DEPRICAP®

Capsules/ Liquid

ڈیپری کیپ کیپسولز/لیکوئیڈ

(فلوآکسیٹین)

(Fluoxetine Capsules/Oral Solution USP)

COMPOSITION:
DEPRICAP Capsules: Each capsule contains:
Fluoxetine USP ... 20mg (as Fluoxetine HCl). [USP Specs.]

DEPRICAP Liquid: Each 5ml (teaspoonful) contains:
Fluoxetine USP ... 20mg (as Fluoxetine HCl). [USP Specs.]

PHARMACODYNAMIC PROPERTIES: Fluoxetine is a Selective Serotonin Reuptake Inhibitor (SSRI) and this probably accounts for the mechanism of action. Fluoxetine has practically no affinity to other receptors such as α_1-, α_2-, and β-adrenergic; serotonergic; dopaminergic; histaminergic1; muscarinic; and GABA receptors.
Major depressive episodes: Fluoxetine has been shown to be significantly more effective than placebo, as measured by the Hamilton Depression Rating Scale (HAM-D). In these studies, Fluoxetine produced a significantly higher rate of response (defined by a 50% decrease in the HAM-D score) and remission compared to placebo.
Obsessive-compulsive disorder: In short-term trials (under 24 weeks), Fluoxetine was shown to be significantly more effective than placebo. There was a therapeutic effect at 20mg/day, but higher doses (40 or 60mg/day) showed a higher response rate. In long-term studies (three short-term studies extension phase and a relapse prevention study), efficacy has not been shown.
Bulimia nervosa: In short-term trials (under 16 weeks), in out-patients fulfilling DSM-III-R-criteria for bulimia nervosa, Fluoxetine 60mg/day was shown to be significantly more effective than placebo for the reduction of binging and purging activities. However, for long-term efficacy no conclusion can be drawn.
Premenstrual Dysphoric Disorder (PMDD): Selective Serotonin Reuptake Inhibitors (SSRIs) have emerged as first-line therapy. Several randomized, placebo-controlled trials in women with PMDD (Premenstrual Dysphoric Disorder) have clearly demonstrated that the SSRIs have excellent efficacy and minimal side effects.

PHARMACOKINETIC PROPERTIES: Absorption: Fluoxetine is well absorbed from the gastrointestinal tract after oral administration. The bioavailability is not affected by food intake. **Distribution:** Fluoxetine is extensively bound to plasma proteins (about 95%) and it is widely distributed (volume of distribution: 20-40 l/kg). Steady-state plasma concentrations are achieved after dosing for several weeks. Steady-state concentrations after prolonged dosing are similar to concentrations seen at 4 to 5 weeks. **Metabolism:** Fluoxetine has a non-linear pharmacokinetic profile with first pass liver effect. Maximum plasma concentration is generally achieved 6 to 8 hours after administration. Fluoxetine is extensively metabolized by the polymorphic enzyme CYP2D6. Fluoxetine is primarily metabolized by the liver to the active metabolite norfluoxetine (desmethylfluoxetine), by desmethylation. **Elimination:** The elimination half-life of Fluoxetine is 4 to 6 days and for norfluoxetine 4 to 16 days. These long half-lives are responsible for persistence of the drug for 5-6 weeks after discontinuation. Excretion is mainly (about 60%) via the kidney. Fluoxetine is secreted into breast milk.

INDICATIONS:
Adults: DEPRICAP (Fluoxetine) is approved for the treatment of major depression (including pediatric depression), obsessive-compulsive disorder (in both adult and pediatric populations), bulimia nervosa, panic disorder and Premenstrual Dysphoric Disorder (PMDD). In addition, Fluoxetine is used to treat trichotillomania. **DEPRICAP** (Fluoxetine) is indicated as a complement of psychotherapy for the reduction of binge-eating and purging activity.
Children and Adolescents Aged 8 Years and Above: Moderate to severe major depressive episode, if depression is unresponsive to psychological therapy after 4-6 sessions. Antidepressant medication should be offered to a child or young person with moderate to severe depression only in combination with a concurrent psychological therapy.

POSOLOGY AND METHOD OF ADMINISTRATION: For oral administration. **Major Depressive Episodes: Adults and the elderly:** The recommended dose is 20mg daily. Dosage should be reviewed and adjusted if necessary, within 3 to 4 weeks of initiation of therapy and thereafter as judged clinically appropriate. Although there may be an increased potential for undesirable effects at higher doses, in some patients, with insufficient response to 20mg, the dose may be increased gradually up to a maximum of 60mg. Dosage adjustments should be made carefully on an individual patient basis, to maintain the patients at the lowest effective dose. Patients with depression should be treated for a sufficient period of at least 6 months to ensure that they are free from symptoms.
Obsessive-compulsive Disorder (OCD): Adults and the elderly: The recommended dose is 20mg daily. Although there may be an increased potential for undesirable effects at higher doses, in some patients, if after two weeks there is insufficient response to 20mg, the dose may be increased gradually up to a maximum of 60mg. If no improvement is observed within 10 weeks, treatment with Fluoxetine should be reconsidered. If a good therapeutic response has been obtained, treatment can be continued at a dosage adjusted on an individual basis. Dosage adjustments should be made carefully on an individual patient basis, to maintain the patient at the lowest effective dose. The need for treatment should be reassessed periodically. Long-term efficacy (more than 24 weeks) has not been demonstrated in OCD.
Bulimia Nervosa: Adults and the elderly: A dose of 60mg/day is recommended. Long-term efficacy (more than 3 months) has not been demonstrated in bulimia nervosa.

DOSAGE IN AGE GROUPS: Adults: The recommended dose may be increased or decreased. Doses above 80mg/day have not been systematically evaluated. Fluoxetine may be administered as a single or divided dose, during or between meals. When dosing is stopped, active drug substances will persist in the body for weeks. This should be borne in mind when starting or stopping treatment. The capsule and liquid dosage forms are bioequivalent.
Children and adolescents aged 8 years and above (moderate to severe major depressive episode): Treatment should be initiated and monitored under specialist supervision. The starting dose is 10mg/day given as 2.5ml of the **Fluoxetine** liquid formulation. Dose adjustments should be made carefully, on an individual basis, to maintain the patient at the lowest effective dose.

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After one to two weeks, the dose may be increased to 20mg/day.
Lower-weight children: Due to higher plasma levels in lower-weight children, the therapeutic effect may be achieved with lower doses. For pediatric patients who respond to treatment, the need for continued treatment after 6 months should be reviewed. If no clinical benefit is achieved within 9 weeks, treatment should be reconsidered.
Elderly: Caution is recommended when increasing the dose, and the daily dose should generally not exceed 40mg. Maximum recommended dose is 60mg/day. A lower or less frequent dose (e.g., 20mg every second day) should be considered in patients with hepatic impairment, or in patients where concomitant medication has the potential for interaction with **Fluoxetine**.

WITHDRAWAL SYMPTOMS SEEN ON DISCONTINUATION OF FLUOXETINE: Abrupt discontinuation should be avoided. When stopping treatment with **Fluoxetine**, the dose should be gradually reduced over a period of at least one to two weeks in order to reduce the risk of withdrawal reactions. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose, but at a more gradual rate.

CONTRA-INDICATIONS: Hypersensitivity to Fluoxetine or to any of its excipients. Fluoxetine is contra-indicated in combination with a non-selective Monoamine Oxidase Inhibitor (MAOI). Similarly, at least 5 weeks should elapse after discontinuing Fluoxetine treatment before starting a MAOI. If Fluoxetine has been prescribed chronically and/or at a high dose, a longer interval should be considered. The combination of Fluoxetine with a reversible MAOI (e.g., moclobemide) is not recommended. Treatment with Fluoxetine can be initiated the following day after discontinuation of a reversible MAOI.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Use in children and adolescents under 18 years of age: Fluoxetine should only be used in children and adolescents aged 8 to 18 years for the treatment of moderate to severe major depressive episodes and it should not be used in other indications. Fluoxetine should be discontinued in any patient entering a manic phase. It is important that the prescriber discusses carefully the risks and benefits of treatment with the child/young person and/or their parents.
Rash and allergic reactions: Rash, anaphylactoid events and progressive systemic events, sometimes become serious (involving skin, kidney, liver or lung) have been reported.
Seizures: Treatment should be discontinued in any patient who develops seizures or where there is an increase in seizure frequency.
Hepatic/Renal function: Fluoxetine is extensively metabolized by the liver and excreted by the kidneys. A lower dose, e.g., alternate day dosing, is recommended in patients with significant hepatic dysfunction. **Pregnancy:** Fluoxetine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers:** Breast feeding is not recommended. **Tamoxifen:** Fluoxetine should whenever possible be avoided during tamoxifen treatment. **Cardiac disease:** Caution is advisable. **Weight loss:** Weight loss may occur in patients taking Fluoxetine, but it is usually proportional to baseline body weight.
Diabetes: In patients with diabetes, treatment with an SSRI may alter glycemic control. Hypoglycemia has occurred during therapy with Fluoxetine and hyperglycemia has developed following discontinuation. Insulin and/or oral hypoglycemic dosage may need to be adjusted.
Suicide/suicidal thoughts or clinical worsening: It is general clinical experience that the risk of suicide may increase in the early stages of recovery.
Withdrawal symptoms seen on discontinuation of SSRIs treatment: Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt. Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), asthenia, agitation or anxiety, nausea and/or vomiting, tremor, and headache are the most commonly reported reactions. Generally, these symptoms are mild to moderate; however, in some patients they may be severe in intensity. They usually occur within the first few days of discontinuing treatment. Generally, these symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged (2-3 months or more). It is therefore advised that **Fluoxetine** should be gradually tapered when discontinuing treatment over a period of at least one to two weeks, according to the patient's needs.
Fluoxetine oral liquid contains sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

INTERACTIONS: Using an NSAID with **Fluoxetine** e.g. Aspirin, Ibuprofen, Naproxen, Celecoxib, Diclofenac, Indomethacin, Meloxicam and others, may cause you to bruise or bleed easily. Tell your doctor about all other medications you are using, especially any other antidepressants such as Amitriptyline, Escitalopram, Imipramine, Sertraline and others e.g. Alprazolam ;Clopidogrel; Clozapine; Flecainide; Haloperidol; Vinblastine; a blood thinner such as Warfarin; Migraine headache medicine such as Almotriptan, Frovatriptan, Sumatriptan, Naratriptan, Rizatriptan or Zolmitriptan; or seizure medication such as Phenytoin or Carbamazepine.

ADVERSE REACTIONS: The incidence of adverse effects with Fluoxetine is less than 1% of treated cases commonly observed. The commonly observed adverse effects associated with Fluoxetine were nervous system complaints; including anxiety, nervousness and insomnia, drowsiness and fatigue / asthenia, tremor, sweating, gastrointestinal complaints; including anorexia, nausea and diarrhoea, dizziness/light headedness, body as whole; primarily asthenia, headache and skin; primarily rash and pruritus.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children. Keep the bottle tightly closed.

AVAILABILITY: DEPRICAP Capsules are available in blister packs of 10 and 30 capsules. **DEPRICAP LIQUID** is available in bottle pack of 60ml.

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
استعمال کے بعد بوتل کو سختی سے بند کر دیں۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.
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