

Prexal®

Olanzapine

COMPOSITION:

Prexal 5: each caplet contains olanzapine 5 mg.

Prexal 10: each caplet contains olanzapine 10 mg.

ACTION:

Olanzapine belongs to a group of medicines called antipsychotics.

Olanzapine is used to treat disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.

Olanzapine can also be used to treat a condition with symptoms such as feeling "high", having abnormal amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability.

CONTRAINDICATIONS:

- If you are hypersensitive (allergic) to olanzapine. An allergic reaction may be recognized as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor.

- If you have been previously diagnosed with narrow-angle glaucoma.

SPECIAL PRECAUTIONS AND WARNINGS:

- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given olanzapine tell your doctor.

- Very rarely, medicines of this type cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor at once.

If you suffer from any of the following illnesses tell your doctor as soon as possible:

- Diabetes
- Heart disease
- Liver or kidney disease
- Parkinson's disease
- Epilepsy
- Prostate problems
- A blocked intestine (Paralytic ileus)
- Blood disorders

As a routine precaution, if you are over 65 years your blood pressure may be monitored by your doctor.

Atypical -second generation- antipsychotic medications (Olanzapine, Aripiprazole, Risperidone & Quetiapine) are not approved for the treatment of dementia-related psychosis because of the increased risk of death compared to placebo.

Pregnancy:

Tell your doctor as soon as possible if you are pregnant or think you may be pregnant. You should not take this medicine when pregnant unless you have discussed this with your doctor.

Breast-feeding:

You should not be given this medicine when breast-feeding.

Driving and using machines:

There is a risk of feeling drowsy when you are given olanzapine. If this happens do not drive or operate any tools or machines. Tell your doctor.

Drug Interactions:

Please inform your doctor if you are taking or have recently taken any other medicines, even those not prescribed. Especially tell your doctor if you are taking medicines for Parkinson's disease. Do not drink any alcohol if you have been given Olanzapine, as olanzapine and alcohol together may make you feel drowsy.

Only take other medicines while you are on olanzapine if your doctor tells you that you can. You might feel drowsy if olanzapine is taken in combination with antidepressants, or medicines taken for anxiety or to help you sleep (tranquillizers). You should tell your doctor if you are taking fluvoxamine (an antidepressant) or ciprofloxacin (an antibiotic), as it may be necessary to change your olanzapine dose.

DOSEAGE AND ADMINISTRATION:

Your doctor will tell you how many olanzapine caplets to take and how long you should continue to take them. The daily dose of olanzapine is between 5 - 20 mg. You should take your olanzapine caplets once a day following the advice of your doctor. Try to take your caplets at the same time each day. It doesn't matter whether you take them with or without food. You should swallow the olanzapine caplets whole with water. Don't stop taking your caplets just because you feel better. It is important that you carry on taking olanzapine for as long as your doctor tells you.

Olanzapine is not for patients who are under 18 years.

- If you take more olanzapine than you should: contact your doctor or hospital straight away.

- If you forget to take olanzapine: take your caplets as soon as you remember. Don't take two doses in one day.

POSSIBLE SIDE EFFECTS:

Like all medicines, olanzapine can have side effects. Adverse effects with olanzapine may include sleepiness or extreme tiredness, putting on weight, dizziness, feeling more hungry, water retention, constipation, dry mouth, restlessness, unusual movement, tremor, rigidity, problems with speech and changes in the levels of some blood cells and circulating fats. Very rarely, some patients have developed inflammation of the pancreas causing severe stomach pain, fever and sickness.

Some people may feel dizzy or faint (with a slow heart rate) in the early stages of treatment, especially when getting up from a laying or sitting position. This will usually pass on its own but if it does not, tell your doctor.

Patients with Alzheimer's disease may have trouble walking. In patients with Parkinson's disease olanzapine may worsen the symptoms.

Rarely olanzapine may cause an allergic reaction (e.g. swelling in the mouth and throat, itching, rash), slow heart rate or make you sensitive to sunlight. Very rarely, there have been reports of liver disease, prolonged and/or painful erection or difficulty in passing urine. Some patients have experienced high blood sugar or worsening of diabetes, with ketoacidosis (ketones in the blood and urine) or coma occurring very rarely. If you suddenly stop taking olanzapine, symptoms such as sweating, unable to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest you reduce the dose gradually before stopping treatment.

Rarely women taking medicines of this type for a long time have started to secrete milk and have missed periods or had irregular periods. If this persists tell your doctor. Very rarely babies born to mothers who have taken olanzapine in the last stage of pregnancy (3rd trimester) may have tremors, be sleepy or drowsy.

Seizures may occur rarely. In most cases, a history of seizures (epilepsy) has been reported. If you notice any side effects not mentioned in this leaflet, please inform your doctor.

STORAGE CONDITIONS:

Store below 30 °C

Do not use after the expiry date.

PRESENTATION:

Prexal 5 : 30 film coated caplets.

Prexal 10 : 30 film coated caplets.

- A medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTRIES
UNION OF ARAB PHARMACISTS

Produced by:

 **JOSWE®** medical

Jordan Sweden Medical and Sterilization Co.

Natur - Jordan

الأردنية الهاشمية للمنتجات الطبية والتقديم ج.م.م. نابور - الأردن

www.joswe.com

(P139/13-04-05/R1)