1.6 Product Information

1.6.3 Patient Information Leaflet (PIL)

Mockup for package insert of OZITAS-10 (Olanzapine Tablets USP 10 mg) is enclosed in subsequent pages.

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

OZITAS

(OLANZAPINE TABLETS USP)

COMPOSITION

Ozitas 2.5
Each film coated tablet contains:
Olanzapine USP 2.5 mg
Ozitas 5
Each film coated tablet contains:
Olanzapine USP 5 mg
Ozitas 7.5
Each film coated tablet contains:
Olanzapine USP 7.5 mg
Ozitas 10
Each film coated tablet contains:
Olanzapine USP 10 mg
Ozitas 15
Each film coated tablet contains:
Olanzapine USP 15 mg
Ozitas 20
Each film coated tablet contains:
Olanzapine USP 20 mg

CLINICAL PHARMACOLOGY

Olanzapine is an antipsychotic agent that demonstrates a broad pharmacologic profile across a number of receptor systems. In preclinical studies, olanzapine exhibited a range of receptor affinities for serotonin 5HT2A/2C, 5HT3, 5HT6, dopamine D1, D2, D3, D4, D5 cholinergic, muscarinic receptors M1-M5, A1 adrenergic and histamine H1 receptors. Olanzapine demonstrated a greater in vitro affinity for serotonin- 5HT2 than dopamine- D2 receptors and greater 5HT2 than D2 activity in vivo, models. Electrophysiological studies demonstrated that olanzapine selectively reduced the firing of mesolimbic dopaminergic neurons, while having little effect on the striatal pathways involved in motor function. Olanzapine reduced a conditioned avoidance response, a test indicative of antipsychotic activity, at doses below those producing catalepsy, an effect indicative of motor side effects.

Olanzapine is well absorbed after oral administration, reaching peak plasma concentrations within 5 to 8 hours. The absorption is not affected by food. Olanzapine is metabolized in the liver by conjugative and oxidative pathways. The major circulating metabolite is the 10-N-glucuronide, which does not pass the blood brain barrier. The predominant pharmacologic activity is from the parent olanzapine. After oral administration, the mean terminal elimination half-life of olanzapine in healthy subjects varied on the basis of age and gender. The plasma protein binding of olanzapine was about 93% over the concentration range of about 7 to about 1000 ng/ml.

INDICATIONS

Olanzapine is indicated for the management of the manifestations of psychotic disorders including schizophrenia.

DOSAGE AND ADMINISTRATION

The recommended starting dose for olanzapine is 10 mg/day, administered as a single daily dose without regard to meals. Daily dosage may subsequently be adjusted on the basis of individual clinical status within the range of 5-20 mg daily. An increase to a dose greater than the routine therapeutic dose of 10 mg/day, i.e. to a dose of 15 mg/day or greater, is recommended only after appropriate clinical reassessment.

Children: Olanzapine has not been studied in subjects under 18 years of age.

Elderly patients: A lower starting dose (5 mg/day) is not routinely indicated but should be considered for those 65 and over when clinical factors warrant.

Patient with hepatitis and/or renal impairment: A lower starting dose (5 mg) may be considered for such patients.

CONTRAINDICATIONS, PRECAUTIONS & WARNINGS & DRUG INTERACTION

Olanzapine is contra-indicated in those patients with a known hypersensitivity to any ingredient of the product. Olanzapine is contraindicated in patients with known risk for narrow-angle glaucoma.

Concomitant illness: While olanzapine demonstrated anticholinergic activity in vitro, experience during the clinical trials revealed a low incidence of related events. Caution is advised when prescribing for patients with prostatic hypertrophy, or paralytic ileus and related conditions. Caution should be exercised in patients with elevated ALT and/or AST, in patients with signs and symptoms of hepatic impairment, in patients with pre-existing conditions associated with limited hepatic functional reserve, and in patients who are being treated with potentially hepatotoxic drugs. In the event of elevated ALT and/or AST during treatment, follow-up should be organised and dose reduction should be considered.

As with other neuroleptic drugs, caution should be exercised in patients with low leucocyte and/or neutrophil counts for any reason, in patients with a history of drug-induced bone marrow depression/toxicity, in patients with bone marrow depression caused by concomitant illness, radiation therapy or chemotherapy and in patients with hyper-eosinophilic conditions or with myeloproliferative disease.

In clinical trials there were no reported cases of NMS, neuroleptic malignant syndrome in patients receiving olanzapine. Clinical manifestations of NMS all antipsychotic drugs including olanzapine must be discontinued. Olanzapine should be used cautiously in patients who have a history of seizures or have conditions associated with seizures.

Given the primary CNS effects of olanzapine, caution should be used when it is taken in combination with other centrally acting drugs and alcohol. It is recommended that blood pressure is measured periodically in patients over 65 years. However, as with other antipsychotics, caution should be exercised when olanzapine is prescribed with drugs known to increase QTc interval, especially in the elderly.

USAGE IN PREGNANCY, LACTATION & CHILDREN.

Human experience is limited during pregnancy, hence this drug should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. It is not known if olanzapine is excreted in human milk. Patients should be advised not to breast-feed an infant if they are taking olanzapine.

DRUG INTERACTIONS

The concomitant administration of activated charcoal reduced the oral bioavailability of olanzapine by 50 to 60%. The metabolism of olanzapine may be induced by concomitant smoking or carbamazepine therapy. In clinical trials with single doses of olanzapine no inhibition of the metabolism of imipramine/desipramine, warfarin, theophylline or diazepam and was evident. Olanzapine showed no interaction when co-administered with lithium or biperiden.

SIDE EFFECTS

The only frequent side effects associated with the use of olanzapine in clinical trials were somnolence and weight gain. Occasional effects associated with the use of olanzapine in clinical trials included dizziness, increased appetite, peripheral oedema, orthostatic hypotension, and mild, transient anti cholinergic effects, including constipation and dry mouth.

OVERDOSAGE

Experience with olanzapine in overdosage is limited. There is no specific antidote to olanzapine, therefore, appropriate supportive measures should be initiated.

STORAGE

Store up to 30°C, protected from light.
Keep out of reach and sight of children.

PRESENTATION

Ozitas 2.5/5/7.5/10/15/20 tablets (Olanzapine tablets USP 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg & 20 mg) are available in strips of 10 tablets.

Manufactured by:
INTAS
INTAS PHARMACEUTICALS LTD.
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80 989 0 8610035