PRAMCIT Tablets

(Citalopram Tablets USP)

COMPOSITION:
Each film coated tablet contains:
Citalopram USP (as Hydrobromide) ... 20mg.
[USP Specs.]

INDICATION:
Treatment of depression and panic disorder with or without agoraphobia.

USES AND ADMINISTRATION:
Citalopram tablets is a selective serotonin reuptake inhibitor (SSRI). **Citalopram** tablets can be administered as a single daily dose any time of the day with or without food. A dose increase if required in increments of 10mg should take place with intervals of 2-3 weeks.

Dosage in depression: Citalopram 1 tablet daily for 2-3 weeks. Dose up to 40mg may be increased on severity of depression.

Dosage in panic disorders: Initially **Citalopram** ½ tablet for first week followed by 1 tablet for 2-3 weeks. Depending on individual patient response, the dose may be increased to a maximum of 40mg daily.

Dosage above 60 years of age: An initial dose of 1 tablet is recommended which may be increased up to 2 tablets daily depending upon severity of case. Reduced doses i.e ½ tablet should be employed in patients with hepatic impairment.

Use in Children: Safety and efficacy have not been established.

Duration of treatment: The antidepressive effect usually sets in after 2 to 4 weeks. Treatment with antidepressants is symptomatic and must therefore be continued for an appropriate length of time, usually for 6 months or longer in order to prevent relapse.

ADVERSE EFFECTS:
Many side effects of **Citalopram** are similar to other tricyclic anti-depressant caused by their anti-muscarinic actions. The most common adverse effect observed in first two weeks of treatment are nausea, drowsiness, vomiting, increased sweating, tremors, dryness of mouth, constipation and increased intra-ocular pressure. The reported adverse effects occurred during treatment only which usually attenuate subsequently.

CONTRA-INDICATIONS:
Citalopram tablets is contra-indicated in patients who have shown hypersensitivity to any of similar tricyclic compound and Monoamino oxidase inhibitors (MAOIs). **Citalopram** is contra-indicated in patients with known QT-interval prolongation or congenital long QT syndrome. **Citalopram** is contra-indicated with medicinal products that are known to prolong the QT-interval.

INTERACTIONS:
The simultaneous use of Citalopram and MAO-inhibitors can result in severe undesirable effects, including serotonin syndrome. Co-administration of Citalopram with medicinal products that prolong the QT interval such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine) etc., is contra-indicated. Cimetidine (potent CYP2D6, 3A4 and 1A2 inhibitor) caused a moderate increase in the average steady state levels of Citalopram. Caution is advised when administering Citalopram in combination with cimetidine.

USE DURING PREGNANCY AND LACTATION:
Clinical experience of use in pregnant women is limited. Reproduction toxicity studies have not given evidence of an increased incidence of foetal damage or other deleterious effects on the reproductive process. **Citalopram** should not be used during pregnancy unless clearly necessary and only after careful consideration of risk/benefit. Information on the excretion of **Citalopram** into breast milk exists but is insufficient for assessment of the risk to the child. Caution is recommended.

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PHARMACOKINETICS: Absorption: Absorption is almost complete and independent of food intake (T_{max} mean 3.8 hours). Oral bioavailability is about 80%.

Distribution: The apparent volume of distribution (Vdβ) is about 12.3L/kg. The plasma protein binding is below 80% for Citalopram and its main metabolites.

Elimination: The elimination half-life is about 36 hours and the systemic plasma clearance is about 0.3L/min and oral plasma clearance is about 0.4L/min. Citalopram is excreted mainly via the liver (85%) and remainder (15%) via the kidney, 12-23% of the daily dose is excreted in urine as unchanged Citalopram.

OVER DOSE EFFECTS: Citalopram tablets is given to patients at potential risk of suicide and some reports of attempted suicide have been received. Detail is often lacking regarding precise dose or combination with other drugs and/or alcohol. There is no known specific antidote to Citalopram. Treatment should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of ECG and vital signs until stable.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children. Use on medical advice only.

PRESENTATION: PRAMCIT (Citalopram) tablets 20mg is available in blister pack of 20's.

پرامسٹ ٹیبلیٹس

(سٹالوپرام ٹیبلیٹس یو ایس پی)

اجزاءترکیب: پرامسٹ میں سٹالوپرام ہائیڈروبرومائیڈ مساوی ۲۰ ملی گرام سٹالوپرام فی گولی موجود ہے۔

فوائد: پرامسٹ افسردگی اور پیدائشی طور پر دماغ کے اندر کیمیاوی مادوں کے توازن کے غیر ہموار ہونے یا اردگرد کے ماحول کے بے جا خوف میں مبتلا مریضوں میں بہت موزوں ہے۔

تجویز کردہ خوراک: بالغوں کیلئے: سٹالوپرام ۲۰ ملی گرام کی ایک گولی روزانہ۔

مرض کی شدت کی صورت میں سٹالوپرام زیادہ سے زیادہ ۴۰ ملی گرام تک روزانہ دی جاسکتی ہے۔

بچوں کیلئے: سٹالوپرام کی افادیت اور تحفظ بچوں میں متعین نہیں ہوسکی ہے۔

مدت استعمال: سٹالوپرام کی افادیت ۲ تا ۴ ہفتہ بعد پتہ چلتی ہے۔ افسردگی اور اس کے ساتھ ملحقہ پیچیدگیوں میں سٹالوپرام کم از کم ۲ سے ۴ ہفتہ میں اثر انداز ہوتی ہے لہذا سٹالوپرام مرض کی شدت کے مطابق عام طور پر ۶ ماہ تک استعمال کی جاتی ہے۔

مضر اثرات: دوسری ذہنی دباؤ کی ادویات کی طرح ابتدائی دو ہفتہ کے علاج کے دوران مندرجہ ذیل اثرات دیکھے گئے ہیں۔ اُلٹی کا محسوس ہونا، منہ یا زبان کا خشک ہونا، زیادہ پسینے کا نکلنا، قبض ہونا، آنکھ کے اندرونی حصے پر دباؤ کا بڑھنا اور ہاتھوں کا کپکپانا وغیرہ۔

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ روشنی، گرمی اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔ ڈاکٹر کی ہدایت کے مطابق دوا استعمال کریں۔

طریقہ فراہمی: پرامسٹ ۲۰ ملی گرام کی گولیاں ۲۰ گولیوں کے بلسٹر پیک میں دستیاب ہے۔

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

PHARMA

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