Package leaflet: Information for the user

Lapatinib STADA Arzneimittel AG 250 mg, filmomhulde tabletten
lapatinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Don't pass it on to others. It may harm them, even if their signs of illness seem the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lapatinib STADA Arzneimittel AG is and what it is used for

Lapatinib STADA Arzneimittel AG is used to treat certain types of breast cancer *(HER2-overexpressing)* which have spread beyond the original tumour or to other organs (*advanced* or *metastatic* breast cancer). It may slow or stop cancer cells from growing, or may kill them.

Lapatinib STADA Arzneimittel AG is prescribed to be taken in combination with another anti-cancer medicine.

Lapatinib STADA Arzneimittel AG is prescribed in **combination with capecitabine**, for patients who have had treatment for advanced or metastatic breast cancer before. This previous treatment for metastatic breast cancer must have included trastuzumab.

Lapatinib STADA Arzneimittel AG is prescribed in **combination with trastuzumab**, for patients who have hormone receptor- negative metastatic breast cancer and have had other treatment for advanced or metastatic breast cancer before.

Lapatinib STADA Arzneimittel AG is prescribed in **combination with an aromatase inhibitor**, for patients with hormone sensitive metastatic breast cancer (breast cancer that is more likely to grow in the presence of hormones), who are not currently intended for chemotherapy.

Information about these medicines is described in separate patient information leaflets. **Ask your doctor** to give you information about these other medicines.

2. What you need to know before you take Lapatinib STADA Arzneimittel AG

Do not take Lapatinib STADA Arzneimittel AG
- if you are allergic to lapatinib or any of the other ingredients of this medicine (listed in Section 6).

Take special care with Lapatinib STADA Arzneimittel AG

Your doctor will run tests to check that your heart is working properly before and during your treatment with Lapatinib STADA Arzneimittel AG.

Tell your doctor if you have any heart problems before you take Lapatinib STADA Arzneimittel AG.

Your doctor also needs to know before you take Lapatinib STADA Arzneimittel AG:
- if you have lung disease
- if you have inflammation of the lung
- if you have any **liver problems**
- if you have any **kidney problems**
- if you have diarrhoea (see section 4).

Your doctor will run tests to check that your liver is working properly before and during your treatment with Lapatinib STADA Arzneimittel AG.

Tell your doctor if any of these apply to you.

Serious skin reactions
Serious skin reactions have been seen with Lapatinib STADA Arzneimittel AG. Symptoms may include skin rash, blisters and skin peeling.

Tell your doctor as soon as possible if you get any of these symptoms.

Other medicines and Lapatinib STADA Arzneimittel AG
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and other medicines you bought without a prescription.

It is especially important to tell your doctor if you are taking, or have recently taken any of the following medicines. Some medicines may affect the way Lapatinib STADA Arzneimittel AG works or Lapatinib STADA Arzneimittel AG may affect how other medicines work. These medicines include some medicines in the following groups:

- St John's Wort – a herb extract used to treat **depression**
- erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, rifabutin, rifampicin, telithromycin – medicines used to treat **infections**
- cyclosporine – a medicine used to **suppress the immune system** for example after organ transplantations
- ritonavir, saquinavir – medicines used to treat **HIV**
- phenytoin, carbamazepine – medicines used to treat **seizures**
- cisapride – a medicine used to treat certain **digestive system** problems
- pimozide – a medicine used to treat certain **mental health problems**
- quinidine, digoxin – medicines used to treat certain **heart problems**
- repaglinide – a medicine used to treat **diabetes**
- verapamil – a medicine used to treat **high blood pressure** or **heart problems** (*angina*)
- nefazodone – a medicine used to treat **depression**
- topotecan, paclitaxel, irinotecan, docetaxel – medicines used to treat certain types of **cancer**
- rosuvastatin – a medicine used to treat **high cholesterol**
- medicines that decrease stomach acidity - used to treat **stomach ulcers** or **indigestion**

Tell your doctor if you are taking, or have recently taken, any of these.

Your doctor will review the medicines you are currently taking to make sure you are not taking something that can't be taken with the Lapatinib STADA Arzneimittel AG. Your doctor will advise you whether an alternative is available.

Lapatinib STADA Arzneimittel AG with food and drink

Don't drink grapefruit juice while you are being treated with Lapatinib STADA Arzneimittel AG. It can affect the way the medicine works.

Pregnancy and breast-feeding

The effect of Lapatinib STADA Arzneimittel AG during pregnancy is not known. You should not use Lapatinib STADA Arzneimittel AG if you are pregnant unless your doctor specifically recommends it.

- **If you are pregnant** or planning to become pregnant, **tell your doctor.**
- **Use a reliable method of contraception** to avoid becoming pregnant while you're taking Lapatinib STADA Arzneimittel AG and for at least 5 days after the last dose.
- **If you become pregnant** during treatment with Lapatinib STADA Arzneimittel AG, **tell your doctor**.

It is not known whether Lapatinib STADA Arzneimittel AG passes into breast-milk. Do not breast-feed while taking Lapatinib STADA Arzneimittel AG and for at least 5 days after the last dose.

- **If you are breast-feeding** or planning to breast-feed, **tell your doctor**.

Ask your doctor or pharmacist for advice before taking Lapatinib STADA Arzneimittel AG if

you are unsure**. Driving and using machines**

You are responsible to decide if you are able to drive a motor vehicle or perform other tasks that require increased concentration. Because of the possible side effects of Lapatinib STADA Arzneimittel AG, your ability to drive or operate machines could be affected. These effects are described in section 4, 'Possible side effects'.

Lapatinib STADA Arzneimittel AG contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Lapatinib STADA Arzneimittel AG

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you're not sure.

Your doctor will decide on the correct dose of Lapatinib STADA Arzneimittel AG depending on the type of breast cancer being treated.

If you are prescribed Lapatinib STADA Arzneimittel AG in **combination with capecitabine**, the usual dose is **5 Lapatinib STADA Arzneimittel AG tablets a day**, as a single dose.

If you are prescribed Lapatinib STADA Arzneimittel AG in **combination with trastuzumab**, the usual dose is **4 Lapatinib STADA Arzneimittel AG tablets a day**, as a single dose.

If you are prescribed Lapatinib STADA Arzneimittel AG in **combination with an aromatase inhibitor**, the usual dose is **6 Lapatinib STADA Arzneimittel AG tablets a day**, as a single dose.

Take the prescribed dose every day for as long as your doctor tells you to.

Your doctor will advise you about the dose of your other anti-cancer medicine, and how to take it.

Taking your tablets

- **Swallow the tablets whole with water**, one after the other, at the same time each day.
- **Take Lapatinib STADA Arzneimittel AG either at least one hour before or at least one hour after food**. Take Lapatinib STADA Arzneimittel AG at the same time in relation to food each day – for example, you could always take your tablet one hour before breakfast.

While you are taking Lapatinib STADA Arzneimittel AG

- Depending on the side effects you experience, your doctor may recommend lowering your dose or temporarily stopping your treatment.
- Your doctor will also carry out tests to check your heart and liver function before and during treatment with Lapatinib STADA Arzneimittel AG.

If you take too much Lapatinib STADA Arzneimittel AG

Contact a doctor or pharmacist immediately. If possible, show them the pack.

If you forget to take Lapatinib STADA Arzneimittel AG

Don't take a double dose to make up for a forgotten dose. Just take the next dose at the scheduled time.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A severe allergic reaction is a rare side effect (may affect up to 1 in 1,000 people) and may develop rapidly.

Symptoms may include:
- skin rash (including itchy, bumpy rash)
- unusual wheezing, or difficulty in breathing
- swollen eyelids, lips or tongue
- pains in muscles or joints
- collapse or blackout.

Tell your doctor immediately if you get any of these symptoms. Don't take any more tablets.

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

- diarrhoea (which may make you dehydrated and lead to more severe complications)
  Tell your doctor immediately at the first sign of diarrhoea (loose stool), as it is important that this is treated right away. Also tell your doctor immediately if your diarrhoea worsens. *There is more advice on reducing the risk of diarrhoea at the end of section 4.*

- rash, dry skin, itching
  Tell your doctor if you get a skin rash. *There is more advice on reducing the risk of skin rash at the end of section 4.*

Other very common side effects

- loss of appetite
- feeling sick (nausea)
- being sick (vomiting)
- tiredness, feeling weak
- indigestion
- constipation
- sore mouth/mouth ulcers
- stomach pain
- trouble sleeping
- back pain
- pain in hands and feet
- joint or back pain
- a skin reaction on the palms of the hands or soles of the feet (including tingling, numbness, pain, swelling or reddening)
- cough, shortness of breath
- headache
- nose bleed
- hot flush
- unusual hair loss or thinning

Tell your doctor if any of these side effects get severe or troublesome.

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

- an effect on how your heart works

In most cases, the effect on your heart will not have any symptoms. If you do experience symptoms associated with this side effect, these are likely to include an irregular heartbeat and shortness of breath.

- liver problems, which may cause itching, yellow eyes or skin (*jaundice*), or dark urine or pain or discomfort in the right upper area of the stomach.
- nail disorders – such as a tender infection and swelling of the cuticles
- skin fissures (deep cracks on the skin or chapped skin)

Tell your doctor if you get any of these symptoms.

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

- treatment-induced lung inflammation, which may cause shortness of breath or cough
  Tell your doctor immediately if you get either of these symptoms.

Other uncommon side effects include:
- blood tests results that show changes in liver function (usually mild and temporary)

Rare side effects (may affect up to 1 in 1,000 people):

- severe allergic reactions (*see the beginning of section 4*)

The frequency of some side effects is not known (it cannot be estimated from the available data):
- irregular heart-beat (change in the electrical activity of the heart)
- severe skin reaction that might include: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever or any combination of these
- pulmonary arterial hypertension (increased blood pressure in the arteries (blood vessels) of the lungs)

If you get other side effects

Tell your doctor or pharmacist if you notice any side effects not listed in this leaflet.

Reducing the risk of diarrhoea and skin rash

Lapatinib STADA Arzneimittel AG can cause severe diarrhoea

If you suffer from diarrhoea while taking Lapatinib STADA Arzneimittel AG:

- drink plenty of fluids (8 to 10 glasses a day), such as water, sports drinks or other clear liquids
- eat low-fat, high protein foods instead of fatty or spicy foods
- eat cooked vegetables instead of raw vegetables and remove the skin from fruits before eating
- avoid milk and milk products (including ice cream)
- avoid herbal supplements (some may cause diarrhoea).

Tell your doctor if your diarrhoea continues.

Lapatinib STADA Arzneimittel AG can cause skin rash

Your doctor will check your skin before and during treatment.
To care for sensitive skin:

- wash with a soap-free cleanser
- use fragrance free, hypoallergenic beauty products
- use sunscreen (Sun Protection Factor [SPF] 30 or higher).

Tell your doctor if you get a skin rash.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below.
Nederlands Bijwerkingen Centrum Lareb
Website: www.lareb.nl.
By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Lapatinib STADA Arzneimittel AG

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lapatinib STADA Arzneimittel AG contains

- The active substance in Lapatinib STADA Arzneimittel AG is lapatinib. Each film-coated tablet contains lapatinib ditosylate monohydrate, equivalent to 250 mg lapatinib.
- The other ingredients are: cellulose, microcrystalline (type 101) (E460), povidone K30 (E1201), sodium starch glycolate (Type A), magnesium stearate (E470b), hypromellose (3 mPa·s and 6 mPa·s) 2910 (E464), titanium dioxide (E171), macrogol 400 (E1521), polysorbate 80 (E433), iron oxide yellow (E172).

What Lapatinib STADA Arzneimittel AG looks like and contents of the pack

Lapatinib STADA Arzneimittel AG film-coated tablets are oval, biconvex, off-white film-coated, debossed with '250' marked on one side and plain on the other.

Lapatinib STADA Arzneimittel AG is supplied in either blisters packs or bottles:

Blister packs
Each pack of Lapatinib STADA Arzneimittel AG contains 70 or 84 tablets in aluminium foil blisters of 10 or 6 tablets each.
Each pack of Lapatinib STADA Arzneimittel AG contains 70 x 1 or 84 x1 tablets in perforated aluminium foil blisters of 10 or 6 tablets each.

Lapatinib STADA Arzneimittel AG is also available in multipacks containing 140 tablets that comprise 2 packs, each containing 70 tablets in aluminium foil blisters.
Lapatinib STADA Arzneimittel AG is also available in multipacks containing 140 x 1 tablets that comprise 2 packs, each containing 70 x 1 tablets in perforated aluminium foil blisters.

Bottles
Lapatinib STADA Arzneimittel AG is also available in plastic bottles containing 84 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen

STADA Arzneimittel AG
Stadastrasse 2-18
Bad Vilbel, 61118, Duitsland

Fabrikant

Remedica Ltd
Aharnon Street, Limassol Industrial Estate, Building 10
3056 Limassol
Cyprus

PharOS MT Ltd.
HF62X, Hal Far Industrial Estate
Birzebbugia BBG3000
Malta

STADA Arzneimittel AG
Stadastrasse 2 – 18,
61118 Bad Vilbel
Duitsland

In het register ingeschreven onder:

RVG 128466 Lapatinib STADA Arzneimittel AG 250 mg, filmomhulde tabletten

Dit medicijn is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Lapatinib STADA Arzneimittel AG 250 mg, filmomhulde tabletten
Duitsland	Lapatinib AL 250 mg Filmtabletten
Italië	LAPATINIB EG

Deze bijsluiter is voor het laatst goedgekeurd in juli 2022.