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

This medicine is dispensed with a doctor's prescription only

IRESSA®

Film-Coated Tablets

Composition

Each film-coated tablet contains: Gefitinib 250 mg

For inactive ingredients, please see section 2 – "Important information regarding some of the ingredients of the medicine" and 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.

The medicine is intended for adults above 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic activity

Iressa is indicated for treatment of non-small cell lung cancer (NSCLC).

Iressa is indicated for treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with an activating mutations of EGFR-TK.

Therapeutic group

Medicines to treat cancer, EGFR inhibitor.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

Do not use the medicine if you are breastfeeding. Do not use this medicine if you have a known sensitivity to gefitinib or to any of the ingredients of the medicine (see section 6).

Special warnings regarding use of the medicine:

During the course of treatment with this medicine, perform periodic liver function tests.

Before treatment with Iressa, tell the doctor if:

- you have suffered in the past from other lung problems. Certain lung problems may worsen during the course of treatment with Iressa.
- you have suffered in the past from liver problems.

Children and adolescents

Iressa is not indicated in children and adolescents under the age of 18.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, especially if you are taking:

- phenytoin or carbamazepine (for epilepsy)
- rifampicin (for tuberculosis)
- itraconazole (for fungal infections)
- barbiturates (medicines to treat sleeping problems)
- herbal medicines containing St. John's Wort (*Hypericum perforatum*, for treatment of depression and anxiety).
- proton pump inhibitors, H_2 antagonists, antacids (for gastric ulcer, digestive disturbances, heartburn and reduction of gastric acidity).

These medicines may affect the way Iressa works.

- warfarin (an oral anticoagulant). If you are taking a medicine that contains this active ingredient, the doctor may perform blood tests more often.

If any of the above applies to you, or if you are uncertain, check with the doctor or pharmacist before taking Iressa.

Use of the medicine and food

The medicine can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or are planning to become pregnant or are breastfeeding, consult the doctor before taking Iressa.

It is recommended to avoid becoming pregnant during the course of treatment with Iressa, since Iressa may harm your baby.

Do not take Iressa if you are breastfeeding for the safety of your baby.

Driving and use of machines

You may feel weak during the course of treatment with Irresa. If this happens, do not drive or use any tools or machines.

Important information regarding some of the ingredients of the medicine

- This medicine contains lactose. If you have been told by a doctor that you have sensitivity to certain sugars, inform the doctor before taking the medicine.
- This medicine contains sodium. This medicine contains less than 1 mmol (23 mg) of sodium per tablet, that is to say it is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The recommended dosage is:

One tablet, once a day.

Do not exceed the recommended dose.

Take the medicine at set intervals, as determined by the attending doctor.

Adhere to the treatment regimen recommended by the doctor.

There is no information regarding halving the tablet.

Do not crush or chew the tablet. Swallow the medicine whole with water.

Do not take antacids (to reduce the acid level of the stomach) two hours before or one hour after taking Iressa.

The tablet can be added to half a glass of water (non-carbonated). Do not use other beverages. Place the tablet in water without crushing it. Mix until the tablet has dissolved (approximately 20 minutes) and drink immediately. To make sure that all the medicine has been drunk, rinse the glass well with half a glass of water and drink again.

If you forget to take this medicine at the scheduled time, take a dose as soon as you remember, as long as it is at least 12 hours before the next dosing time. Never take two doses together.
If less than 12 hours remain until the next dosing time, do not take the forgotten dose.

If you took an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

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 further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Iressa 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 them.

Refer to a doctor immediately if the following effects occur; you may need urgent medical treatment:

- Allergic reactions (common), particularly if the signs include swollen face, lips, throat or tongue, difficulty swallowing, hives (allergic skin reaction) and difficulty breathing.

- Serious breathlessness or sudden worsening of breathlessness, possibly accompanied by a cough or fever.

  Patients taking Iressa may develop an inflammation of the lungs called interstitial lung disease. This may affect 1 in 100 patients taking Iressa and can be life-threatening.
- Dehydration (common) caused as a result of severe or long-term diarrhea, vomiting, nausea or loss of appetite.
- Eye problems (uncommon), such as pain, redness, watery eyes, light sensitivity, changes in vision or ingrowing eyelashes. This may indicate that you have an ulcer on the surface of the eye (cornea).

Refer to the doctor as soon as possible if you notice any of the following side effects:

Very common side effects (occurring in more than one in ten users):

- Diarrhea
- Vomiting
- Nausea
- Skin reactions such as an acne-like rash, sometimes accompanied by itching, dry and/or cracked skin
- Loss of appetite
- Weakness
- Redness or ulcer in the mouth
- Increase of the liver enzyme alanine aminotransferase in blood tests; if its level is too high, the doctor may tell you to stop taking Iressa.

Common side effects (occurring in 1-10 out of 100 users):

- Nail problems
- Dry mouth
- Hair loss
- Dry, red and irritated eyes
- Red and sore eyelids
- Nosebleed, blood in the urine
- Fever

- Protein in the urine (shown in a urine test)
- Increase of bilirubin and another liver enzyme, aspartate aminotransferase, seen in blood tests; if these values are too high, the doctor may tell you to stop taking Iressa.
- Increase of creatinine levels in blood tests (related to kidney function).
- Cystitis (burning sensation during urination, frequent and urgent need to urinate).

Uncommon side effects (occurring in 1-10 out of 1,000 users):

- Inflammation of the pancreas, whose signs include very severe pain in the upper part of the stomach, severe nausea and vomiting.
- Inflammation of the liver, whose symptoms may include a general feeling of being unwell, with or without jaundice (yellow skin or eyes). This effect is uncommon; however, some patients have died from this.
- Gastrointestinal perforation.
- Skin reaction on the palms of the hands and soles of the feet including tingling, numbness, pain, swelling or reddening (known as palmar-plantar erythrodysaesthesia syndrome or hand and foot syndrome).

Rare side effects (occurring in 1-10 out of 10,000 users):

- Inflammation of the blood vessels in the skin, a condition that may give the appearance of bruising or patches of non-blanching rash on the skin upon application of pressure.
- Hemorrhagic cystitis (burning sensation during urination, frequent and urgent need to urinate with blood in the urine).

If a side effect occurs, if a side effect worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the "Report on side effects due to medication therapy" link on the Ministry of Health home

page (www.health.gov.il), which refers to the online form for side effects reporting, or by entering the link:
https://sideeffects.health.gov.il

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) that appears on the package. The expiry date refers to the last day of that month.
- Do not store this medicine at a temperature that exceeds 30°C. Store in the original package to protect from moisture.
- After the first opening: the blister pack should be used within one month of opening the flow-wrap.

Do throw away the medicine via household waste. Please consult the pharmacist how to destroy it.
In any case of doubt, consult the pharmacist who dispensed the medicine to you.
Do not store different medications in the same package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone, sodium lauryl sulfate, magnesium stearate, hypromellose, macrogol 300, titanium dioxide, yellow iron oxide, red iron oxide.
Each tablet contains 163.5 mg lactose (monohydrate)
Each tablet contains 3.86 mg sodium

What the medicine looks like and the contents of the package:
The package contains 3 aluminum envelopes; each aluminum envelope contains a blister with 10 tablets.

The tablet is round, biconvex and brown, with IRESSA 250 imprinted on one side and smooth on the other side.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 129 82 30895

Manufacturer:
AstraZeneca UK Limited, Macclesfield, UK.

License holder:
AstraZeneca (Israel) Ltd., 1 Atirei Yeda St., Kfar Saba 4464301.

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