ES-PRAMCIT Tablets

(Escitalopram Tablets USP)

COMPOSITION:
Each film coated tablet contains:
Escitalopram Oxalate USP ... 5mg, 10mg & 20mg. [USP Specs.]

MODE OF ACTION:
Escitalopram Oxalate is a Selective Serotonin (5-HT) Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to normalize the levels of serotonin in the brain. Disturbances in the serotonin system of the brain are key factors in the development of depression and related disorders.

PHARMACOKINETIC PROPERTIES:
Absorption: Absorption is almost complete and independent of food intake. (Mean time to maximum concentration (mean T_{max}) is 4 hours after multiple dosing). As with racemic citalopram, the absolute bioavailability of Escitalopram Oxalate is expected to be about 80%.
Distribution: The apparent volume of distribution ($V_{d,\beta}/F$) after oral administration is about 12 to 26 L/kg. The plasma protein binding is below 80% for Escitalopram Oxalate and its main metabolites.
Elimination: The elimination half-life ($t_{½\beta}$) after multiple dosing is about 30 hours and the oral plasma clearance (Cl_{oral}) is about 0.6L/min. The major metabolites have a significantly longer half-life. Escitalopram Oxalate and major metabolites are assumed to be eliminated by both the hepatic (metabolic) and the renal routes, with the major part of the dose excreted as metabolites in the urine.

INDICATIONS:
ES-PRAMCIT tablet (Escitalopram Oxalate) is used for the treatment of depression. This disease is characterized by low/depressed mood, lack of energy, melancholia feelings of little or no worth and sleeping disorders. Depression may also be accompanied by suicidal thoughts. Depressed patients may further suffer from symptoms of anxiety.
ES-PRAMCIT tablet (Escitalopram Oxalate) is also used for the treatment of panic disorder with or without agoraphobia. This disease is characterized by patients developing unexpected attacks of intense panic or anxiety when faced with particular situations or due to the fear of experiencing new attacks. Precisely what triggers the attacks varies from patient to patient. The attacks recur when the patient faces the same situation again. Also indicated for the treatment of social phobia and obsessive-compulsive disorder.

CONTRA-INDICATION:
Hypersensitivity to the active substance or to any of the excipients. Concomitant treatment with non-selective, irreversible monoamine oxidase inhibitors (MAO-inhibitors) is contraindicated due to the risk of serotonin syndrome with agitation, tremor, hyperthermia etc. The combination of Escitalopram Oxalate with reversible MAO-A inhibitors (e.g. moclobemide) or the reversible non-selective MAO-inhibitor linezolid is contraindicated due to the risk of onset of a serotonin syndrome. Escitalopram Oxalate is contraindicated in patients with known QT interval prolongation or congenital long QT syndrome. Escitalopram Oxalate is contraindicated together with medicinal products that are known to prolong the QT interval.

PRECAUTIONS:
Taking medication known as non-selective monoamine oxidase inhibitors (MAOIs), such as phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine which are also used for the treatment of depression. If you have taken any of these medicines you will need to wait 14 days before you start taking Escitalopram tablets. After stopping Escitalopram tablets you must allow 7 days before taking any of these medicines. If your treatment is changed from the so-called selective MAO-A inhibitor, moclobemide, (also used in the treatment of depression) to Escitalopram tablets it is recommended that one day should elapse after you have finished taking moclobemide before you start taking your Escitalopram tablets. After stopping Escitalopram tablets it is recommended to allow 7 days before starting moclobemide. Although not generally recommended, it may happen that your doctor decides that you should receive moclobemide concomitantly with Escitalopram tablets. This combination may, in extraordinary cases prove beneficial. There exists, however, a risk of adverse effects from this combination. Therefore your doctor will usually prescribe low doses of both medicines at the start of the treatment. If you are treated with both moclobemide, Escitalopram tablets and experience symptoms like high fever and abrupt contractions of muscles with tremors, feel agitated and confused, you must stop taking both medicines and consult your doctor immediately. Consult your doctor before starting treatment of Escitalopram tablets if you have a severe liver disease or diabetes, epilepsy or a history of seizures or fits (seizures are a potential risk with all antidepressant medication), episodes of mania, subcutaneous bleeding. Please tell your doctor if you are taking or have taken any other medicines (including those purchased without prescription) during the last 14 days. Escitalopram tablets and the following medicines should be combined with caution: Lithium, selegiline, imipramine and desipramine, metoprolol, sumatriptan and similar medicines; tramadol and cimetidine.
Pregnancy and breast-feeding: Pregnant women should not usually take Escitalopram tablets nor should mothers breast-feed their babies while taking this medicine.

DOSAGE AND ADMINISTRATION:
Escitalopram tablets is taken every day as a single daily dose. Escitalopram tablets can be taken with or without food. Swallow the tablets with a drink or water. Do not chew them.
Adults: Depression: The usual dose is 10mg per day. The recommended maximum dose is 20mg per day.

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Panic disorder: The starting dose is 5mg per day for the first week before increasing the dose to 10-15mg per day. The dose may be increased to a maximum of 20mg per day. Patients who are prone to panic attacks may actually experience a temporary period of heightened anxiety after starting treatment which generally resolves during the first 1-2 weeks. Therefore, a low starting dose is recommended in panic disorder.
Elderly patients: The usual starting dose is 5mg per day. It is recommended that the maximum dose is kept below 20mg.
Patients with special risks: It is recommended that patients with liver disease receive an initial dose of 5mg daily for the first two weeks which may be increased to 10mg daily.
Children and adolescents (< 18 years): Escitalopram tablets should not be given to children or adolescents.

OVERDOSE:
Clinical data on Escitalopram Oxalate overdose are limited and many cases involve concomitant overdoses of other drugs. In the majority of cases mild or no symptoms have been reported. Fatal cases of Escitalopram Oxalate overdose have rarely been reported with Escitalopram Oxalate alone; the majority of cases have involved overdose with concomitant medications. Doses between 400 and 800mg of Escitalopram Oxalate alone have been taken without any severe symptoms. There is no antidote, treatment should be supportive and symptomatic.

DURATION OF TREATMENT:
As with other medicines for the treatment of depression and panic disorder, it may take a few weeks before you feel any improvement. Therefore, you should continue to take Escitalopram tablets even if it takes some time before you feel any improvement in your condition. Never change the dose of the medicine without talking to your doctor first. The duration of treatment may vary for each individual. You should continue to take the tablets for as long as your doctor recommends, even if you begin to feel better. The underlying illness may persist for a long time and if you stop your treatment too soon, your symptoms may return. Therefore, it is recommended that treatment is continued for at least 6 months after you feel well again.

WARNING:
Abrupt cessation of this kind of medication may cause discontinuation symptoms such as dizziness, nausea and headache. When you have completed your course of treatment it is therefore advised that the dose of Escitalopram tablets is gradually reduced over a couple of weeks.

SIDE EFFECTS:
Some people may experience unwanted effects (side-effects) whilst taking Escitalopram tablets. The side effects are generally mild and usually disappear after a few days treatment. Please be aware that several of the effects may also be symptoms of your illness and therefore wane when you start to get better. If the side effects are troublesome or last for more than a week or two, tell your doctor.
The common side effects are: Nausea, decreased appetite, difficulties in falling asleep, feeling sleepy, dizziness, yawning, diarrhoea, constipation, increased sweatning, sexual disturbances, fatigue and fever.

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

PRESENTATION:
ES-PRAMCIT (Escitalopram Oxalate) tablet 5mg is available in blister pack of 14'sx1.
ES-PRAMCIT (Escitalopram Oxalate) tablet 10mg is available in blister pack of 10'sx2.
ES-PRAMCIT (Escitalopram Oxalate) tablet 20mg is available in blister pack of 14'sx1.

ایس پرامسٹ گولیاں
(ایسیٹالوپرام)

اجزاءترکیب: ایس پرامسٹ میں ایسیٹالوپرام اوگزالیٹ مساوی ایسیٹالوپرام ۵ملی گرام، ۱۰ملی گرام اور ۲۰ ملی گرام فی گولی ہے۔

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

تجویز کردہ خوراک:

بالغوں کیلئے: ایس پرامسٹ ۱۰ملی گرام کی ایک گولی روزانہ۔ مرض کی شدت کی صورت میں ایسیٹالوپرام زیادہ سے زیادہ ۲۰ملی گرام روزانہ تک دی جا سکتی ہے۔

بچوں کیلئے: ایس پرامسٹ کی افادیت اور تحفظ بچوں میں متعین نہیں ہو سکی ہے۔

مدت استعمال: ایسیٹالوپرام کی افادیت ۲تا۴ ہفتہ بعد پتہ چلتی ہے۔ افسردگی اور اس کے ساتھ ملحقہ پیچیدگیوں میں ایسیٹالوپرام کم از کم ۲سے۴ ہفتہ میں اثر انداز ہوتی ہے لہذا ایسیٹالوپرام 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۔
الٹی کا محسوس ہونا، بھوک میں کمی، منہ یا زبان کا خشک ہونا، زیادہ پسینے کا نکلنا، قبض ہونا، آنکھ کے اندرونی حصہ پر دباؤ کا بڑھنا اور ہاتھوں کا کپکپانا وغیرہ۔

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

طریقہ فراہمی: ایس پرامسٹ ۵ملی گرام ۱۴گولیوں کے بلسٹر پیک میں دستیاب ہے۔
ایس پرامسٹ ۱۰ملی گرام ۲۰گولیوں کے بلسٹر پیک میں دستیاب ہے۔
ایس پرامسٹ ۲۰ملی گرام ۱۴گولیوں کے بلسٹر پیک میں دستیاب ہے۔

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