Package leaflet: Information for the user

Tarceva 25 mg film-coated tablets
Tarceva 100 mg film-coated tablets
Tarceva 150 mg film-coated tablets
Erlotinib

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 further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are 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 Tarceva is and what it is used for
2. What you need to know before you take Tarceva
3. How to take Tarceva
4. Possible side effects
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1. What Tarceva is and what it is used for

Tarceva contains the active substance erlotinib. Tarceva is a medicine used to treat cancer by preventing the activity of a protein called epidermal growth factor receptor (EGFR). This protein is known to be involved in the growth and spread of cancer cells.

Tarceva is indicated for adults. This medicine can be prescribed to you if you have non-small cell lung cancer at an advanced stage. It can be prescribed as initial therapy or as therapy if your disease remains largely unchanged after initial chemotherapy, provided your cancer cells have specific EGFR mutations. It can also be prescribed if previous chemotherapy has not helped to stop your disease.

This medicine can also be prescribed to you in combination with another treatment called gemcitabine if you have cancer of the pancreas at a metastatic stage.

2. What you need to know before you take Tarceva

Do not take Tarceva:
- if you are allergic to erlotinib or any of the ingredients of this medicine (listed in section 6).

Warnings and precautions:
- if you are taking other medicines that may increase or decrease the amount of erlotinib in your blood or influence its effect (for example antifungals like ketoconazole, protease inhibitors, erythromycin, clarithromycin, phenytoin, carbamazepine, barbiturates, rifampicin, ciprofloxacin, omeprazole, ranitidine, St. John's Wort or proteasome inhibitors), talk to your doctor. In some cases these medicines may reduce the efficacy or increase the side effects of Tarceva and your doctor may need to adjust your treatment. Your doctor might avoid treating you with these medicines while you are receiving Tarceva.
- if you are taking anticoagulants (a medicine which helps to prevent thrombosis or blood clotting e.g. warfarin), Tarceva may increase your tendency to bleed. Talk to your doctor, he will need to regularly monitor you with some blood tests.

- if you are taking statins (medicines to lower your blood cholesterol), Tarceva may increase the risk of statin related muscle problems, which on rare occasions can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage, talk to your doctor.
- if you use contact lenses and/or have a history of eye problems such as severe dry eyes, inflammation of the front part of the eye (cornea) or ulcers involving the front part of the eye, tell your doctor.

See also below "Other medicines and Tarceva"

You should tell your doctor:
- if you have sudden difficulty in breathing associated with cough or fever because your doctor may need to treat you with other medicines and interrupt your Tarceva treatment;
- if you have diarrhoea because your doctor may need to treat you with anti-diarrhoeal (for example loperamide);
- immediately, if you have severe or persistent diarrhoea, nausea, loss of appetite, or vomiting because your doctor may need to interrupt your Tarceva treatment and may need to treat you in the hospital;
- if you have ever had problems with your liver. Tarceva may cause serious liver problems and some cases have been fatal. Your doctor may perform blood tests while you are taking this medicine to monitor whether your liver functions properly;
- if you have severe pain in the abdomen, severe blistering or peeling of skin. Your doctor may need to interrupt or stop your treatment;
- if you develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light, please tell your doctor or nurse immediately as you may need urgent treatment (see Possible Side Effects below).
- if you are also taking a statin and experience unexplained muscle pain, tenderness, weakness or cramps. Your doctor may need to interrupt or stop your treatment.

See also section 4 "Possible side effects".

Liver or kidney disease
It is not known whether Tarceva has a different effect if your liver or kidneys are not functioning normally. The treatment with this medicine is not recommended if you have a severe liver disease or severe kidney disease.

Glucuronidation disorder like Gilbert's syndrome
Your doctor must treat you with caution if you have a glucuronidation disorder like Gilbert's syndrome.

Smoking
You are advised to stop smoking if you are treated with Tarceva as smoking could decrease the amount of your medicine in the blood.

Children and adolescents
Tarceva has not been studied in patients under the age of 18 years. The treatment with this medicine is not recommended for children and adolescents.

Other medicines and Tarceva
Tell your doctor or pharmacist if you are taking, have recently taken any other medicines or might take any other medicines.

Tarceva with food and drink
Do not take Tarceva with food. See also section 3 'How to take Tarceva'

Pregnancy and breast-feeding
Avoid pregnancy while being treated with Tarceva. If you could become pregnant, use adequate contraception during treatment, and for at least 2 weeks after taking the last tablet.

If you become pregnant while you are being treated with Tarceva, immediately inform your doctor who will decide if the treatment should be continued.
Do not breast-feed if you are being treated with Tarceva, and for at least 2 weeks after taking the last tablet.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Tarceva has not been studied for its possible effects on the ability to drive and use machines but it is very unlikely that your treatment will affect this ability.

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

Tarceva contains a sugar called lactose monohydrate.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Tarceva.

3. How to take Tarceva

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

The tablet should be taken at least one hour before or two hours after the ingestion of food.

The usual dose is one tablet of Tarceva 150 mg each day if you have non-small cell lung cancer.

The usual dose is one tablet of Tarceva 100 mg each day if you have metastatic pancreatic cancer. Tarceva is given in combination with gemcitabine treatment.

Your doctor may adjust your dose in 50 mg steps. For the different dose regimens Tarceva is available in strengths of 25 mg, 100 mg or 150 mg.

If you take more Tarceva than you should
Contact your doctor or pharmacist immediately.
You may have increased side effects and your doctor may interrupt your treatment.

If you forget to take Tarceva
If you miss one or more doses of Tarceva, contact your doctor or pharmacist as soon as possible.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Tarceva
It is important to keep taking Tarceva every day, as long as your doctor prescribes it for you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. **Possible side effects**

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

Contact your doctor as soon as possible if you suffer from any of the below side effects. In some cases your doctor may need to reduce your dose of Tarceva or interrupt treatment:

- Diarrhoea and vomiting (very common: may affect more than 1 out of 10 people). Persistent and severe diarrhoea may lead to low blood potassium and impairment of your kidney function, particularly if you receive other chemotherapy treatments at the same time. If you experience more severe or persistent diarrhoea contact your doctor immediately as your doctor may need to treat you in the hospital.

- Eye irritation due to keratoconjunctivitis (very common: may affect more than 1 out of 10 people) , conjunctivitis and keratitis (common: may affect up to 1 in 10 people).

- Form of lung irritation called interstitial lung disease (uncommon in European patients; common in Japanese patients: may affect up to 1 in 100 people in Europe and up to 1 in 10 in Japan). This disease can also be linked to the natural progression of your medical condition and can have a fatal outcome in some cases. If you develop symptoms such as sudden difficulty in breathing associated with cough or fever contact your doctor immediately as you could suffer from this disease. Your doctor may decide to permanently stop your treatment with Tarceva.

- Gastrointestinal perforations have been observed (uncommon: may affect up to 1 in 100 people). Tell your doctor if you have severe pain in your abdomen. Also, tell your doctor if you had peptic ulcers or diverticular disease in the past, as this may increase this risk.

- In rare cases inflammation of the liver (hepatitis) was observed (may affect up to 1 in 1,000 people). Symptoms may include a general feeling of being unwell, with or without possible jaundice (yellowing of the skin and eyes), dark urine, nausea, vomiting and abdominal pain. In rare cases liver failure was observed. This can potentially be fatal. If your blood tests indicate severe changes in your liver function, your doctor may need to interrupt your treatment.

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

- Rash which may occur or worsen in sun exposed areas. If you are exposed to sun, protective clothing, and/or use of sunscreen (e.g. mineral-containing) may be advisable
- Infection
- Loss of appetite, decreased weight
- Depression
- Headache, altered skin sensation or numbness in the extremities
- Difficulty in breathing, cough
- Nausea
- Mouth irritation
- Stomach pain, indigestion and flatulence
- Abnormal blood tests for the liver function
- Itching
- Tiredness, fever, rigors

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

- Dry skin
- Loss of hair
- Bleeding from the nose
- Bleeding from the stomach or the intestines

- Inflammatory reactions around the fingernail
- Infection of hair follicles
- Acne
- Cracked skin (skin fissures)
- Reduced kidney function (when given outside the approved indications in combination with chemotherapy)

Uncommon side effects (may affect up to 1 in 100 people):
- Inflammation of kidneys (nephritis)
- Excess of protein in the urine (proteinuria)
- Eyelash changes
- Excess body and facial hair of a male distribution pattern
- Excess pigmentation of the skin
- Eyebrow changes
- Brittle and loose nails

Rare side effects (may affect up to 1 in 1,000 people):
- Flushed or painful palms or soles (Palmar plantar erythrodysaesthesia syndrome)

Very rare side effects (may affect up to 1 in 10,000 people):
- Cases of perforation or ulceration of the cornea
- Severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome)
- Inflammation of the coloured part of the eye

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Tarceva

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 blister and the carton 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 Tarceva contains:
- **The active substance** of Tarceva is erlotinib. Each film-coated tablet contains 25 mg, 100 mg or 150 mg of erlotinib (as erlotinib hydrochloride) depending on the strength.
- **The other ingredients** are:
  Tablet core: lactose monohydrate, cellulose microcrystalline, sodium starch glycolate type A, sodium laurilsulfate, magnesium stearate (see also section 2 for lactose monohydrate and

sodium).

Tablet coat: hypromellose, hydroxypropyl cellulose, titanium dioxide, macrogol.

What Tarceva looks like and contents of the pack:
Tarceva 25 mg is supplied as a white to yellowish, round, film-coated tablet with 'T 25' engraved on one side and is available in pack sizes of30 tablets.
Tarceva 100 mg is supplied as a white to yellowish, round, film-coated tablet with 'T 100' engraved on one side and is available in pack sizes of30 tablets.
Tarceva 150 mg is supplied as a white to yellowish, round, film-coated tablet with 'T 150' engraved on one side and is available in pack sizes of30 tablets.

Marketing Authorisation Holder
Neon Healthcare Ltd.
8 The Chase, John Tate Road
Hertford, SG13 7NN, United Kingdom

Manufacturer
Delpharm Milano S.r.l.
Via Carnevale 1
20054 Segrate
Italy

Or

CHEPLAPHARM Registration GmbH
Weiler Straße 5e
79540 Lörrach
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
Neon Healthcare Ltd.
Email: medinfo@neonhealthcare.com

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