## Information For the User Quetiapine Fumarate I.P. 50mg Tablet

# **Qtpair 50 Tablet**

**Brand Name:** Qtpair 50 Tablet

Dosage Form: Tablet

Therapeutic Category: Atypical Antipsychotic

## **Composition:**

Each film-coated tablet contains:

• Quetiapine Fumarate I.P. equivalent to Quetiapine 50 mg

• Excipients – q.s.

• Colour: Approved colour used

## Pharmacology & Mechanism of Action:

Quetiapine is an atypical antipsychotic that exerts its effect through antagonism of multiple neurotransmitter receptors in the brain. It has high affinity for serotonin (5-HT2A), dopamine (D2), histamine (H1), and adrenergic ( $\alpha$ 1 and  $\alpha$ 2) receptors. The combination of serotonin and dopamine antagonism is believed to improve both the positive and negative symptoms of schizophrenia while reducing extrapyramidal side effects. Quetiapine also affects sleep patterns and mood regulation through histaminergic and serotonergic mechanisms.

#### **Indications:**

- Schizophrenia
- Bipolar disorder manic and depressive episodes
- Adjunct in treatment-resistant depression (if prescribed)
- Generalized anxiety disorder (off-label use under physician discretion)

#### **Dosage & Administration:**

- Usual starting dose: 50 mg once or twice daily
- Dose should be adjusted gradually as per patient response and tolerability
- To be taken with or without food
- Swallow whole with water; do not crush or chew
- Dosage should be individualized under medical supervision

#### **Contraindications:**

- Known hypersensitivity to Quetiapine or any excipient in the formulation
- Concurrent use with potent CYP3A4 inhibitors unless clinically justified

## **Warnings & Precautions:**

- May cause drowsiness; caution when operating machinery or driving
- Monitor patients for suicidal ideation, especially at the beginning of therapy
- Risk of orthostatic hypotension, particularly in elderly or volume-depleted patients
- Monitor blood glucose, lipids, body weight, and liver function regularly
- Use with caution in patients with cardiovascular disease, history of seizures, or metabolic syndrome
- Gradual dose reduction is recommended when discontinuing the drug

## **Drug Interactions:**

- CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin) can increase plasma levels
- CYP3A4 inducers (e.g., phenytoin, carbamazepine) may reduce effectiveness
- Potentiates the sedative effects of alcohol and other CNS depressants

#### **Adverse Effects:**

- Common: Sedation, dizziness, dry mouth, constipation, weight gain
- Less common: Elevated cholesterol, orthostatic hypotension, fatigue
- Rare: Extrapyramidal symptoms, hyperglycemia, neuroleptic malignant syndrome

#### **Overdose:**

Symptoms may include drowsiness, hypotension, tachycardia, and rarely seizures or QT prolongation

Treatment is supportive; close monitoring of cardiovascular and respiratory status is required No specific antidote is available

### **Storage:**

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

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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