effects listed here or in the package leaflet or if you need help managing them.



# Symptoms to be aware of and to contact your doctor about

Notify your treatment team immediately if you notice any of the following:

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## Low number of different types of blood cells

- Fever, chills
- Feeling of weakness
- Frequently occurring infections with symptoms such as sore throat or mouth ulcers



## Serious liver problems

- Yellow skin or yellowing of the whites of the eyes
- Dark or brown urine
- Nausea or vomiting
- Pain in right upper abdomen
- Prone to bleeding or bruising



## Signs of heart problems

- Chest pain or tightness
- Change in heartbeat (faster or slower)
- Heart palpitations
- Feeling light-headed, fainting, dizziness
- Blue discolouration of lips
- Shortness of breath
- Swelling (oedema) in lower limbs or skin

Notify your treatment team immediately if you notice any of the following:

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### Skin reactions

- Extensive rash, skin redness, blistering on lips, eyes or mouth, peeling of the skin, mucous membrane damage
- Sweating, fever
- Itchy, dry or yellow skin
- Bruising



### Signs of sepsis (infection in the bloodstream)

- Serious infection with increased heart rate
- Shortness of breath or rapid breathing
- Fever and chills



### Interstitial lung disease/ pneumonitis

- Inflammation of the lungs
- Dry cough
- Chest pain, fever
- Shortness of breath and breathing difficulties



### Possible symptoms

- Coughing, shortness of breath
- Headaches
- Constipation
- Back pain
- Muscle cramps
- Frequent infections
- Dry eyes

**If you notice any side effects, it is important that you tell your doctor so that they can treat you, if necessary.**

You may receive the following advice:

- Changes to your lifestyle
- Taking other medications in addition to Kisqali and the aromatase inhibitor or fulvestrant
- Temporary interruption of treatment or reduction of the dose of Kisqali

# Support helps you to find your feet

With the right support, you can cope with your everyday life.

## Take advantage of many types of help

It is normal for new questions to keep popping up during the therapy. This brochure is intended to help you understand the therapy and apply it in your everyday life.

In addition to your doctor, patient organisations can also provide you with further valuable information. On the opposite page you will find web addresses with additional information on your diagnosis and treatment, help with dealing with your medical care and your daily activities at the same time.

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## The most important information at your fingertips

Not only will new questions come up in everyday life, but certain treatment routines will also be repeated. There are tools that can help you prepare for this, too.

We support you with materials that accompany you every day:

- Your patient passport summarises important information about your treatment such as dosage, appointments and safety information; in addition, the passport includes a patient card for your wallet.
- The interaction card helps the pharmacist spot possible incompatibilities of other medicines with Kisqali, the aromatase inhibitor or fulvestrant when filling prescriptions.
- The logbook helps you with documenting what tablets you have taken each day.

# Communication gives you something to lean on

Build supportive relationships with other women with advanced metastatic breast cancer and do not hesitate to contact your doctor with any questions or concerns.

Further information about breast cancer and how to deal with it can be found on the following website:

## Leben mit Brustkrebs

[www.Leben-mit-Brustkrebs.de](http://www.Leben-mit-Brustkrebs.de)

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## Organisations that are there to help you find support:

### Allianz gegen Brustkrebs

[www.allianz-gegen-brustkrebs.de](http://www.allianz-gegen-brustkrebs.de)

### Frauenselbsthilfe nach Krebs

[www.frauenselbsthilfe.de](http://www.frauenselbsthilfe.de)

### Brustkrebs Deutschland

[www.brustkrebsdeutschland.de](http://www.brustkrebsdeutschland.de)

### Mamazone

[www.mamazone.de](http://www.mamazone.de)



### MyTime initiative – making moments precious

A joint project by “Mamma Mia! Das Brustkrebsmagazin”, Brustkrebs Deutschland e. V. and Novartis

Facebook page: @Mytime.LebenmitBrustkrebs

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“When you have advanced metastatic breast cancer, many things are uncertain. It’s reassuring to know that I’m not alone.”

# Glossary



## Aromatase inhibitors

Group of drugs that reduce the amount of the hormone oestrogen produced by the body

## Cycle

A treatment phase that is repeated regularly with periods of rest in between

## Dose

The amount of medicine to be taken at once

## Electrocardiogram (ECG)

A test that shows heart activity as a line graph. One heart condition that an ECG can detect is, for example, QTc prolongation, in which the time between heartbeats is longer than normal.

## Electrolytes

Minerals in the blood with an electrical charge, which affect various bodily functions

## Enzyme

A substance in living organisms that triggers chemical reactions

## Fulvestrant

Blocks the action of oestrogen in the body, which can slow down the growth of *hormone receptor-positive* cancer

## Hormone

A chemical substance in the body that controls the activities of cells or organs

## Hormone receptor-positive (HR+)

Indicates cancer cells with hormone receptors. Hormones enter the cells via these *receptors* and promote tumour growth.

## **Letrozole**

A drug that reduces the amount of oestrogen produced by the body, which can slow down the growth of hormone receptor-positive cancer

## **LHRH agonist**

Reduces the formation of oestrogen and thus the concentration in the body

## **Metastatic breast cancer**

Advanced disease in which secondary tumours have formed in other parts of the body

## **Oestrogen**

A hormone that occurs naturally in the body and may promote the growth of cancer cells

## **Progression**

When the cancer worsens or spreads after tests or treatment

## **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 function.

## **Receptor**

A protein inside or on the surface of a cell, which substances can bind to

## **Side effect**

An undesirable symptom caused by treatment

## **White blood cell**

A type of blood cell used by the body to fight off infection

### **Image credits**

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# Three questions for a good life

**The three questions for a good life can be a wonderful habit – almost a ritual.**

Dr Luc Isebaert developed this tool, which has helped many people to find happiness again.

Perhaps it will help you to write down the questions and your answers in a special book of happiness and read it before going to bed.

**1.** What did I do today that made me feel happy or satisfied?

.....  
.....

**2.** What did others do today that makes me happy?  
What did I do to let them know so they might do it again?

.....  
.....

**3.** What did I hear, smell, feel, see or experience today that made me happy?

.....  
.....

# Notes



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In the Medical InfoService, doctors, pharmacists and scientists are happy to address your concerns and provide you with information.



### Information about Novartis products with regard to ...

- Administration and effects of medications and active ingredients
- Application, handling and storage
- Combinations and interactions with other medicines and substances
- Area of application, background to the disease and therapies

### We offer ...

- Individual information in a personal discussion
- Information and service materials



#### Phone

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#### Email

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#### Website

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#### Live chat

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<sup>a</sup> Mon to Fri from 8 am to 6 pm

### Please note:

Communication via the specified phone and email contacts generally takes place in German.

## Novartis Pharma GmbH

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