AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
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LEAFLET

FLUOXETINE TABLETS USP 20 MG

COMPOSITION:
Each film coated tablet contains:
Fluoxetine Hydrochloride USP
Equivalent to Fluoxetine ..... 20 mg
Excipients ..... q.s.
Approved colour used.

CLINICAL PHARMACOLOGY:
It is a selective serotonin reuptake inhibitor for oral administration.

INDICATIONS AND USAGE:
It is indicated for all types of depression, especially where no sedation is required.

Major Depressive Disorder :
Fluoxetine is indicated for the acute and maintenance treatment of Major Depressive Disorder in adult patients and in pediatric patients aged 8 to 18 years.

Obsessive Compulsive Disorder :
Fluoxetine is indicated for the acute and maintenance treatment of obsessions and compulsions in adult patients and in pediatric patients aged 7 to 17 years with Obsessive Compulsive Disorder.

Bulimia Nervosa:
Fluoxetine is indicated for the acute and maintenance treatment of binge-eating and vomiting behaviors in adult patients with moderate to severe bulimia nervosa.

Panic Disorder:
Fluoxetine is indicated for the acute treatment of Panic Disorder, with or without agoraphobia, in adult.

DOSAGE:
As directed by the physician.

SIDE EFFECTS AND ADVERSE REACTIONS :
Anxiety, nervousness, insomnia, drowsiness, fatigue or lrthargy, tremor, sweating, G.I complaints like anorexia, nausea, diarrhea, light headedness.

OVERDOSAGE AND TREATMENT :
Ensure an adequate airway, oxygenation, and ventilation. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with a large-bore or gastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion, or in symptomatic patients. Activated charcoal should be administered. Due to the large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. No specific antidotes for Fluoxetine are known.

CONTRAINDICATIONS :
It is contraindicated in severe renal failure, nursing mothers, hypersensitivity.

DRUG INTERACTIONS :
Tryptophan may produce agitation, restlessness and gastric distress. Increased sedative effects on the CNS. Fluoxetine reduces the breakdown of tricyclic antidepressants, change in serum lithium level.

WARNINGS AND PRECAUTION :
Atleast 14 days gap between discontinuation of MAO inhibitor and initiation of Fluoxetine. Pregnancy, lactation, possibility of suicide attempt, mania, hypomania or convulsions. Care should be taken when operating machines and while driving.

STORAGE:
Store under normal storage conditions (15°C to 30°C)
Protect from light.

Keep all medicines out of reach of children.

PRESENTATION :
Blister packs of 10 x 10 Tablets.
Jar packs of 100 / 1000 Tablets.

Manufactured in India by:
AGOG PHARMA LTD.
Plot No. 33, Sector II, The Vasai Taluka Indl.
Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.