**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory.**

GEFITINIB TABLETS IP

IRESSA 250mg™– Abbreviated Prescribing Information

- INDICATIONS
  - IRESSA is indicated for the first line treatment of patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have activating mutations of the EGFR TK (see section Warnings and Precautions).
  - IRESSA is indicated for the treatment of patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have previously received chemotherapy or who are not suitable for chemotherapy.
- DOSAGE & ADMINISTRATION: Recommended dose is 250 mg orally, once daily with or without food. No dosage adjustment is required based on patient age, body weight, gender, ethnicity, renal function or in patients with moderate to severe hepatic impairment due to liver metastases.
- CONTRAINDICATIONS: Known severe hypersensitivity to the active substance or to any of the excipients of this product.
- WARNINGS & PRECAUTIONS:
  - Interstitial lung disease (ILD): ILD occurred in patients taking IRESSA. Withhold IRESSA for worsening of respiratory symptoms. Discontinue IRESSA if ILD is confirmed.
  - Hepatotoxicity: Obtain periodic liver function testing. Withhold IRESSA for Grade 2 or higher for ALT and/or AST elevations. Discontinue for severe hepatic impairment.
  - Gastrointestinal perforation: Discontinue IRESSA for gastrointestinal perforation.
  - Ocular Disorders including Keratitis: Withhold IRESSA for signs and symptoms of severe or worsening ocular disorders including keratitis. Discontinue for persistent ulcerative keratitis.
  - Embryo-foetal Toxicity: Can cause foetal harm. Advise of potential risk to a foetus and use of effective contraception.
- ADVERSE REACTIONS: The most commonly reported adverse drug reactions (ADRs), reported in more than 20% of the patients and greater than placebo were skin reactions and diarrhea.
- INTERACTIONS: Co-administration with rifampicin (a known potent CYP3A4 inducer) in healthy volunteers reduces mean gefitinib AUC by 83% of that without rifampicin. Concomitant administration with potent inhibitors of CYP3A4 activity may increase gefitinib plasma concentrations. Monitor adverse reactions if concomitant use with IRESSA. Drugs Affecting Gastric pH: Avoid concomitant use of IRESSA with proton pump inhibitors, if possible. Haemorrhage in patients taking warfarin: Monitor changes in prothrombin time or INR.

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- PHARMACOLOGICAL PROPERTIES:

  ### Mechanism of action

  Gefitinib is a selective inhibitor of the epidermal growth factor receptor (EGFR) tyrosine kinase, commonly expressed in solid human tumours of epithelial origin. Inhibition of EGFR tyrosine kinase activity inhibits tumour growth, metastasis and angiogenesis and increases tumour cell apoptosis

  ### Pharmacokinetic properties

  Following oral dosing, absorption is moderately slow and the mean terminal half-life is 41 hours. Administration of gefitinib once daily results in 2 to 8-fold accumulation with steady state exposures achieved after 7 to 10 doses. At steady state, circulating plasma concentrations are typically maintained within a 2 to 3-fold range over the 24-hour dosing interval. Gefitinib exhibits Mean absolute bioavailability of 59%, has 1400L of Volume of Distribution, is metabolized majorly by Cytochrome P450 3A4 and has total plasma clearance of 500 mL/min.

- PRESENTATION & STORAGE: Brown, round, biconvex, film-coated tablet impressed with "IRESSA 250" on one side and plain on the other. Each film-coated tablet contains: Gefitinib IP 250mg. Store protected from light and moisture.

- SHELF LIFE: Refer outer carton.

IRESSA™ is a trademark of AstraZeneca group of companies.

Consult full prescribing information before prescribing.

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For more information, refer full prescribing information Version 3, dated 1st Dec 2013