Information For the User Quetiapine Fumarate I.P. 25mg Tablet

Qtpair 25 Tablet

Brand Name: Qtpair 25 Tablet

Dosage Form: Tablet

Therapeutic Category: Atypical Antipsychotic

Composition:

Each film-coated tablet contains:

• Quetiapine Fumarate I.P. equivalent to Quetiapine 25 mg

• Excipients -q.s.

• Colour: Approved colour used

Pharmacology & Mechanism of Action:

Quetiapine is an atypical antipsychotic that acts as an antagonist at multiple neurotransmitter receptors in the brain. It shows high affinity for serotonin 5-HT₂ and dopamine D₂ receptors, which is believed to contribute to its antipsychotic effects. It also exhibits antagonism at histamine H₁ and adrenergic α_1 receptors, contributing to its sedative and orthostatic hypotensive properties. Quetiapine has a lower incidence of extrapyramidal side effects compared to typical antipsychotics.

Indications:

- Schizophrenia
- Bipolar disorder manic and depressive episodes
- Adjunctive treatment in major depressive disorder (as per physician's guidance)
- Generalized anxiety disorder (off-label, if prescribed)

Dosage & Administration:

- Initial dose: 25 mg once or twice daily
- May be increased gradually as per clinical response and tolerability
- Dosage must be individualized by the physician
- Can be taken with or without food
- Swallow whole with water do not crush or chew

Contraindications:

- Hypersensitivity to Quetiapine or any component of the formulation
- Concomitant use with strong CYP3A4 inhibitors unless benefits outweigh risks

Warnings & Precautions:

- May cause sedation and dizziness; caution during activities requiring mental alertness
- Risk of orthostatic hypotension especially in elderly
- Monitor for signs of suicidal thoughts or worsening depression
- Use cautiously in patients with cardiovascular disease, seizures, liver impairment, or diabetes
- Gradual withdrawal recommended to avoid withdrawal symptoms
- Periodic monitoring of lipid profile, glucose levels, weight, and blood pressure is advised

Drug Interactions:

• Metabolized mainly by CYP3A4 – inhibitors like ketoconazole may increase levels

- Inducers like phenytoin or carbamazepine may reduce plasma concentrations
- Caution with other CNS depressants additive sedative effects

Adverse Effects:

- Common: Drowsiness, dizziness, dry mouth, constipation, weight gain
- Less common: Orthostatic hypotension, increased appetite, blurred vision, elevated cholesterol
- Rare: Extrapyramidal symptoms, neuroleptic malignant syndrome, tardive dyskinesia

Overdose:

Symptoms: Drowsiness, sedation, tachycardia, hypotension

Severe overdose may lead to QT prolongation, seizures, or respiratory depression

Treatment: Supportive care and monitoring of cardiovascular function. No specific antidote

available

Storage:

Store in a cool and dry place below 25°C Protect from moisture and direct light Keep out of reach of children

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I,

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