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1 x 10 Tablets

PEROXA® 20 mg
(Paroxetine as HCl USP)

(USP Specifications)

پیروکسا ۲۰ ملی گرام
(پیروکسیٹین ایز ہائیڈروکلورائیڈ یو ایس پی)

Composition:
Each film coated tablet contains: Paroxetine as HCl USP .... 20mg.

CLINICAL PARTICULARS
Indications:
Depression:
Treatment of symptoms of depressive illness of all types including reactive and severe depression and depression accompanied by anxiety. Following an initial satisfactory response, continuation with PEROXA therapy is effective in preventing relapse of Depression.
Anxiety Disorders:
- Treatment of symptoms and prevention of relapse of Obsessive Compulsive Disorder (OCD).
- Treatment of symptoms and prevention of relapse of Panic Disorder with or without agoraphobia.
- Treatment of Social Anxiety Disorder/Social Phobia.
- Treatment of symptoms and prevention of relapse of Generalised Anxiety Disorder.
- Treatment of post-traumatic Stress Disorder.

Children and adolescents (less than 18 years)
All Indications:
PEROXA is not indicated for use in children or adolescents aged less than 18 years. Controlled clinical studies in children and adolescents with major depressive disorder failed to demonstrate efficacy, and do not support the use of PEROXA in the treatment of depression in this Population.
The safety and efficacy of PEROXA in children aged less than 7 years has not been studied.
Dosage and Administration
Adults
For oral administration.
It is recommended that PEROXA can be administered once daily in the morning with food. The tablets should be swallowed rather than chewed.
As with all antidepressant drugs, dosage should be reviewed and adjusted if necessary within two to three weeks of initiation of therapy and thereafter as judged clinically appropriate. Patients should be treated for a sufficient period to ensure that they are free from symptoms. This period may be several months for depression and may be even longer for OCD and panic disorder. As with many psychoactive medications, abrupt discontinuation should be avoided.
Depression:
The recommended dose is 20 mg daily. In some patients it may be necessary to increase the dose. This should be done gradually by 10 mg increments to a maximum of 50 mg according to the patients response.
Obsessive Compulsive Disorder:
The recommended dose is 40 mg daily. Patients should start on 20 mg daily and the dose may be increased weekly in 10 mg increments. Some patients will benefit from having their dose increased up to a maximum of 60 mg daily.
Panic Disorder:
The recommended dose is 40 mg daily. Patients should be started on 10 mg daily and the dose increased weekly in 10 mg increments according to the patient's response. Some patients may benefit from having their dose increased up to a maximum of 50 mg daily. As is generally recognised, there is the potential for worsening of panic symptomatology during early treatment of panic disorder, a low initial starting dose is therefore recommended.
Social Anxiety Disorder/Social Phobia:
The recommended dose is 20 mg daily. Patients not responding to 20 mg dose may benefit from dose increases in 10 mg increments as required, up to a maximum of 50 mg/day. Dose changes should occur at intervals of at least 1 week.
Generalised Anxiety Disorder:
The recommended dose is 20 mg daily. Some patients not responding to a 20 mg dose may benefit from having dose increases in 10 mg increments as required. up to a maximum of 50 mg/day according to the patient's response
Contraindications
Known hypersensitivity to paroxetine and excipients.
PEROXA should not be used in combination with monoamine oxidase (MAO) inhibitors (including linezolid, an antibiotic which is a reversible non-selective MAO inhibitor) or within 2 weeks of terminating treatment with MAO inhibitors. Likewise, MAO inhibitors should not be introduced within 2 weeks of cessation of therapy with PEROXA.
PEROXA sholud not be used in combination with thioridazine, because, as with other drugs which inhibit the hepatic enzyme CYP450 2D6, paroxetine can elevate plasma levels of thioridazine. Administration of thioridazine alone can lead to Qtc interval prolongation with associated serious ventricular arrhythmia such as torsades de pointes, and sudden death. PEROXA should not be used in combination with pimozide.
PRECAUTIONS:
Before taking paroxetine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies.Before using this medication, tell your doctor or pharmacist your medical history, especially of personal or family history of bipolar/manic-depressive disorder, personal or family history of suicide attempts, liver problems, kidney problems, low sodium in the blood, severe loss of body water (dehydration), seizures, stomach/intestinal ulcers, glaucoma (narrow-angle type). This drug may make you dizzy or drowsy. Use caution while driving, using machinery, or doing any other activity that requires alertness. Avoid alcoholic beverages. This drug passes into breast milk. Consult your doctor before breast-feeding.

Back
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Rare: Convulsions, akathisia,
Very rare:serotonin syndrome (symptoms may include agitation, confusion, diaphoresis, hallucinations, hyperreflexia, myoclonus, shivering, tachycardia and tremor). Reports of extrapyramidal disorders including oro-facial dystonia have been received in patients sometimes with underlying movement disorders or who were using neuroleptic medication.
Eye disorders
Common: blurred vision. Uncommon: mydriasis.
Very rare: acute glaucoma.
cardiac disorders
Uncommon:sinus tachycardia
Vascular disorders
Uncommon:postural hypotension.
Respiratory, thoracic and mediastinal disorders
Common:yawning.
Gastrointestinal disorders
Very common:nausea. Common: constipation, diarrhoea, dry mouth.
Very rare: gastrointestinal bleeding.
Hepato-biliary disorders
Rare: elevation of hepatic enzymes. Very rare: hepatic events (such as hepatitis, sometimes associated with jaundice and/or liver failure). Elevation of hepatic enzymes has been reported. Post-marketing reports of hepatic events (such as hepatitis, sometimes associated with jaundice, and/or liver failure) have also been received very rarely. Discontinuation of paroxetine should be considered, if there is prolonged elevation of liver function test results.
Skin & subcutaneous tissue disorders
Common: sweating. Uncommon: skin rashes. Very rare: photosensitivity reactions.
Renal & urinary disorders
Uncommon: urinary retention, urinary incontinence.
Reproductive system & breast disorders
Very common: sexual dysfunction. Rare: hyperprolactinaemia / galactorrhoea.
MISSED DOSE:
If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.
Pharmacokinetics
Paroxetine is well absorbed after oral dosing and undergoes first-pass metabolism. The elimination half-life is variable but is generally about one day. Steady state systemic levels are attained by 7 to 14 days after starting treatment and pharmacokinetics do not appear to change during long-term therapy.
Incompatibilities
There are no known incompatibilities with paroxetine tablets.
STORAGE:
Store at room temperature (25°C - 30°C). Protect from sunlight, heat & moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.
PRESENTATION:
PEROXA 20mg Tablets available in 1x 10's Packs.

Manufactured by:
LISKO
Lisko Pakistan (Pvt.) Ltd.
L-10-D Block-21 Shaheed Rashid Minhas Road, F.B. Industrial Area,Karachi.

Marketed by:
ORGANIC Pharmaceuticals