Quitapex Film Coated Tablets 25, 100 & 200 mg
Quitapex Extended Release Tablets 300 & 400 mg

Active Substance: Quetiapine fumarate.

COMPOSITION:

Each Quitapex 25 mg tablet contains: 28.784 mg quetiapine fumarate equivalent to 25 mg quetiapine.

Each Quitapex 100 mg tablet contains: 115.14 mg quetiapine fumarate equivalent to 100 mg quetiapine.

Each Quitapex 200 mg tablet contains: 230.273 mg quetiapine fumarate equivalent to 200 mg quetiapine.

Each extended release tablet 300 mg contains: 345 mg quetiapine fumarate equivalent to 300 mg quetiapine.

Each extended release tablet 400 mg contains: 461 mg quetiapine fumarate equivalent to 400 mg quetiapine.

Inactive of Quitapex tablets 25, 100, 200 mg: Dibasic calcium phosphate dehydrate, microcrystalline cellulose, lactose monohydrate, povidone K-90, crospovidone, colloidal silicon dioxide, magnesium stearate, methocel E-5, PEG 6000, talc, titanium dioxide, FD&C red No. 40.

Inactive of Quitapex extended release tablets 300, 400 mg: Hypermellose (K15), sodium citrate dihydrate, microcrystalline cellulose, lactose monohydrate, magnesium stearate (vegetable), hypromellose (E5), polyethylene glycol 6000, titanium dioxide, mannitol, allura red, talc.

DOSAGE FORM:

Film coated tablets.

PHARMACODYNAMICS:

Quetiapine interacts with several neurotransmitter receptors.

Quetiapine exhibits a high affinity for serotonin (5HT2) receptors in the brain than it does for dopamine D1 and D2 receptors. Quetiapine also has high affinity at histaminergic and adrenergic α1 receptors with lower affinity at adrenergic α 2 receptors. Quetiapine has no affinity at cholinergic muscarinic and benzodiazepine receptors.

PHARMACOKINETICS:

Quetiapine is rapidly absorbed after oral dose and reaches peak plasma concentration in 1.5 hours. The bioavailability of quetiapine is marginally affected by administration of food.

Elimination of quetiapine is mainly via hepatic metabolism and the elimination half life is approximately 6 hours. The plasma protein binding is approximately 83%.

Mean plasma clearance was reduced by approximately 25% in patients with severe renal impairment and/or hepatic impairment.

INDICATIONS AND USE:

In the treatment of schizophrenia.

In the treatment of manic episodes associated with bipolar disorder.

DOSAGE AND ADMINISTRATION:

• *Quitapex Tablets:*

Quitapex should be administered twice daily with or without food. The dose is gradually increased over several days or weeks to achieve the desired effect.

- For Schizophrenia: The initial dose is 25 mg twice daily and dose can be increased up to 50 mg two or three times daily and the target dose is 300-400 mg daily, most patients respond between 150-750 mg daily.

- For Bipolar Disorders: The initial dose is 50 mg twice daily and dose can be increased up to 100-400 mg daily. Most patients respond to 400-800 mg daily.

Dose adjustment depends on the response and the tolerability of the patient within the range of 200-800 mg daily.

- For Elderly: Dose should be started with 25 mg daily increased up to 50 mg daily.

• *Quitapex Extended Release Tablets:*

- For Schizophrenia: Quitapex extended release tablets should be administered once daily preferably in the evening. The recommended initial dose is 300 mg. The effective dose range for Quitapex extended release tablets is 400-800 mg per day depending on the response and tolerance of the individual patient. Dose increase can be made at intervals as short as 1 day and in increments of up to 300 mg daily, individual dosage adjustments may be necessary. Quitapex extended release tablets should be swallowed whole and not split, chewed or crushed.

Quitapex extended release tablets should be taken without food or with a light meal.

CONTRAINDICATIONS:

Quitapex is contraindicated in patients sensitive to quetiapine or any other ingredient of the product.

SIDE EFFECTS:

The most common side effects are somnolence, dizziness, dry mouth, mild asthenia, constipation, tachycardia, orthostatic hypotension and dyspepsia. And with other antipsychotic, weight gain, syncope, neuroleptic malignant syndrome, leucopenia and peripheral edema, high blood sugar and diabetes.

DRUG INTERACTIONS:

- Ketoconazole increases in the AUC concentration of quetiapine.
- Not recommended with grapefruit.
- Carbamazepine increases the clearance of quetiapine.
- Imipramine and fluxetine delay the pharmacokinetics of quetiapine.
- Used with caution with drugs that cause electrolyte imbalance or to increase QTc interval.
- Thioridazine increases the clearance of quetiapine with approximately 70%.

PREGNANCY AND LACTATION:

- Quetiapine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- It is recommended that women receiving quetiapine should not breast feed.

PEDIATRIC USE:

The safety and effectiveness of quetiapine in pediatric patients have not been established.

PRECAUTIONS AND WARNINGS:

- Quetiapine should be used with caution in patients with known cardiovascular diseases, cerebrovascular diseases and cases of predisposing hypertension.
- Quetiapine may induce orthostatic hypotension which is common with elderly patients.
- Tardive dyskinesia, if signs and symptoms of tardive dyskinesia appear in a patient on quetiapine, drug discontinuation should be considered.
- Used with caution in combination with other centrally acting drugs or alcohols.
- Gradual withdrawal is advised to avoid withdrawal reactions.
- A life – threatening nervous problem (neuroleptic malignant syndrome) may result from quetiapine use.
- High blood sugar & diabetes may be developed during use of quetiapine.

- Increase chance of death in elderly patients with dementia.
- Increase risk of suicidal thinking and behavior in children, adolescent and young adult taking antidepressant for major depressive disorder and other psychiatric.
- May increase blood pressure in children & adolescent.
- Periodical monitoring of blood pressure is recommended.

INSTRUCTIONS FOR PATIENTS:

To be used under medical supervision.

PACKAGE AND STORAGE:

Quitapex 25, 100 & 200 mg F.C. tablets: Carton box contains 3 Alu / PVC blisters of 10 F.C. tablets + Insert lealfet.

Quitapex 300 & 400 XR tablets: Carton box contains 3 Alu / PVDC blisters of 10 extended release tablets + Insert lealfet.

- Store in a dry place at temperature not exceeding 30º C.

Keep All Medicines Out of Reach of Children

Manufactured by: Apex Pharma - S.A.E - Badr City -Egypt.

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