Abridged Prescribing Information

Erlomy™ (Erlotinib)

Composition: Each film-coated tablet contains: Erlotinib Hydrochloride IP equivalent to erlotinib 100 and 150 mg. **Indications: Non-Small-Cell Lung Cancer (NSCLC).** Erlotinib is indicated as monotherapy for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. **Dosage and Administration:** NSCLC**:** The recommended daily dose of erlotinib is 150 mg taken at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity occurs. When dose reduction is necessary, the erlotinib dose should be reduced in 50 mg decrements. There is no evidence that treatment beyond progression is beneficial. **Special populations**: a) Pregnancy: It may cause fetal harm when administered to pregnant women. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment of erlotinib. Adequate contraceptive methods should be used during therapy and for at least 2 weeks after completing therapy. b) Nursing mothers: It is recommended that nursing be discontinued when receiving therapy with Erlotinib. c) Pediatric use: The safety and effectiveness of Erlotinib in pediatric patients have not been established. d) Geriatric use: No dosage adjustments are recommended in elderly patients. **Contraindications:** Erlotinib is contraindicated in patients with severe hypersensitivity reactions to Erlotinib or any of its components. The concomitant use of erlotinib with potent inducers of cytochrome P-450 (CYP) isoenzyme 3A4 (eg: Rifabutin, rifampin, rifapentin, phenytoin, carbamazepine, phenobarbital, St. John's wort) should be avoided. Patients on oral anticoagulants should be closely monitored when doses of erlotinib are started, modified or discontinued. **Interactions:** CYP3A4 inhibitors or a combined CYP3A4 and CYP1A2 inhibitor increase erlotinib plasma concentrations. Avoid concomitant use. If not possible, reduce erlotinib dose. CYP3A4 inducers decrease erlotinib plasma concentrations. Avoid concomitant use. If not possible, increase erlotinib dose. Cigarette smoking and CYP1A2 inducers decrease erlotinib plasma concentrations. Avoid concomitant use. If not possible, increase erlotinib dose. Drugs that increase gastric pH decrease erlotinib plasma concentrations. For proton pump inhibitors, avoid concomitant use if possible. For H2 receptor antagonists, take erlotinib 10 hours after H2 receptor antagonist dosing. For use with antacids, separate dosing by several hours. **Warnings and Precautions:** a) In patients receiving erlotinib for treatment of NSCLC and pancreatic cancer, there have been reports of interstitial lung disease. Symptoms started from 5 days to more than 9 months after initiating erlotinib therapy. b) Cases of hepatic failure, renal failure, gastrointestinal perforations, bullous and blistering conditions, myocardial infarction, cerebrovascular accident, microangiopathic hemolytic anemia with thrombocytopenia and ocular disorders have been reported during the use of erlotinib. **Adverse Reactions**: Diarrhea, nausea, vomiting, stomatitis, rash, acne, pruritus, dry skin, interstitial lung disease, dyspnea, couth, elevated liver enzymes, hyperbilirubinemia and conjunctivitis. **Storage:** Store at a temperature not exceeding 30°C.

Dated: 7th September 2017

For more details and information, please refer the pack insert or full prescribing information.