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# Exapro<sup>®</sup>

(Escitalopram)  
Tablet

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#### COMPOSITION:

##### Exapro Tablet 5 mg:

Each film coated tablet contains:  
Escitalopram Oxalate USP equivalent to  
Escitalopram ..... 5 mg.

##### Product Specs.: USP

##### Exapro Tablet 10 mg:

Each film coated tablet contains:  
Escitalopram Oxalate USP equivalent to  
Escitalopram ..... 10 mg.

##### Product Specs.: USP

##### Exapro Tablet 20 mg:

Each film coated tablet contains:  
Escitalopram Oxalate USP equivalent to  
Escitalopram ..... 20 mg.

##### Product Specs.: USP

#### DESCRIPTION:

Exapro tablet (Escitalopram Oxalate) is a potent selective serotonin reuptake inhibitor (SSRI). It is the active isomer of citalopram.

#### DOSAGE:

**In adults:** The initial dose of Exapro tablets is 10 mg once daily. If required, the dose might be increased to 20 mg 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.

#### INDICATIONS:

- Treatment of major depressive disorder.
- Prevention of depression relapse.

#### CONTRAINDICATIONS:

Exapro tablet is contraindicated in patients with known hypersensitivity to Escitalopram Oxalate, citalopram or any ingredient of the product.

#### 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, light headedness, skin rash, itching, suicidal thoughts, and vomiting have occurred.

#### 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 Exapro tablets should not be coadministered 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 Exapro tablets and starting an MAOI. Chances of Mania or Hypomania Mania/hypomania might occur in patients treated with Escitalopram. In such cases Exapro tablets should be discontinued also. Exapro tablets should be used with caution in patients with history of mania.

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#### Use in patients with history of seizures:

Like other antidepressants, Exapro tablets should be cautiously used in patients with a history of seizure disorder.

#### Use during pregnancy:

The safety of Exapro tablets during pregnancy has not been established. Therefore, Exapro tablets should not be used during pregnancy, unless the expected benefits to the patient markedly outweigh the possible hazards to the fetus.

#### Use in nursing mothers:

The safety of Exapro tablets during breastfeeding has not been established. Since Escitalopram is excreted in human milk. Exapro 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.

#### OVERDOSE:

Use of Escitalopram in high doses of up to 600 mg 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 and vital sign monitoring and general symptomatic and supportive measures. There is no specific antidote for Escitalopram.

#### DRUG INTERACTIONS:

Because of reported drug interactions, special caution should be exercised while co-administering Exapro tablets with monoamine oxidase inhibitors (MAOIs), CNS drugs, alcohol, cimetidine, ketoconazole, desipramine and metoprolol.

#### INSTRUCTIONS:

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

#### PRESENTATION:

Exapro Tablet 5 mg	:	Pack of 14 tablets.
Exapro Tablet 10 mg	:	Pack of 14 tablets.
Exapro Tablet 20 mg	:	Pack of 14 tablets.

ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔  
گرمی، دھوپ اور نمی سے بچائیں۔  
بچوں کی پہنچ سے دور رکھیں۔  
صرف ڈاکٹر کے نسخے پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

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25029-0001-012-0000-0000



Manufactured by:  
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