Prexa

(Escitalopram) Tablets, USP

پریکسا ٹیبلیٹس

(ایسیٹالوپرام)

COMPOSITION:
Prexa 5mg Tablets: Each film coated tablet contains: Escitalopram (as oxalate) USP ... 5mg.
Prexa 10mg Tablets: Each film coated tablet contains: Escitalopram (as oxalate) USP ... 10mg.
Prexa 20mg Tablets: Each film coated tablet contains: Escitalopram (as oxalate) USP ... 20mg.
[USP Specs.]

DESCRIPTION: Escitalopram 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.

INDICATIONS: Major Depressive Disorder: Prexa is indicated for the acute and maintenance treatment of major depressive disorder in adults and in adolescents 12 to 17 years of age. A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, a suicide attempt or suicidal ideation.
Generalized Anxiety Disorder: Prexa is indicated for the acute treatment of Generalized Anxiety Disorder (GAD) in adults. Generalized Anxiety Disorder (DSM-IV) is characterized by excessive anxiety and worry (apprehensive expectation) that is persistent for at least 6 months and which the person finds difficult to control. It must be associated with at least 3 of the following symptoms: restlessness or feeling keyed up or on edge, being easily fatigued, difficulty concentrating or mind going blank, irritability, muscle tension, and sleep disturbance.

DOSAGE AND ADMINISTRATION: Prexa is taken every day as a single daily dose. **Prexa** 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.
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): Prexa should not be given to children or adolescents.

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.

CLINICAL PHARMACOLOGY: Pharmacokinetic: 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 is expected to be about 80%.
Distribution: The apparent volume of distribution ($V_{d,\beta}/F$) after oral administration is about 12 to 26L/kg. The plasma protein binding is below 80% for Escitalopram 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 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.

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 contra-indicated due to the risk of serotonin syndrome with agitation, tremor, hyperthermia etc. The combination of Escitalopram with reversible MAO-A inhibitors (e.g. moclobemide) or the reversible non-selective MAO-inhibitor linezolid is contra-indicated due to the risk of onset of a serotonin syndrome. Escitalopram is contra-indicated in patients with known QT interval prolongation or congenital long QT syndrome. Escitalopram is contra-indicated together with medicinal products that are known to prolong the QT interval.

WARNING AND PRECAUTIONS: 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. 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

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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.

SIDE EFFECTS: The following are the side effects are described below:
Nausea, decreased appetite, difficulties in falling asleep, feeling sleepy, dizziness, yawning, diarrhoea, constipation, increased sweatning, sexual disturbances, fatigue and fever.

DRUG INTERACTIONS: Triptans: There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treatment of escitalopram with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases.
CNS Drugs: Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally acting drugs.
Alcohol: Although Prexa did not potentiate the cognitive and motor effects of alcohol in a clinical trial, as with other psychotropic medications, the use of alcohol by patients taking Prexa is not recommended.
Drugs that interfere with hemostasis (NSAIDs, aspirin, warfarin, etc.): Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of the case-control and cohort design that have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding have also shown that concurrent use of an NSAID or aspirin may potentiate the risk of bleeding. Altered anticoagulant effects, including increased bleeding, have been reported when SSRIs and SNRIs are coadministered with warfarin. Patients receiving warfarin therapy should be carefully monitored when Prexa is initiated or discontinued.
Cimetidine: In subjects who had received 21 days of 40mg/day racemic citalopram, combined administration of 400mg twice a day cimetidine for 8 days resulted in an increase in citalopram AUC and C of 43% and 39%, respectively. The clinical significance of these findings is unknown.
Digoxin: In subjects who had received 21 days of 40mg/day racemic citalopram, combined administration of citalopram and digoxin (single dose of 1mg) did not significantly affect the pharmacokinetics of either citalopram or digoxin.
Lithium: Coadministration of racemic citalopram (40mg/day for 10 days) and lithium (30mmol/day for 5 days) had no significant effect on the pharmacokinetics of citalopram or lithium. Nevertheless, plasma lithium levels should be monitored with appropriate adjustment to the lithium dose in accordance with standard clinical practice. Because lithium may enhance the serotonergic effects of escitalopram, caution should be exercised when **Prexa** and lithium are coadministered.
Pimozide and Celexa: In a controlled study, a single dose of pimozide 2mg co-administered with racemic citalopram 40mg given once daily for 11 days was associated with a mean increase in QTc values of approximately 10 msec compared to pimozide given alone. Racemic citalopram did not alter the mean AUC or C_{max} of pimozide. The mechanism of this pharmacodynamic interaction is not known.
Sumatriptan: There have been rare postmarketing reports describing patients with weakness, hyperreflexia, and incoordination following the use of an SSRI and sumatriptan. If concomitant treatment with sumatriptan and an SSRI (e.g., fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram) is clinically warranted, appropriate observation of the patient is advised.
Theophylline: Combined administration of racemic citalopram (40mg/day for 21 days) and the CYP1A2 substrate theophylline (single dose of 300mg) did not affect the pharmacokinetics of theophylline. The effect of theophylline on the pharmacokinetics of citalopram was not evaluated.

OVERDOSE: Clinical data on Escitalopram 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 overdose have rarely been reported with Escitalopram alone; the majority of cases have involved overdose with concomitant medications. Doses between 400 and 800mg of Escitalopram alone have been taken without any severe symptoms. There is no antidote, treatment should be supportive and symptomatic.

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

PRESENTATION:
PREXA 5mg Tablets are available in pack size of 14's.
PREXA 10mg Tablets are available in pack size of 10's.
PREXA 20mg Tablets are available in pack size of 14's.

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

surge
Manufactured for:
Surge Laboratories (Pvt.) Ltd.
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Manufactured by: **Nabiqasim Industries (Pvt.) Ltd.**
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