110 mm

FLUTEX®

FLUOXETINE CAPSULES USP 20 mg

COMPOSITION:
Each hard gelatin capsule contains:
Fluoxetine Hydrochloride USP
Equivalent to Fluoxetine 20 mg
Excipients q.s.
Approved colours are used in hard gelatin capsule shell.

PHARMACALOGICALCLASSIFICATION: SSRI

PHARMACOLOGICAL ACTION: Metabolized to norfluoxetine, fluoxetine is a selective serotonin-reuptake inhibitor (SSRI), it blocks the reuptake of serotonin at the serotonin reuptake pump of the neuronal membrane, enhancing the actions of serotonin on 5HT1Autoreceptors.
SSRIs bind with significantly less affinity to histamine, acetylcholine, and norepinephrine receptors than tricyclic antidepressant drugs.

Pharmacokinetics and Metabolism: Well absorbed from the GI tract following oral administration. Oral bioavailability is estimated to be at least 60-80%. Peak plasma concentrations occur within 4-8 hours following oral administration of conventional dosage preparations.
Volume of distribution 20-45 L/kg
Protein binding 94.5%

Metabolism: Limited data from animal studies suggest that fluoxetine may undergo first-pass metabolism may occur via the liver and/or lungs. Fluoxetine appears to be extensively metabolized, likely in the liver, to norfluoxetine and other metabolites. Norfluoxetine, the principal active metabolite, is formed via N-demethylation of fluoxetine. Norfluoxetine appears to be comparable pharmacologic potency as fluoxetine. Fluoxetine and norfluoxetine both undergo phase II glucuronidation reactions in the liver. It is also thought that fluoxetine and norfluoxetine undergo O-dealkylation to form p-trifluoromethylphenol, which is then subsequently metabolized to hippuric acid.

Enzyme	Metabolite	Reaction	K_m	V_{max}
Cytochrome P450 2D6	Norfluoxetine	N-demethylation	0	0
Cytochrome P450 3A4	Norfluoxetine	N-demethylation		
Cytochrome P450 3A4	para-Trifluoromethylphenol	O-dealkylation		
Cytochrome P450 2C9	Norfluoxetine	N-demethylation		
Cytochrome P450 2C19	para-Trifluoromethylphenol	O-dealkylation		

Route of elimination: The primary route of elimination appears to be hepatic metabolism to inactive metabolites excreted by the kidney.
Half-life 1-3 days
Clearance Not Available

INDICATIONS:
FLUTEX® is a selective serotonin reuptake inhibitor indicated for: Acute and maintenance treatment of Major Depressive Disorder (MDD) in adult and pediatric patients aged 8 to 18 years, Acute and maintenance treatment of Obsessive Compulsive Disorder (OCD) in adult and pediatric patients aged 7 to 17 years, Acute and maintenance treatment of Bulimia Nervosa in adult patients Acute treatment of Panic Disorder with or without agoraphobia, in adult patients FLUTEX and olanzapine in combination for: Acute treatment of Depressive Episodes Associated with Bipolar I Disorder in adults. Acute treatment of Treatment Resistant Depression in adults (Major Depressive Disorder in adult patients who do not respond to 2 separate trials of different antidepressants of adequate dose and duration in the current episode).

CONTRA-INDICATIONS:
Do not use with an MAOI (Monoamine Oxidase Inhibitors) or within 14 days of discontinuing an MAOI due to risk of drug interaction. At least 5 weeks should be allowed after stopping FLUTEX before treatment with an MAOI, Do not use with pimozide due to risk of drug interaction or QTc prolongation. Do not use with thioridazine due to QTc interval prolongation or potential for elevated thioridazine plasma levels. Do not use thioridazine within 5 weeks of discontinuing FLUTEX. When using FLUTEX and olanzapine in combination, also refer to the Contraindications section of the package insert for Symbyax.

WARNINGS AND PRECAUTIONS:
Clinical Worsening and Suicide Risk Monitor for clinical worsening and suicidal thinking and behaviour.
Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported with FLUTEX. Discontinue FLUTEX and initiate supportive treatment.
Allergic Reactions and Rash Discontinue upon appearance of rash or allergic phenomena.
Activation of Mania/Hypomania: Screen for Bipolar Disorder and monitor for mania/hypomania.
Seizures Use cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold.
Altered Appetite and Weight Significant weight loss has occurred.
Abnormal Bleeding may increase the risk of bleeding. Use with NSAIDs, aspirin, warfarin, or drugs that affect coagulation may potentiate the risk of gastrointestinal or other bleeding .
Anxiety and Insomnia may occur.
Potential for Cognitive and Motor Impairment has potential to impair judgment, thinking, and motor skills. Use caution when operating

190 mm

Front

machinery.
Long Half-Life Changes in dose will not be fully reflected in plasma for several weeks.
FLUTEX and Olanzapine in Combination When using FLUTEX and olanzapine in combination, also refer to the Warnings and Precautions section of the package insert for Symbyax.

DOSAGE AND ADMINISTRATION :

Indication	Adult	Pediatric
Major Depressive Disorder (MDD)	20 mg/day in am (initial dose)	10 to 20 mg/day (initial dose)
Obsessive Compulsive Disorder (OCD)	20 mg/day in am (initial dose)	10 mg/day (initial dose)
Bulimia Nervosa	60 mg/day in am	-
Panic Disorder	10 mg/day (initial dose)	-
Depressive Episodes Associated with Biploar I Disorder	Oral in combination with olanzapine: 5 mg of oral olanzapine and 20 mg of fluoxetine once daily (initial dose)	-
Treatment Resistant Depression	Oral in combination with olanzapine: 5 mg of oral olanzapine and 20 mg of fluoxetine once daily (initial dose)	-

Consider tapering the dose of fluoxetine for pregnant women during the third trimester.
A lower or less frequent dosage should be used in patients with hepatic impairment, the elderly, and for patients with concurrent disease or on multiple concomitant medications
Dosing with FLUTEX Weekly capsules-initiate 7 days after the last daily dose of FLUTEX 20 mg FLUTEX and olanzapine in combination.
Dosage adjustments, if indicated, should be made with the individual components according to efficacy and tolerability. Fluoxetine monotherapy is not indicated for the treatment of Depressive Episodes associated with Bipolar Disorder or treatment resistant depression. Safety of the co-administration of doses above 18 mg olanzapine with 75 mg fluoxetine has not been evaluated.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Get emergency medical help if you have any of these signs of an allergic reaction to FLUTEX: skin rash or hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Report any new or worsening symptoms to your doctor, such as: mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Call your doctor at once if you have any of these serious side effects while taking FLUTEX: severe blistering, peeling, and red skin rash; very stiff (rigid) muscles, high fever, sweating, fast or uneven heartbeats, tremors, overactive reflexes; nausea, vomiting, diarrhea, loss of appetite, feeling unsteady, loss of coordination; or headache, trouble concentrating, memory problems, weakness, confusion, hallucinations, fainting, seizure, shallow breathing or breathing that stops. Less serious FLUTEX side effects may include: cold symptoms such as stufly nose,sneezing, sore throat; drowsiness, dizziness, feeling nervous; mild nausea, upset stomach, constipation; increased appetite, weight changes; sleep problems(insomnia); decreased sex drive, impotence, or difficulty having an orgasm; or dry mouth.

KNOWN SYMPTOMS OF OVERDOSAGE:
Overdose may cause nausea, vomiting, fever, sleepiness, rapid or uneven heartbeat, confusion, fainting, seizures, or coma.
Seek emergency medical attention.

IDENTIFICATION: FLUTEX:
Ivory/Ivory coloured hard gelatin size 2 capsules having printing 'Flutex' in green colour on cap & fidson in green colour on body.

PRESENTATION:
Printed Alu-Alu blister of 10 capsules and in a carton (3x10's).

STORAGE INSTRUCTIONS:
Store below 30°C. Protect from light.
Keep all medicines out of the reach of children.

NAFDAC REG. NO: 04-8881

vsi
Manufactured by :
V. S. International Pvt. Ltd.
Plot No.: 17&18, Golden Indl. Estate,
Somnath Road, Dabhel, Daman - 396215, India.

FIDSON
Marketed by :
Fidson Healthcare Plc.
268, Ikorodu Road, Obanikoro, Lagos, Nigeria.
email: info@fidson.com Website: www.fidson.com

Back

Product Name	**FLUTEX**	**Item Code :**	**XXXXXXX**	**Reference Art. :**	**PMF0007**
Packaging Material	**Pack Insert**	**Reason of Change :**	**NEW**	**Specification :**	
Foil Width	**NA**	**Country :**	**NIGERIA**	**GSM**	**60 GSM**
Blister Type	**NA**	**Pack Size :**	**3 x 10's Tablets**	**Board / Paper**	**Maplitho Paper**
Blister Size	**NA**	**Barcode No :**	**NA**	**Varnish Type**	**NA**
Foil Thickness	**NA**	**Pharmacode :**	**NA**	**Grain Direction**	**NA**
Carton Size	**NA**	**Min. Font Size :**	**6 Pt.**	**Braille**	**NA**
Leaflet Size	**110 (L) x 190 (H) mm**	**Language :**	**Eng**	**Finishing Operation**	**NA**
No of Colors : 1	**Black**			**Brand Embossing**	**No**
				Inside Printing	**No**
Remark (if Any) :			**Change Part Layout No. :**		
			Developed For :		

	PREPARED BY	**CHECKED BY**			**APPROVED BY**	**AUTHORISED BY**
SIGNATURE						
DATE						
NAME						
DEPARTMENT	**GRAPHIC DESIGNER**	**PACKING DEV.**	**PACKING DEPT.**	**QUALITY ASSURANCE**	**REGULATORY AFFAIRS**	**QUALITY ASSURANCE**