Parazona

(Paroxetine 20mg Tablets)

پیرازونا

۲۰ ملی گرام گولیاں

Parazona CR

(Paroxetine 12.5mg, 25mg & 37.5mg Tablets)

پیرازونا سی آر

۱۲.۵، ۲۵ اور ۳۷.۵ ملی گرام گولیاں۔

DESCRIPTION:
Paroxetine HCl is an orally administered psychotropic drug. It is the hydrochloride salt of a phenylpiperidine compound identified chemically as (-)-trans-4R (4-fluorophenyl)-3S-[(3,4 1-methylenedioxphenoxy) methyl] piperidine hydrochloride hemihyderate and has the empirical formula of $C_{19}H_{20}FNO_3.HCl.1/2H_2O$. The molecular weight is 374.8.

COMPOSITION:

PARAZONA 20mg Tablets
Each film coated tablet contains:
Paroxetine HCl hemihydrate USP equivalent to paroxetine .....20mg.

PARAZONA CR 12.5mg Tablets
Each enteric film coated controlled release tablet contains:
Paroxetine HCl hemihydrate USP equivalent to paroxetine.....12.5mg.

PARAZONA CR 25mg Tablets
Each enteric film coated controlled release tablet contains:
Paroxetine HCl hemihydrate USP equivalent to paroxetine.....25mg.

PARAZONA CR 37.5mg Tablets
Each enteric film coated controlled release tablet contains:
Paroxetine HCl hemihydrate USP equivalent to paroxetine.....37.5mg.

CLINICAL PHARMACOLOGY:

Mechanism of action:
The efficacy of paroxetine is presumed to be linked to potentation of serotonergic activity in the central nervous system resulting from inhibition of neuronal reuptake of serotonin (5-hydroxytryptamin, 5-HT.). Paroxetine blocks the uptake of serotonin into human platelets. In vitro studies in animals also suggest that paroxetine is a potent and highly selective inhibitor of neuronal serotonin reuptake and has only very weak effects on norepinephrine and dopamine neuronal reuptake. Paroxetine has little affinity for muscarinic, alpha1-, alpha2-, beta-adrenergic-, dopamine (D2), 5-HT1-, 5-HT2, and histamine (H1)-receptors.

Pharmacokinetic:
Paroxetine HCl is completely absorbed after oral administration. The mean elimination half-life is aproximately 21 hours after oral dosing of 30mg tablets for 30 days. Paroxetine is extensively metabolized and the metabolites are considered to be inactive. Nonlinearity in pharmacokinetics is observed with increasing doses. Paroxetine metabolism is mediated in part by CYP2D6, and the metabolites are primarily excreted in the urine and to some extent in the feces.

INDICATIONS:

Depression:
Paroxetine HCl is indicated for the treatment of major depressive disorder. A major depressive episode implies a prominent and relatively persistent depressed or dysphoric mood that usually interferes with daily functioning. Paroxetine therapy is effective in preventing relapse of depression.

Obsesssive Compulsive Disorder:
The obsessions or compulsions cause marked distress, are time consuming, or significantly interfere with social or occupational functioning. Obsessive compulsive disorder is characterized by recurrent and persistent ideas, thoughts, impulses, or images (obsessions) that are ego-dystonic and/or repetitive, purposeful, and intentional behaviors (compulsions).

Panic Disorder:
Panic disorder is characterized by the occurrence of unexpected panic attacks and associated concern about having additional attacks, worry about the implications or consequences of the attacks, and/or a significant change in behavior related to the attacks.

Social and Generalized Anxiety Disorder:
Paroxetine HCl is indicated for the treatment of social anxiety disorder, also known as social phobia. Social anxiety disorder is characterized by a marked and persistent fear of 1 or more social or performance situations. Exposure to the feared situation almost invariably provokes anxiety,which may approach the intensity of a panic attack. Generalized Anxiety Disorder is characterized by excessive anxiety and worry (apprehensive expectation) that is persistent for at least 6 month and which the person finds difficult to control. It must be associated with at least 3 of the following 6 symptoms: Restlessness or feeling keyed up or on edge, being easily fatigued, difficulty concentrating or mind going blank, irritablity, muscle tension, sleep disturbance.

Posttraumatic Stress Disorder:
PTSD involves exposure to a traumatic event that involved actual or threatened death or serious injury, or threat to the physical integrity of self or others, and a response that involves intense fear, helplessness, or horror. Symptoms include re-experiencing of the event in the form of intrusive thoughts, flashbacks, or dream.

CONTRAINDICATIONS:
Known hypersensitivity to paroxetine HCl. It should not be used in combination with MAOI, thioridazine, pimozide.

DOSAGE AND ADMINISTRATION:

PARAZONA Tablet:
For oral administration it is recommended that paroxetine be administered once daily in morning with food. The tablets should be swallowed rather than chewed. As with all anti-depresent drugs, dosage should be reviewed and adjusted if necessary within two to three weeks of initiation of therapy and thereafter as judged clinically appropriate.

ADULTS:

Depression:
The recommended dose is 20mg daily in some patients it may be necessary to increase the dose. This should be done gradually by 10mg increments to a maximum of 50mg according to the patient's response.

Obsessive Compulsive Disorder:
The recommended dose is 40mg daily. Patients should be started on 20mg daily and the dose increased weekly in 10mg increments. Some patients will benefit from having their dose increased up to a maximum of 60mg daily.

Panic Disorder:
The recommended dose is 40mg daily. Patients should be started on 20mg daily and the dose increased weekly in 10mg increments according to the patient's response. Some patients may benefit from having their dose increased up to a maximum of 50mg daily.

Social Anxiety Disorder / Social Phobia:
The recommended dose is 20mg daily. Patients not responding to 20mg dose may benefit from dose increase in 10mg increments as required up to maximum of 50mg per day. Dose Changes should occur at intervals of at least one week.

Generalized Anxiety Disorder:
The recommended dose is 20mg daily. Patients not responding to a 20mg dose may benefit from having dose increases in 10mg increments as required, up to a maximum of 50mg per day according to patient's response.

Post-Traumatic Stress Disorder:
The recommend dose is 20mg daily. Patients not responding to a 20mg dose may benefit from having dose increases in 10mg increments as required. up to maximum of 50mg per day according to patient's response.

Elderly:
Increased plasma concentrations of paroxetine occur in elderly subjects. Dosing should commence at the adult starting dose and may be increased weekly in 10mg increments to a maximum 40mg daily according to the patient's response.

Children:
The use of paroxetine in children is not recommended as safety and efficacy of paroxetine has not been established in this population.
Renal/Hepatic Impairment Increased plasma concentrations of paroxetine occur in patients with severe renal imapirment (creatinine clearance <30 ml/min) or severe hepatic impairment. The recommended dose is 20mg daily. Incremental dosage if required, should be restricted to the lower end of the range.

PARAZONA CR Tablet:

ADULTS:
Paroxin-CR tablets should be administered as a single daily dose, usually in the morning, with or without food.

Major Depressive Disorder:
The recommended initial dose is 25mg/day. Some patients not responding to a 25mg dose any may benefit from dose increases in 12.5mg/day increments, up to a maximum of 62.5mg/day according to the patient response. Dose changes should occur at intervals of at least one week.

Panic Disorder:
Patients should begin treatment on 12.5mg/day and the dose increased weekly in 12.5mg/day increments according to patient response. Some patients may benefit from having their dose increased up to a maximum of 75mg/day.

Premenstrual Dysphoric Disorder:
The recommended initial dose is 12.5mg/day. Some patients not responding to a 12.5mg. dose may benefit from having their dose increased to a 25mg/day. Dose changes should occur at intervals of at least one week.

Social Anxiety Disorder/Social Phobia:
The recommended initial dose is 12.5mg daily. Some patients not responding to a 12.5mg dose may benefit from having dose increases in 12.5mg/day increments as required, up to a maximum of 37.5mg/day according to the patient's response. Dose changes should occur at intervals of at least one week.

USE IN SPECIFIC POPULATION:

Pregnancy: Pregnancy Category D
Epidemiological studies have shown that infants exposed to paroxetine in the first trimester of pregnancy have an increased risk of congenital malformations, particularly cardiovascular malformations.

Nursing Mothers: Like many other drugs, paroxetine is secreted in human milk, and caution should be exercised.

Pediatric Use: Safety and effectiveness in the pediatric population have not been established.

WARNING & PRECAUTIONS:

Epilepsy: As with other anti-depresants, paroxetine should be used with caution in patients with epilepsy.

Seizures: Overall, the incidence of seizures is <0.1% in patients treated with paroxetine. Paroxetine should be discontinued in any patients who develop seizures.

Glaucoma: As with other SSRIs, paroxetine infrequently causes mydriasis and should be used with caution in patients with narrow angle glaucoma.

Neuroleptics: Paroxetein should be used with caution in patients already recieving neuroleptics, since sypmtoms suggestive of Neuroleptic malignant syndrome have been reported with this combination.

Pregnancy and lactation: Although animal studies have not shown any teratogenic or selective embryo toxic effects, the safety of paroxetine in human pregnancy has not been established and it should not be used during pregnancy or by nursing mothers unless the potential benefit outweights the possible risk.

Effects on Ability to Drive and use Machines: Clinical experience has shown that therapy with paroxetine is not associated with, impairment of cognitive or psychomotor function. However, as with all psychoactive drugs, patients should be cautioned about their ability to drive a car and operate machinery.

DRUG INTERACTION:

MAOI's/Tryptophan/other SSRI's:
Co-administration with serotonergic drugs may lead to a high Incidence of serotonin associated effects. Symptoms have included agitation, confusion, diaphoresis, hallucinations, hyper-reflexia, myoclonus, shivering, tachycardia and tremor

Alcohol:
Although paroxetine does not increase the impairment of mental and motor skills caused by alcohol, the concomitant use of paroxetine and alcohol in patients in not advised.

Lithium:
Studies in depressed patients stabilized on lithium have not demostrated any pharmacokinetics interation between paroxetine and lithium. However, since experience is limited, the concurrent administration of paroxetine and lithium should be undertaken with caution. Lithium levels should be monitored.

Phenytoin/anticonvulsants:
Co-administration of paroxetine with phenytoin is associated with decreased plasma concentrations of paroxetine and increased adverse experiences: any subsequent dosage adjustment should be guided by clinical effect.

Warfarin/oral anticoagulants:
A pharmacodynamic interaction between paroxetine and warfarin may exist. This may result in changes in the prothrombin time and increased bleeding. Paroxetine should therefore be administered with great caution to patients recieving oral anticoagulants.

Tricycle anti-depressants:
The effects of the concomitant administration of paroxetine with Tricyclic anti-depressants have not been studied. The concomitant use of proxetine with these drugs should therefore be approached with caution.

Procyclidine:
Paroxetine can significantly increase the plasma levels of procyclidine. The dose of procyclidine should be reduced if anticholinergic effects are seen.

P450 Isoenzymes:
As with other anti-depressants, including other SSRI's paroxetine inhibits the hepatic cytochrome P450 enzyme CYP2D6. Inhibition of CYP2D6 may lead to increased plasma concentrations of co-administered drugs metabolized by this enzyme. These include certain Tricycle anti-depressants (e.g. Amitriptyline, nortriptyline, Imipramine and despiramine.) Phenothiazine Neuroleptics (e.g. perphenazine and thioridazine), type antiarrythmics (e.g, propafenone and flecainide) and metoprolol, a beta-adrenergic blocking agent.)

ADVERSE EFFECTS:
. Agitation, hallucinations, coma, or other changes in mental status
. Coordination problems or muscle twitching (overactive reflexes)
. High or low blood pressure
. Sweating or fever
. Nausea, vomiting, or diarrhea
. Muscle rigidity
. Blurred vision
. Rash and itching
. Excessive happiness or irritability
. Talking more or faster than usual

OVERDOSAGE:
No specific antidote is known. The treatment should consist of those general measures employed in the management of overdose with any antidepressant. Supportive care with frequent monitoring of vital signs and careful observation is indicated.

INSTRUCTIONS:
- Store below 30°C.
- Protect from light & moisture.
- Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

HOW SUPPLIED:
PARAZONA (Paroxetine) 20mg Tablets are available in pack of 10's
PARAZONA CR (Paroxetine) 12.5mg Tablets are available in pack of 30's
PARAZONA CR (Paroxetine) 25mg Tablets are available in pack of 30's
PARAZONA CR (Paroxetine) 37.5mg Tablets are available in pack of 10's

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: دوا کو ڈاکٹر کی تشخیص کے بغیر استعمال نہ کریں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

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