PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

IRESSA ® 250 mg film coated tablets

(gefitinib)

Read all of this leaflet carefully before you start taking IRESSA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- IRESSA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What IRESSA is and what it is used for:

IRESSA contains the active substance gefitinib which blocks a protein called 'epidermal growth factor receptor' (EGFR). This protein is involved in the growth and spread of cancer cells.

IRESSA is used to treat adults with non-small cell lung cancer. This cancer is a disease in which malignant (cancer) cells form in the tissues of the lung.

2. What you need to know before you take IRESSA

Do not take IRESSA

- if you are hypersensitive (allergic) to gefitinib or any of the other ingredients of IRESSA (listed in section 6)
- if you are breast feeding
- if you are pregnant

Warnings and precautions

Take special care with IRESSA:

- if you have ever had any other lung problems. Some lung problems may get worse during treatment with IRESSA.
- if you have ever had problems with your liver

Children and adolescents

IRESSA is not indicated in children and adolescents under 18 years.

Other medicines and IRESSA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- If you take any of the following medicines: phenytoin, carbamazepine, rifampicin, barbiturates, St John's Wort or itraconazole, or any medicines that reduce the acidity in your stomach, such as ranitidine. These medicines may affect the way IRESSA works.

- If you take warfarin (to prevent blood-clots), as IRESSA may affect it. Your doctor may need to check your blood more often.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

It is recommended that you avoid becoming pregnant during treatment with IRESSA because IRESSA could harm your baby. Do not take IRESSA if you are breast-feeding for the safety of your baby.

Driving and using machines

If you feel weak whilst taking this medicine, you should not drive or use tools or machines.

IRESSA contains lactose

IRESSA contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars (lactose or galactose), contact your doctor before taking this medicine.

IRESSA contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per dose that means it is essentially ‘sodium-free’.

3. How to take IRESSA

Do not share medicines prescribed for you with any other person.

Always take IRESSA exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

- The usual dose is one 250 mg tablet per day.
- Take the tablet at about the same time each day.
- You can take the tablet with or without food.
- Do not take antacids (medicines to reduce the acid level of your stomach) 2 hours before or 1 hour after taking IRESSA.

If you have trouble swallowing the tablet, dissolve it in half a glass of still (non-fizzy) water. Do not use any other liquids. Do not crush the tablet. Swirl the water until the tablet has dissolved. This may take up to 20 minutes. Drink the liquid straight away. To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it.

Your doctor will tell you how long your treatment with IRESSA will last.
If you have the impression that the effect of IRESSA is too strong or too weak, tell you doctor or pharmacist.

If you take more IRESSA than you should (Overdose)

An increase of frequency and severity of some adverse reactions can occur, mainly diarrhoea and skin rash. See possible side effects (Section 4). Treatment is symptomatic and supportive, in particular for severe diarrhoea.
In any case, consult your doctor or pharmacist.
If neither is available, contact the nearest hospital or poison control centre.

If you forget to take IRESSA

What to do if you forget to take a tablet depends on how long it is until your next dose.

- If it is 12 hours or more until your next dose: take the missed tablet as soon as you remember. Then take the next dose as usual.
- If it is less than 12 hours until your next dose: skip the missed tablet. Then take the next tablet at the usual time.

Do not take a double dose (two tablets at the same time) to make up for a forgotten dose.

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

4. Possible side effects

IRESSA can have side effects.

Not all side effects reported for IRESSA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IRESSA, please consult your health care provider for advice.

If any of the following happens, stop taking IRESSA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reaction (frequent), particularly if symptoms include swollen face, lips, tongue or throat, difficulty to swallow, hives, nettle rash and difficulty breathing.
- Serious breathlessness, or sudden worsening breathlessness, possibly with a cough or fever. This may mean that you have an inflammation of the lungs called 'interstitial lung disease'. This may affect about 1 in 100 patients taking IRESSA and can be life-threatening.
- Severe skin reactions (less frequent) affecting large portions of your body. The signs may include redness, pain, ulcers, blisters, and shedding of the skin. The lips, nose, eyes and genitals may also be affected.
- Dehydration (frequent) caused by long term or severe diarrhoea, vomiting (being

sick), nausea (feeling sick) or loss of appetite.

- Eye problems (less frequent), such as pain, redness, watery eyes, light sensitivity, changes in vision or ingrowing eyelashes. This may mean that you have an ulcer on the surface of the eye (cornea).

These are all very serious side effects. If you have them, you may have had a serious reaction to IRESSA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Most frequent side effects:

- Diarrhoea
- Vomiting
- Nausea
- Skin reactions such as acne-like rash, sometimes itchy with dry and/or cracked skin
- Loss of appetite
- Weakness
- Red or sore mouth
- Increase of a liver enzyme known as alanine aminotransferase in a blood test; if too high, your doctor may tell you to stop taking IRESSA

Frequent side effects:

- Dry mouth
- Dry, red or itchy eyes
- Red and sore eyelids
- Nail problems
- Hair Loss

- Fever
- Bleeding (such as nosebleed or blood in your urine)
- Protein in your urine (shown in a urine test)
- Increase of bilirubin and the other liver enzyme known as aspartate aminotransferase in a blood test, if too high, your doctor may tell you to stop taking IRESSA.
- Increase of creatinine levels in a blood test (related to kidney function)
- Cystitis (burning sensations during urination and frequent, urgent need to urinate)

Less Frequent side effects:

- Inflammation of the pancreas. The signs include very severe pain in the upper part of the stomach area and severe nausea and vomiting.
- Inflammation of the liver. Symptoms may include a general feeling of being unwell, with or without possible jaundice (yellowing of the skin and eyes). This side effect is less frequent, 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).
- Inflammation of the blood vessels in the skin. This may give the appearance of bruising or patches of non-blanching rash on the skin.
- Haemorrhagic cystitis (burning sensations during urination and frequent, urgent need to urinate with blood in the urine). If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side

effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of IRESSA.

5. How to store IRESSA:

Store all medicines out of the sight and reach of children.

Store at or below 30 ^{o}C

Store in the original package in order to protect from moisture.

Do not use IRESSA after the expiry date stated on the blister / carton.

The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IRESSA contains

The active substance is gefitinib. Each tablet contains 250 mg of gefitinib. The other ingredients (excipients) are lactose monohydrate, microcrystalline cellulose (E460), croscarmellose sodium, povidone (K29-32) (E1201), sodium laurilsulfate,magnesium stearate, hypromellose (E464), macrogol 300, titanium dioxide (E171), yellow iron oxide (E172) and red iron oxide (E172).

What IRESSA looks like and contents of the pack

IRESSA is a round brown tablet marked with 'IRESSA 250' on one side and plain on the other.

IRESSA comes in blister packs of 30 tablets. The blister foil may be perforated or non-perforated.

Holder of Certificate of Registration

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West, Bryanston

Johannesburg, 2191

☎ (011) 797 6000

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Access to the corresponding Professional Information

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