PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with

a doctor's prescription only

100 mg

Film-coated Tablets

Composition: Each Tarceva® 100 mg

tablet contains:

TARCEVA® 150 mg

Roche Film-coated Tablets

Composition: Each Tarceva® 150 mg tablet contains:

erlotinib 100 mg erlotinib 150 mg * For information on inactive ingredients see section 6 -"Further Information"

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it

seems to you that their ailment is similar.

If you experience any side effects, refer to your doctor or pharmacist. This includes any possible side effects that are not listed in this leaflet (see section 4 - "Side Effects").

The medicine is not intended for use in children and adolescents below the age of 18. IMPORTANT INFORMATION FOR YOUR REVIEW

Avoid pregnancy during the course of treatment with

- Tarceva®, and do not breast-feed during the course of treatment with the medicine. It is recommended that you stop smoking while under treatment with Tarceva®.
- Take the medicine on an empty stomach at least one
- hour before or two hours after completing a meal. Do not take the medicine with grapefruits or with grapefruit juice.

 • Tarceva® contains a type of sugar called lactose.
- 1. WHAT IS THE MEDICINE INTENDED FOR?

Tarceva® is intended for treatment of adults and can be

Treatment of patients with advanced non-small cell lung cancer (NSCLC) if previous chemotherapy treatment was unsuccessful in stopping your disease.

First line treatment in patients with advanced non-small cell lung cancer (NSCLC) if the general lung cancer (NSCLC) if the general lung cancer cells of the patients with advanced non-small lung cancer (NSCLC) if the general lung cancer cells of the general lung cancer cell

- cell lung cancer (NSCLC) if the cancer cells express mutations in EGFR.
- Maintenance treatment in patients with advanced non-small cell lung cancer (NSCLC) if the cancer cells express mutations in EGFR and your disease remains largely unchanged after initial chemotherapy treatment. Treatment in patients with advanced-stage or metastatic
- pancreatic cancer, in combina medicinal treatment (gemcitabine). with standard in combination Therapeutic group:

Antineoplastic, tyrosine kinase inhibitors.

Therapeutic activity: Tarceva® contains the active ingredient erlotinib. Tarceva®

Drug interactions

Antibiotics

cancer.

is a medicine used to treat cancer by preventing the activity of a growth factor protein called **EGFR** (epidermal growth factor receptor). This protein is known to be involved in the growth and spread of cancer cells. 2. BEFORE USING THE MEDICINE

■ Do not use this medicine if: you are sensitive (allergic) to

the active ingredient (erlotinib) or to any of the medicine's ingredients (listed in section 6).

 you are breastfeeding. ■ Special warnings regarding the use of the medicine you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

It is especially important to inform the doctor or pharmacist if you are taking other medicines that may increase or decrease the amount of the active ingredient (erlotinib) in your blood or influence its effect. Medicines such as: Ántifungals (such as ketoconazole)

Protease inhibitors - a group of antiviral medicines for treatment of AIDS/HIV and hepatitis C.

Antibiotics ciprofloxacin). (such as clarithromycin, erythromycin, epilepsy Medicines (such as phenytoin, carbamazepine).

 Sedatives and hypnotics (such as barbiturates). Medicines for tuberculosis (such as rifampicin). Proton pump inhibitors (such as omeprazole).

 H₂-receptor antagonist antihistamines (such as ranitidine).
 Medicines and herbal remedies for depression (such as • Proteasome inhibitors - a group of medicines to treat

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®.

• Anticoagulants (medicines that help to prevent thrombosis or blood clotting, e.g., warfarin) since **Tarceva®** may increase the tendency to bleed. Consult the doctor; he will need to regularly monitor you through blood tests.

Medicines to lower your blood cholesterol level (statins) since Tarceva® may increase the risk of muscle problems associated with statin treatment, · Medicines to

which, on rare occasions, can lead to serious muscle

cell breakdown (rhabdomyolysis), resulting in kidney damage. Consult with your doctor.

If you are using contact lenses and/or have a history of eye problems such as severe dryness of the eyes, inflammations or ulcers in the front part of the eyes (cornea), consult the doctor. Tell your doctor if: you have <u>sudden</u> difficulty in breathing associated with cough or fever since the doctor may give you other medicines and discontinue treatment with **Tarceva**[®].

you have diarrhea since the doctor may give you an anti-diarrheal (for example loperamide).

- immediately, if you have severe or persistent diarrhea, nausea, loss of appetite or vomiting since the doctor may discontinue the treatment with Tarceva® and treat you in the hospital. you have severe pain in the abdomen, severe blistering or peeling of skin. Your doctor may temporarily interrupt
- or permanently stop the treatment.
- you develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light. Refer to a doctor or nurse immediately, as you may need urgent treatment (see Side Effects section below). you are taking statins and experience unexplained muscle pain, muscle tenderness, muscle weakness or cramps. The doctor may stop the treatment.
 For further information, see section 4 - "Side Effects".
- Liver or kidney disease It is not known whether Tarceva® has a different effect in cases where your liver or kidneys are not functioning normally. The treatment with Tarceva® is not

recommended if you have a severe liver disease or severe

metabolic disorder associated with glucuronidation, like Gilbert's syndrome Your doctor must treat you with caution if you have a metabolic disorder associated with glucuronidation such

as Gilbert's syndrome.

kidney disease

<u>Children and adolescents</u> **Tarceva**® has not been studied in patients under the age of 18 years. The treatment with this medicine is not intended for children and adolescents. Use of Tarceva® with food and drink Do not take **Tarceva®** with food (see section 3 - "How Should You Use the Medicine?").

Take the medicine on an empty stomach - at least one hour before or two hours after completing a meal. Do not take the medicine with grapefruits or with grapefruit

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult a doctor or pharmacist before using medicines.

Avoid pregnancy while being treated with Tarceva®. If you are of child-bearing age and might become pregnant, vou should use reliable contraception during treatment with the medicine and for at least two weeks after taking the last tablet.

If you become pregnant during the course of treatment with <code>Tarceva®</code>, immediately inform your doctor so he can decide if the treatment should be continued.

Do not breastfeed during the course of treatment with <code>Tarceva®</code> and at least up to 2 weeks after taking the last

Tarceva® has not been studied for its possible effects on the ability to drive or operate machinery; however, it is very unlikely that the treatment with Tarceva® will affect

these abilities

tablet. your doctor or pharmacist before using this medicine. **Driving and using machines**

free"

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult

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

Important information regarding some of the ingredients of the medicine

Tarceva® contains a sugar called lactose monohydrate. If you have been told by your doctor that you have an

intolerance to some sugars, consult the doctor before

<u>Tarceva® contains sodium</u>
This medicine contains less than 1 mmol (less than 23 mg) of sodium per tablet and is therefore considered as "sodium

instructions

The dose and treatment regimen will be determined by

medicinal treatment for this disease (gemcitabine). Your doctor may adjust your dose in 50 mg increments. For the different dose regimens, **Tarceva®** is available in

strengths of 100 mg or 150 mg. Do not exceed the recommended dose.

If you accidentally took a higher dose

Contact your doctor or pharmacist immediately.

You may have increased side effects and your doctor

may stop your treatment.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor

or proceed to a hospital emergency room, and bring the package of the medicine with you. If you forget to take the medicine

If you forgot to take one or more doses of the medicine, contact your doctor or pharmacist as soon as possible. If

you forgot to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult the doctor. If you stop taking the medicine It is very important to keep taking **Tarceva®** every day, as

long as your doctor prescribes it for you. Adhere to the treatment regimen as recommended by

the doctor. Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting

How can you contribute to the success of the treatment? Do not take medicines in the dark! Check the label and

the dose each time you take medicine. Wear glasses if you need them If you have any further questions on the use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS As with any medicine, use of **Tarceva®** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of

Refer to your doctor as soon as possible if you suffer from any of the following side effects. In some cases, your doctor might reduce your dose of **Tarceva®** or stop the treatment: Diarrhea and vomiting (very common side effects that may affect more than 1 in 10 users). Severe or persistent diarrhea may lead to low blood potassium levels and impaired kidney function, particularly if

you receive other chemotherapy treatments at the same time. If you experience severe or persistent diarrhea, **refer to your doctor** immediately; he may need to treat you in a hospital. Eye irritation due to conjunctivitis/ keratoconjunctivitis (very common side effects that may affect more than 1 in 10 users) and keratitis

(common side effect that may affect up to 1 in 10 users).

A form of lung irritation called interstitial lung disease (this side effect is uncommon in European patients, but is common in Japanese patients. May affect up to 1 in 100 users in Europe and up to 1 in 10 users in Japan). This disease can be linked to the natural progression of your medical condition and in some cases, may have a fatal outcome. If you develop symptoms such as sudden difficulty in breathing associated with cough or fever, refer to your doctor immediately, as you could be suffering from this disease. Your doctor may decide to permanently stop your treatment with **Tarceva®**. Gastrointestinal perforations have been observed (uncommon side effect that may affect up to 1 in 100

users). Refer to your doctor if you have severe pain in the abdomen. Also, tell your doctor if you had a peptic ulcer (a sore in the mucous membrane of the digestive system) or diverticular disease in the past, as these may increase the risk of perforations. • In rare cases, liver failure was observed (rare side effect which may affect up to 1 in 1,000 users). If your blood tests indicate severe changes in liver function, the

doctor may need to stop the treatment with Tarceva®. Additional side effects Very common side effects (may affect more than 1 in 10 users):
• Skin rash which may occur or worsen in sun-exposed

and/or use of sun screens are advisable Infections Loss of appetite, decreased weight Depression Headache, altered skin sensation or numbness in the

areas. If you are exposed to sun, protective clothing,

Mouth irritation Stomach pain, indigestion and flatulence (excessive amount of gas or air in the stomach or intestine)

• Difficulties in breathing, cough

Nausea

Abnormal blood tests for liver function Itching, dry skin and loss of hairTiredness, fever, rigors

Common side effects (may affect up to 1 in 10 users): Nosebleed Bleeding from the stomach or the intestines Inflammatory reactions around the fingernails

Infections in hair follicles Acne

Cracked skin

Stevens-Johnson syndrome) Inflammation of the colored part of the eye

Reporting side effects

https://sideeffects.health.gov.il

 Reduced kidney function (when the medicine is given outside the approved indications in combination with chemotherapy)

Eyebrow changes

Brittle or loose nails

Uncommon side effects (may affect up to 1 in 100 users): Eyelash changes Excess body and facial hair of a male distribution pattern

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

Very rare side effects (may affect up to 1 in 10,000 users): · Cases of perforation or ulceration of the cornea · Severe blistering or peeling of the skin (suggestive of

If one of the side effects worsens, or if you suffer from a

side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for

reporting side effects, or by entering the link:

5. HOW SHOULD THE MEDICINE BE STORED? Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by

the doctor. • Do not use the medicine after the expiry date (exp. date) appearing on the package and the blisters. The

contains:

6. FURTHER INFORMATION

expiry date refers to the last day of that month.

• Storage conditions: Do not store the medicine above 30°C Do not discard the medicine in the household waste bin or in wastewater. Ask the pharmacist how to dispose of the medicine to protect the environment.

In addition to the active ingredient the medicine also

sodium starch glycolate, magnesium stearate, sodium laurylsulfate. Film-coating mixture: hypromellose, hydroxypropyl cellulose, titanium dioxide, macrogol 400.
Each Tarceva® 100 mg tablet contains approximately

Tablet core: cellulose microcrystalline, lactose monohydrate,

69.21 mg lactose. Each Tarceva® 150 mg tablet contains approximately 103.82 mg lactose.

What does the medicine look like and what are the

contents of the package
Tarceva® 100 mg is supplied as round, white to yellowish film-coated tablets with "T100" engraved on one side. Tarceva® 150 mg is supplied as round, white to yellowish film-coated tablets with "T150" engraved on one side.

Each package contains 30 tablets. License holder and address: Roche Pharmaceuticals (Israel) Ltd.

P.O.B. 6391, Hod Hasharon 4524079. www.roche.co.il Manufacturer's name and address:

F. Hoffmann-La Roche Ltd., Basel, Switzerland. This leaflet was revised in July 2021 according to MOH

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Tarceva® 100 mg film-coated tablets: 133.43.31233

Tarceva® 150 mg film-coated tablets: 133.41.31234

Roche)

Always use this medicine according to your doctor's

the doctor only.

For treatment of lung cancer: The usual dose is generally

one Tarceva® 150 mg tablet a day.

Usual dose

Check with the doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

starting treatment with this medicine. 3. HOW SHOULD YOU USE THE MEDICINE?

For treatment of metastatic pancreatic cancer: The usual dose is generally one Tarceva® 100 mg tablet a day. Tarceva® will be given in combination with the standard