

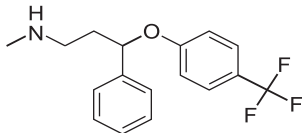
FLUTIN 20mg Capsule

(Fluoxetine)

فلوئین
(فلوآکسیٹین) کیپسول

DESCRIPTION:

Flutin (fluoxetine) capsule, USP is a psychotropic drug for oral administration. It is also marketed for the treatment of premenstrual dysphoric disorder .It is designated (\pm)-N-methyl-3-phenyl-3-[(α,α , trifluoro-p-tolyl)oxy]propylamine hydrochloride and has the empirical formula of $C_{17}H_{18}F_3NO \cdot HCl$. Its molecular weight is 345.79 g/mol.



CLINICAL PHARMACOLOGY:

PHARMACOKINETICS

Absorption, Distribution, Metabolism and Excretion Systemic bioavailability — In man, following a single oral 40-mg dose, peak plasma concentrations of Fluoxetine from 15 to 55 mg/mL are observed after 6 to 8 hours. The Pulvule, oral solution and Flutin (fluoxetine) Weekly capsule dosage forms of Fluoxetine are bioequivalent. Food does not appear to affect the systemic bioavailability of Fluoxetine, although it may delay its absorption by 1 to 2 hours, which is probably not clinically significant. Thus, Fluoxetine may be administered with or without food.

METABOLISM — Fluoxetine is extensively metabolized in the liver to norfluoxetine and a number of other unidentified metabolites. The only identified active metabolite norfluoxetine is formed by demethylation of fluoxetine.

PHARMACODYNAMICS

The antidepressant, antiobsessive compulsive and antilulimic actions of fluoxetine are presumed to be linked to its inhibition of CNS neuronal uptake of serotonin. Studies at clinically relevant doses in man have demonstrated that fluoxetine blocks the uptake of serotonin into human platelets. Studies in animals also suggest that fluoxetine is a much more potent uptake inhibitor of serotonin than of norepinephrine. Antagonism of muscarinic, histaminergic and α_1 adrenergic receptors has been hypothesized to be associated with various anticholinergic, sedative and cardiovascular effects of classical tricyclic antidepressant (TCA) drugs. Fluoxetine binds to these and other membrane receptors from brain tissue much less potently in vitro than do the tricyclic drugs.

INDICATIONS AND USAGE:

Major depressive disorder

Flutin (fluoxetine) is indicated for the treatment of major depressive disorder. Adult — The efficacy of Flutin (fluoxetine) was established in 5- and 6-week trials with depressed adult (≥ 18 years of age) and geriatric outpatients whose diagnoses corresponded most closely to the DSM-III (currently DSM-IV) category of major depressive disorder (see CLINICAL TRIALS). The effects of Flutin (fluoxetine) in hospitalized depressed patients have not been adequately studied. The efficacy of Flutin (fluoxetine) 20 mg once daily in maintaining a response in major depressive disorder for up to 38 weeks following 12 weeks of open-label acute treatment (50 weeks total) was demonstrated.

in a placebo-controlled trial. The efficacy of Flutin (fluoxetine) once weekly in maintaining a response in major depressive disorder has been demonstrated in a placebo-controlled trial for up to 25 weeks following open-label acute treatment of 13 weeks with Flutin (fluoxetine) 20 mg daily for a total treatment of 38 weeks. However, it is unknown whether or not Flutin (fluoxetine) Weekly given on a once weekly basis provides the same level of protection from relapse as that provided by Flutin (fluoxetine) 20 mg daily.

Obsessive compulsive disorder

Adult — Flutin (fluoxetine) is indicated for the treatment of obsessions and compulsions in patients with obsessive compulsive disorder (OCD), as defined in the DSM-III-R; i.e., the obsessions or compulsions cause marked distress, are time-consuming or significantly interfere with social or occupational functioning. The efficacy of Flutin (fluoxetine) was established in 13-week trials with obsessive compulsive outpatients whose diagnoses corresponded most closely to the DSM-III-R category of OCD (see CLINICAL TRIALS). OCD is characterized by recurrent and persistent ideas, thoughts, impulses or images (obsessions) that are ego-dystonic and/or repetitive purposeful and intentional behaviors (compulsions) that are recognized by the person as excessive or unreasonable.

CONTRAINDICATIONS:

Flutin (fluoxetine) is contraindicated in patients known to be hypersensitive to it. Monoamine oxidase inhibitors — There have been reports of serious, sometimes fatal, reactions (including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma) in patients receiving fluoxetine in combination with a monoamine oxidase inhibitor (MAOI), and in patients who have recently discontinued fluoxetine and an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome.

PRECAUTIONS:

General Abnormal Bleeding — Published case reports have documented the occurrence of bleeding episodes in patients treated with psychotropic drugs that interfere with serotonin reuptake. Anxiety and Insomnia — In US placebo-controlled clinical trials for major depressive disorder, 12% to 16% of patients treated with Flutin (fluoxetine) and 7% to 9% of patients treated with placebo reported anxiety, nervousness or insomnia.

STORAGE INSTRUCTIONS:

Keep out of the reach of Children
Store at 25° C.
Protect from Sunlight and moisture.

HOW SUPPLIED:

Flutin (fluoxetine) 20 mg Capsule in a Pack of 10's, 14's and 30's.

Manufactured by :



PHARMA LORD | 12km, Lahore
(PVT.) LIMITED | Road, Layyah.
Pakistan
www.pharma-lord.com

فلوٹن

فلوٹن کپسول (کدیسول)

خوراک: ڈاکٹر ہدایت کے مطابق استعمال کریں۔

ہدایت: بچوں کی پہنچ سے دور رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔ ۲۵ ڈگری سینٹی گریڈ

سے کم درجہ حرارت پر رکھیں۔