Rolax®

(USP Specification)
Escitalopram
(USP Specification)

10mg & 20mg Film Coated Tablets

COMPOSITION:
ROLAX 10mg Tablets: Each film coated tablet contains:
Escitalopram as oxalate ..... 10mg.
(USP Specification)

ROLAX 20mg Tablets: Each film coated tablet contains:
Escitalopram as oxalate ..... 20mg.
(USP Specification)

DESCRIPTION:
ROLAX tablet (Escitalopram) is a potent selective serotonin re-uptake inhibitor (SSRI). It is the active isomer of citalopram.

CLINICAL PARTICULARS:
Indications:
- Treatment of major depressive disorder
- Prevention of depression relapse

Dosage:
In adults: The initial dose of **ROLAX** tablets is 10 mg once daily. If required, the dose might be increased to 20mg after a minimum of one week period.
In old age: Single oral dose of 10 mg/day is recommended.
In hepatic dysfunction: Not more than 10 mg/day.
In renal dysfunction: No dosage adjustment is required in mild to moderate renal impairment. It should be cautiously given in severe renal dysfunction.
Contraindications:
ROLAX tablet is contraindicated in patients with known hypersensitivity to escitalopram , citalopram or any ingredient of the product.

Precautions:
Use with Monoamine Oxidase Inhibitors (MAOIs): Like with other SSRIs, combination with monoamine oxidase inhibitor (MAOI) might result in serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability, rapid changes in vital signs, and mental status changes, including extreme agitation progressing to delirium and coma. The patients who switch from an SSRI to an MAOI might present with the same features. Hence **ROLAX** tablets should not be co-administered with an MAOI or within 2 weeks of discontinuing treatment with an MAOI. Also, at least a gap of 2 weeks should be given after discontinuing **ROLAX** tablets and starting an MAOI.
Chances of mania or hypomania: Mania/hypomania might occur in patients treated with **ROLAX** tablets. In such cases **ROLAX** tablets should be discontinued. Also, **ROLAX** tablets should be used with caution in patients with history of mania.
Use in patients with history of seizures: Like other antidepressants, **ROLAX** tablets should be cautiously used in patients with a history of seizure disorder.
Drug Interactions:
Because of reported drug interactions, special caution should be exercised while co-administering **ROLAX** tablets with monoamine oxidase Inhibitors (MAOIs), CNS drugs, alcohol, cimetidine, ketoconazole, desipramine and metoprolol.
Pregnancy:
The safety of **ROLAX** tablets during pregnancy has not been established. Therefore, **ROLAX** tablets should not be used during pregnancy, unless the expected benefits to the patient markedly outweigh the possible hazards to the fetus.
Lactation:
The safety of **ROLAX** tablets during breastfeeding has not been established. Since escitalopram is excreted in human milk. **ROLAX** tablets should not be administered to nursing mothers unless the expected benefits to the patient markedly outweigh the possible hazards to the child.
Use in Children:
Safety and efficacy in children under the age of 18 years have not been established.
Use in Old Age:
Though no overall differences in safety or efficacy between old age patients and younger patients was observed, dose of 10 mg is the recommended dosage for elderly patients.
Side Effects:
The side effects reported are agitation, restlessness, blurred vision, diarrhea, difficulty in sleeping, drowsiness, dry mouth, fever, frequent urination, headache, indigestion, nausea, increased or decreased appetite, increased sweating, sexual difficulties like decreased sexual ability or libido & ejaculatory delay, change in taste, tremor, and weight changes.
Rarely confusion, dizziness, lightheadedness, skin rash, itching, suicidal thoughts, and vomiting have occurred.
Overdose:
Use of escitalopram in high doses of up to 600mg has been found to be associated with reversible symptoms like dizziness, sweating, nausea, vomiting, tremor and somnolence. Rarely confusion, loss of consciousness, convulsions, coma, sinus tachycardia, cyanosis, hyperventilation and rhabdomyolysis might occur.
In such cases following measures should be taken: airway maintenance, gastric lavage, use of activated charcoal, cardiac arid vital sign monitoring and general symptomatic and supportive measures. There is no specific antidote for escitalopram.

STORAGE:
Store at 20°C-25°C. Protect from light and moisture.
(excursions permitted to 15°C-30°C)

HOW SUPPLIED
ROLAX 10mg Tablets: Pack of 10 film coated tablets.
ROLAX 20mg Tablets: Pack of 10 film coated tablets

TO BE SOLD ON THE PRESCRIPTION OF A REGISTERED MEDICAL PRACTITIONER ONLY.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Lactose & Gluten Free

رولکس

اسیٹالوپرام

10 ملی گرام اور 20 ملی گرام فلم کوٹڈ گولیاں

خوراک وہدایات

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔
دوا کو 25°C-20°C درجہ حرارت پر، نمی اور روشنی سے محفوظ رکھیں۔
(درجہ حرارت کی حد 15°C سے 30°C ہے)

NEXT PHARMACEUTICAL

Manufactured by:
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