Deprozet® (Capsules)

26500
Ref. No.:B2126500/23.01

Fluoxetine Hydrochloride
Antidepressant

DEPROZET® 20MG CAPSULES

PRESENTATION:
Deprozet® Capsules 20mg: White, granular powder filled in green / yellow coloured hard gelatin capsule printed COSMOS / COSMOS on body and cap. Each capsule contains: Fluoxetine Hydrochloride equivalent to Fluoxetine 20mg.

CLINICAL PHARMACOLOGY:
Prevention of the reuptake of monoamine transmitters such as serotonin, which potentiates their action in the brain, appears to be associated with antidepressant activity. SSRIs such as fluoxetine preferentially inhibit the reuptake of serotonin compared with noradrenaline, and have limited direct action at other neurotransmitter sites, including muscarinic receptors. They therefore cause fewer antimuscarinic or sedative side-effects than the tricyclic antidepressants and are less cardiotoxic.

Pharmacokinetics:
Fluoxetine is readily absorbed from the gastrointestinal tract with peak plasma concentrations appearing about 6 to 8 hours after oral doses. Systemic bioavailability does not appear to be affected by food. Fluoxetine is extensively metabolised, by demethylation, in the liver to its primary active metabolite norfluoxetine. Excretion is mainly via the urine. Fluoxetine is widely distributed throughout the body. Fluoxetine has a relatively long elimination half-life of about 1 to 3 days after acute use and 4 to 6 days after long-term use; that of its metabolite, norfluoxetine, is even longer, being about 4 to 16 days. These long half-lives have clinical implications. Steady-state plasma concentrations will only be attained after several weeks. Additionally, fluoxetine and its metabolites may persist for a considerable time after treatment, and this has led to precautions concerning the subsequent use of other serotonergic drugs.
Fluoxetine and norfluoxetine are distributed into breast milk.

USES:
Deprozet® provides an alternative for the treatment of depression. It is also used as part of the management of obsessive compulsive disorders with or without agoraphobia, and as part of the management of bulimia nervosa. It is also used in the treatment of premenstrual dysphoric disorder.

DOSAGE AND ADMINISTRATION:
In the treatment of depression: The usual dose of Deprozet® is 20mg daily in the morning gradually increased up to a maximum of 80mg daily (60mg in the elderly). Doses above 20mg a day may be administered in 2 divided doses.
In the management of bulimia nervosa: Doses of 60mg daily.
In the management of obsessive compulsive disorders: The initial dose is 20mg daily increased after several weeks if there is no response to up to 60mg daily.
Premenstrual dysphoric disorder: Dose of 20mg daily.
Children: 8 yrs and above: 10mg daily then increased to 20mg daily after 1 or 2 weeks.

CONTRA-INDICATIONS AND WARNINGS:
Adverse Effects:
Adverse effects include dry mouth and gastro-intestinal disturbances such as nausea, vomiting, dyspepsia, constipation and diarrhoea, anorexia, and loss of weight may also occur. Neurological side effects include anxiety, restless, nervousness and insomnia or drowsiness and fatigue, headache, tremor, dizziness, convulsions, extrapyramidal effects and sexual dysfunction have also occurred. Excessive sweating and pruritus, skin rashes, urticaria have also been reported

Overdosage:
Treatment involves emesis induction or gastric lavage followed by symptomatic and supportive therapy.

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Interactions:
Although different antidepressants have been used together under expert supervision in refractory cases of depression, severe adverse reactions including the *serotonin syndrome* may occur. Sequential prescribing of different types of antidepressant may also produce adverse reactions, and an appropriate drug-free interval should elapse between stopping one type of antidepressant and starting another. SSRIs should not generally be given to patients receiving MAOIs or for at least 2 weeks after their use. No treatment-free period is necessary after stopping a reversible inhibitor of monoamine oxidase type A (RIMA) and starting an SSRI. At least one week should elapse between withdrawing an SSRI and starting any drug liable to provoke a serious reaction (e.g. phenelzine). For fluoxetine the drug free interval is 5 weeks and may need to be further extended if therapy has been prolonged or if high doses have been given.
Adverse effects such as the serotonin syndrome may also occur when the SSRIs are given with other drugs known to act on the same neurotransmitter, a consequence of synergistic interaction.

Pregnancy and Breastfeeding:
Pregnancy: Fluoxetine should not be used during pregnancy unless the clinical condition of the woman requires treatment with fluoxetine and justifies the potential risk to the foetus.
Breastfeeding: If treatment with fluoxetine is considered necessary, discontinuation of breastfeeding should be considered; however, if breastfeeding is continued, the lowest effective dose of fluoxetine should be prescribed.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 25ºC. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

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