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XLLUNORIDE® (rufinamide) Tablet, Film Coated for Oral Use

XLLUNORIDE® (rufinamide) Oral Suspension

Epilepsy is a chronic (meaning it lasts for a long time) condition that is defined by seizures.¹ Lennox-Gastaut syndrome (LGS) is a rare and severe form of epilepsy.

(Lennox-Gastaut syndrome treatment)

XLLUNORIDE®
(rufinamide) 200mg, 400mg TABLETS
40mg/mL ORAL SUSPENSION



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(rufinamide) 200mg, 400mg TABLETS
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XLLUNORIDE® (rufinamide) is a prescription medication approved for the adjunctive treatment of seizures associated with LGS in children 4 years and older and adults.

INDICATIONS AND USAGE

XLLUNORIDE® (rufinamide) is an anti-epileptic drug indicated for:

- Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults.

XLLUNORIDE® should be given with food. Tablets can be administered whole, as half tablets, or crushed.

The prescribed amount of the oral suspension should be measured using the provided adapter and dosing syringe.

Children four years and older with LGS: Treatment should be initiated at a daily dose of approximately 10 mg/kg/day administered in two equally divided doses.

The dose should be increased by approximately 10 mg/kg increments every other day to a target dose of 45 mg/kg/day or 3200 mg/day, whichever is less, administered in two equally divided doses.

Adults with LGS: Treatment should be initiated at a daily dose of 400-800 mg/day administered in two equally divided doses. The dose should be increased by 400-800 mg every other day until a maximum dose of 3200 mg/day, administered in two equally divided doses is reached.

Important Information for Women

XLLUNORIDE® may make hormonal contraceptives (birth control pills) less effective. Additional nonhormonal forms of birth control are recommended when using XLLUNORIDE®. Healthcare providers should be informed if patients are pregnant or planning on becoming pregnant.

Also, XLLUNORIDE® is likely to be passed through breast milk to the baby and could cause serious side effects in the baby. A decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

XLLUNORIDE® should be given with food. Tablets can be administered whole, as half tablets or crushed, for dosing flexibility.

Food and Drug Administration (FDA) approved .Prescription Only (POM)

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