

# Description

Parotin<sup>®</sup> is a preparation of Paroxetine which is a potent and selective inhibitor of 5-hydroxytryptamine (5-HT, serotonin) uptake. Paroxetine works by enhancing the serotonergic activity in the central nervous system resulting from inhibition of neuronal reuptake of serotonin (5-hydroxytryptamine, 5-HT), in addition with blocking the reuptake of serotonin into human platelets and has only very weak effects on norepinephrine and dopamine neuronal reuptake.

# Indication and usage

Parotin<sup>®</sup> is indicated for -

- Major depressive disorder
- Panic disorder
- Social anxiety disorder

- Obsessive compulsive disorder
- Generalized anxiety disorder
- Post-traumatic stress disorder

# Dosage and administration

### Adults

- Major depression, social anxiety disorder, post-traumatic stress disorder, generalized anxiety disorder: The recommended dose is 20mg daily, usually to be taken in the morning and maximum dose up to 50mg daily.
- Obsessive-compulsive disorder: The initial dose is 20mg daily, usually to be taken in the morning and maximum dose up to 60mg daily.
- Panic disorder: The initial dose is 10mg daily, usually to be taken in the morning and maximum dose up to 60mg daily.

## **Elderly**

The maximum dose for elderly is 40mg daily.

## Children under 18 years

Paroxetine is not recommended.

# Use in pregnancy and lactation

Paroxetine should only be used during pregnancy when strictly indicated. Abrupt discontinuation should be avoided during pregnancy. Neonates should be observed if maternal use of paroxetine continues into the later stages of pregnancy, particularly the third trimester.

Small amount of Paroxetine are excreted into breast milk and caution should be exercised when Paroxetine is administered to a nursing woman. In published studies, as no sign of drug effects were observed in infants, breast-feeding can be considered.

## **Side effects**

The most common side effects are somnolence, insomnia, agitation, abnormal dreams (including nightmares), increases in cholesterol levels, decreased appetite, dizziness, tremor, headache, blurred vision, yawning, nausea, constipation, diarrhea, vomiting, dry mouth, sweating, sexual dysfunction, asthenia, body weight gain.

The less common side effects are arrhythmias, confusion, urinary incontinence, panic attacks, depersonalization, neuroleptic malignant syndrome-like events, peripheral edema, acute glaucoma, hepatic disorders, priapism, tinnitus, extra pyramidal reactions and withdrawal reactions.

### **Precautions**

Paroxetine should be used with caution in patients with mania, epilepsy, seizures, bone fracture, diabetes, ECT, glaucoma, cardiac conditions, hyponatraemia, haemorrhage, renal/hepatic impairment.

### **Contraindications**

Paroxetine is contraindicated in patients with a hypersensitivity to Paroxetine or any of the exipients.

# **Drug interactions**

Paroxetine should not be used with pimozide, tyrptophan, drug metabolizing enzyme inducers /inhibitors, thioridazine, alcohol, fosamprenavir/ritonavir, MAOIs, lithium, phenytoin/anticonvulsants, warfarin, drugs affecting gastric pH, NSAIDs and acetylsalicylic acid.

## **Pharmaceutical precautions**

Keep away from the reach of children. Store in a cool and dry place protected from light. To be taken and sold only on the prescription of a registered physician.

#### Presentation

Parotin<sup>®</sup> 10 tablet: Each tablet contains Paroxetine 10mg as Hydrochloride Hemihydrate BP. Parotin<sup>®</sup> 20 tablet: Each tablet contains Paroxetine 20mg as Hydrochloride Hemihydrate BP.

#### Packaging

Parotin<sup>®</sup> 10 tablet: Carton of 30 tablets in blister pack. Parotin<sup>®</sup> 20 tablet: Carton of 30 tablets in blister pack.

® Registered Trade Mark

