

PART III: CONSUMER INFORMATION



This leaflet is part III of a three-part "Product Monograph" published when IRESSA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about IRESSA.

Contact your doctor or pharmacist if you have any questions about the drug.

Read all of this leaflet carefully before you start taking IRESSA. Keep this leaflet. You may need to read it again.

ABOUT IRESSA

What IRESSA is used for:

IRESSA is used for the initial treatment of adult patients with non-small cell lung cancer (NSCLC) that is locally advanced (not suitable for a curative therapy) or metastatic (when cancer cells have spread from the lung to the other part of the body) who have activating mutations of the Epidermal Growth Factor Receptor tyrosine kinase (EGFR-TK).

What IRESSA does:

IRESSA works by attaching to Epidermal Growth Factor Receptors (EGFRs) on the surface of cancer cells and blocking the signalling from EGFRs that are involved in the growth and spread of cancer cells. IRESSA works only in non-small cell lung cancer cells that have a mutation in their EGFRs.

Do not use IRESSA if:

- You are allergic to gefitinib or any of the other ingredients of IRESSA.

What the medicinal ingredient is:

gefitinib

What the important nonmedicinal ingredients are:

lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone, sodium lauryl sulphate, magnesium stearate, hypromellose, macrogol 300, titanium dioxide, yellow iron oxide and red iron oxide.

What dosage forms IRESSA comes in:

IRESSA is an oral tablet and each tablet contains 250 mg gefitinib. IRESSA comes in blister packs of 30 tablets.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

IRESSA should be prescribed by a health care professional experienced in the treatment and management of patients with cancer.

IRESSA should not be used in patients with EGFR mutation negative tumours.

IRESSA has not been studied in patients with severely reduced kidney function.

Isolated cases of liver failure have been reported in patients taking IRESSA, and some patients have died from this.

BEFORE you use IRESSA, talk to your doctor or pharmacist if:

- You have, or have had, lung diseases other than lung cancer. Some of them may worsen during treatment with IRESSA.
- You are pregnant, or plan to become pregnant.
- You are breastfeeding.
- You have a disorder affecting the liver.
- You have eye problems or wear contact lenses.
- You have kidney problems.
- You smoke, are at an advanced age, have a history of gastrointestinal ulceration, have cancer that has spread to the bowel, or are taking steroids or non-steroidal anti-inflammatory drugs.

Bleeding has been reported with the use of IRESSA such as nosebleed, blood in the urine, coughing up of blood and bleeding from the lungs.

IRESSA is not expected to impair your ability to drive or use machines. However, some patients may occasionally feel weak. If this happens, you should not drive or operate machinery.

IRESSA is not recommended for use in patients under 16 years of age.

INTERACTIONS WITH IRESSA

Please inform your doctor if you are taking or have taken any medicines (including medicines taken some time ago), even those available over the counter.

Your doctor especially needs to know if:

- You take any of the following medicines: phenytoin, carbamazepine, rifampicin, barbiturates, St John's Wort, itraconazole, ketoconazole, protease inhibitors (drugs to treat HIV/AIDS) or macrolide antibiotics such as erythromycin or clarithromycin. These medicines may affect the way IRESSA works. Your doctor should also know if you drink grapefruit juice.
- You take warfarin (to prevent blood-clots), as IRESSA may affect it. Your doctor may need to check your blood more often.
- You take any medicines which are used to help reduce stomach acid (e.g., ranitidine, sodium bicarbonate, proton-pump inhibitors).

PROPER USE OF IRESSA

Usual dose:

Take one 250 mg tablet, once a day, every day, at about the same time. You can take IRESSA with or without food.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose, take the last missed dose as soon as you remember, as long as it is at least 12 hours before the next dose is due.

If it is less than 12 hours until the next dose, do not take the dose you have missed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, IRESSA can have side effects. These are usually mild to moderate in intensity, and reversible. Side effects often start during the first month of taking IRESSA.

Talk to your doctor if any of the following happens to you. You may need further examinations or treatment:

Very common side effects (Greater than or equal to 10 of every 100 patients):

- Diarrhea, nausea, vomiting, stomatitis (red and sore mouth)
- Loss of appetite
- Skin reactions such as rash, itching dry and/or cracked skin
- Weakness (asthenia)

Common side effects (Greater than or equal to 1 every 100 patients, but less than 10 of every 100 patients):

- Dry mouth
- Nosebleed or blood in the urine
- Protein in your urine (shown in a urine test)
- Burning sensations during urination and frequent, urgent need to urinate (cystitis)
- Nail problems
- Loss of hair
- Eye problems (dry, red, itchy eye or red and sore eyelid)
- Fever

Uncommon side effects (Greater than or equal to 1 of every 1000 patients, but less than 1 of every 100 patients):

- Unexpected bleeding if you are taking warfarin.

The following side effects can also occur with IRESSA, and they are seen when a blood test is taken:

Very common (Greater than or equal to 10 of every 100 patients):

- Changes to the level of one liver enzyme known as alanine aminotransferase (ALT).

Common (Greater than or equal to 1 every 100 patients, but less than 10 of every 100 patients):

- Changes to the level of bilirubin and the other liver enzyme known as aspartate aminotransferase (AST).
- Changes to the level of creatinine in your blood, which shows how well your kidneys

are working. This is often a consequence of diarrhea or vomiting, which may lead to severe dehydration.

Uncommon (Greater than or equal to 1 of every 1000 patients, but less than 1 of every 100 patients):

- Changes to the way your blood clots, if you are taking warfarin (medicine to prevent blood-clotting).

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM	
Symptom / effect	Talk with your doctor or pharmacist in all cases
Common (Greater than or equal to 1 every 100 patients, but less than 10 of every 100 patients)	
Dehydration following persistent or severe diarrhoea, vomiting, nausea (feeling sick), or loss of appetite. Dehydration may lead to renal dysfunction if left untreated.	√
Serious breathlessness, or sudden worsening breathlessness, possibly with a cough or fever. Some patients taking IRESSA get an inflammation of the lungs called interstitial lung disease and some patients have died from this.	√
Uncommon (Greater than or equal to 1 of every 1000 patients, but less than 1 of every 100 patients)	
New eye problems, such as pain, redness, watery eyes, light sensitivity, or changes in vision. Ulcers on the surface of the eye (cornea), sometimes with in-growing eyelashes have been observed.	√
Inflammation of the pancreas with symptoms such as very severe pain in the upper part of the stomach area and severe nausea (feeling sick) and vomiting.	√
Allergic reactions, including swelling of the lips and hives or nettle-rash.	√
Inflammation of the liver or liver failure. Symptoms may include a general feeling of being unwell, nausea, vomiting, with or without possible jaundice (yellowing of the skin and eyes).	√
Gastrointestinal perforation (a hole through the wall of the stomach or intestine, which may be detected by X-Ray or scan)	√
Rare (Greater than or equal to 1 in every 10000, but less than 1 in every 1000 patients)	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist in all cases
Inflammation of the blood vessels in the skin. This may give the appearance of bruising or patches of non-blanching rash on the skin.	√
Severe skin reactions affecting large portions of the body including redness, pain, ulcers, blisters, skin sloughing or involvement of lips and mucous membranes (toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme).	√
Burning sensations during urination and frequent, urgent need to urinate with blood in the urine (hemorrhagic cystitis)	√

This is not a complete list of side effects. For any unexpected effects while taking IRESSA, contact your doctor or pharmacist.

HOW TO STORE IRESSA

Keep out of the reach and sight of children.

Store at room temperature, 15 to 30°C.

Keep IRESSA in the original package in order to protect it from moisture.

Do not use IRESSA after the expiry date on the blister pack.

Remember to return any unused IRESSA to your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada website at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing. Please refer to the CONSUMER INFORMATION leaflet located at www.astrazeneca.ca to see if more up-to-date information has been posted.

Customer Inquiries – 1 (800) 668-6000,
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