

## Lefenta 600

Lefamulin INN 600 mg

**Composition:** Each film coated tablet contains Lefamulin INN 600 mg as Lefamulin Acetate.

**Pharmacology:** Lefamulin is a systemic pleuromutilin antibacterial. It inhibits bacterial protein synthesis through interactions (hydrogen bonds, hydrophobic interactions, and Van der Waals forces) with the A- and P-sites of the peptidyl transferase center (PTC) in domain V of the 23s rRNA of the 50S subunit.

**Indications:** It is indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae* and *Chlamydia pneumoniae*. To reduce the development of drug resistant bacteria and maintain the effectiveness of Lefamulin and other antibacterial drugs, it should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

**Dosage and administration:** For treatment of adults with CABP, the recommended dosage of Lefamulin is 600mg orally every 12 hours for 5 days. It should be taken at least 1 hour before a meal or 2 hours after a meal. Swallow this tablets whole with water. Do not crush or divide the tablets. Or, as directed by the registered physician.

**Contraindication:** It is contraindicated in patients with known hypersensitivity to lefamulin, pleuromutilin class drugs, or any of the components. Concomitant use of Lefamulin tablets with CYP3A substrates that prolong the QT interval is contraindicated.

**Precaution: QT Prolongation:** Lefamulin has the potential to prolong the QT interval. Avoid use in patients with known QT prolongation, ventricular arrhythmias, and patients receiving drugs that prolong the QT interval. **Clostridium difficile-associated Diarrhea:** CDAD has been reported with use of nearly all antibacterial agents, including Lefamulin, and may range in severity from mild diarrhea to fatal colitis.

**Side Effects:** Most common side effects are: diarrhea, nausea, vomiting, hepatic enzyme elevation.

**Pregnancy and Lactation:** Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception. A lactating woman should pump and discard human milk for the duration of treatment with Lefamulin and for 2 days after the final dose.

**Use in Children:** The safety and effectiveness of Lefamulin in patients less than 18 years of age has not yet been established.

**Drug Interactions:** Concomitant use of oral or intravenous Lefamulin with strong CYP3A4 inducers or P-gp inducers or strong CYP3A inhibitors or P-gp inhibitors which may decrease the efficacy of Lefamulin or increase the risk of adverse reactions with Lefamulin tablets. Concomitant use of Lefamulin Tablets with strong CYP3A4 substrates increases the AUC and C<sub>max</sub> of CYP3A4 substrates, which may increase the risk of toxicities associated with cardiac conduction. Concomitant use with strong CYP3A substrates with Lefamulin tablets requires close monitoring for adverse effects of these drugs (For example: alprazolam, diltiazem, verapamil, simvastatin, vardenafil). Avoid concomitant use of Lefamulin tablets with drugs that prolong QT such as (For example: Class IA, Class III antiarrhythmic agents, antipsychotics, erythromycin, moxifloxacin, and tricyclic antidepressants).

**Overdose:** Treatment of overdose with Lefamulin should consist of observation and general support measures. Lefamulin and its primary metabolite are not dialyzable.

**Storage:** Store below 30°C in a cool and dry place. Protect from light and moisture. Keep out of the reach of children.

**Packing:** Each box contains 10's tablets in a blister pack.



Manufactured by

**DRUG INTERNATIONAL LTD.**

Tongi, Gazipur, Bangladesh

04/2024/Nil