## Information For the User Quetiapine Fumarate I.P. 100mg Tablet

# **Qtpair 100 Tablet**

**Brand Name:** Qtpair 100 Tablet

**Dosage Form:** Tablet

Therapeutic Category: Atypical Antipsychotic

## **Composition:**

Each film-coated tablet contains:

• Quetiapine Fumarate I.P. equivalent to Quetiapine 100 mg

• Excipients -q.s.

• Colour: Approved colour used

## Pharmacology & Mechanism of Action:

Quetiapine is an atypical antipsychotic that acts by antagonizing multiple neurotransmitter receptors in the brain. It exhibits high affinity for serotonin 5-HT<sub>2</sub>A and dopamine D<sub>2</sub> receptors. Its antipsychotic activity is believed to be mediated through a combination of dopamine type 2 (D2) and serotonin type 2A (5HT2A) receptor antagonism. It also has affinity for histamine H1 and adrenergic  $\alpha$ 1- and  $\alpha$ 2-receptors.

### **Indications:**

- Schizophrenia
- Bipolar disorder manic and depressive episodes
- Bipolar maintenance therapy (in combination)
- Adjunct treatment for major depressive disorder (as approved by physician)

## **Dosage & Administration:**

- Dose must be individualized by the physician based on indication, age, and patient response
- Adults (schizophrenia or bipolar disorder): Starting dose usually 50 mg/day, titrated up to effective dose of 300–800 mg/day in divided doses
- Should be taken with or without food
- Dose adjustments may be required in elderly or hepatic impairment
- Taper gradually if discontinuing to avoid withdrawal effects

#### **Contraindications:**

- Hypersensitivity to Quetiapine or any excipient in the formulation
- Concomitant use with strong CYP3A4 inhibitors (e.g., ketoconazole) unless dose adjustment is made

#### **Warnings & Precautions:**

- Increased risk of mortality in elderly patients with dementia-related psychosis
- May cause sedation, orthostatic hypotension, and metabolic changes (weight gain, lipid, and glucose elevation)
- Monitor for extrapyramidal symptoms and tardive dyskinesia
- Caution in patients with cardiovascular disease, seizure disorders, or hepatic impairment
- Avoid use with alcohol and CNS depressants

## **Drug Interactions:**

- CYP3A4 inhibitors (e.g., erythromycin, ketoconazole) may increase serum levels
- Inducers like phenytoin, carbamazepine may reduce efficacy
- Additive sedation with CNS depressants
- Monitor QT prolongation risk with other QT-prolonging drugs

## **Adverse Effects:**

- Very common: Somnolence, dizziness, dry mouth
- Common: Weight gain, constipation, orthostatic hypotension, increased appetite
- Less common: Extrapyramidal symptoms, increased blood sugar or lipid levels
- Rare: Neuroleptic malignant syndrome, seizures, priapism

#### Overdose:

Symptoms: Drowsiness, hypotension, tachycardia, QT prolongation, seizures Treatment: Supportive care with monitoring of cardiovascular and respiratory status Activated charcoal may be used if within a few hours of ingestion

## **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,

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