PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The dispensing of this medicine requires a doctor's prescription Read this package insert carefully in its entirety before using this medicine

The format of this leaflet was determined by the Ministry of Health and its content has been checked and approved

# **ORAP FORTE** Tablets

**Composition:** Each tablet contains: Pimozide 4 mg

Inactive ingredients: Calcium hydrogen phosphate dihydrate, Maize starch, Microcrystalline cellulose, Talc, Polyvidone K30, Cottonseed oil hydrogenated, Yellow ferric oxide (E172), Indigotindisulphonate (E132-Aluminium Lake).

Therapeutic group: An antipsychotic drug of the diphenylbutylpiperidine class.

# Therapeutic activity: A neuroleptic preparation.

## When should the preparation not be used?

Do not breastfeed while using this medicine. Do not take **Orap Forte** if you suffer from a very slow heart rate. Do not use this medicine if there is a known sensitivity to any of its ingredients

Do not use this medicine if you suffer from depression. Do not use this medicine if you are suffering from Parkinson's disease.

Do not use this medicine if you experience drowsiness or slowness resulting from an illness, from taking medications or from drinking alcohol

- Iresulting from an illness, from taking medications or from drinking alcohol.
  Do not use this medicine if you have heart problems, particularly heart rate disorders, irregular electrical activity of the heart (sometimes called "OT segment prolongation"), if you have a family history of electrical activity disorders of the heart or if you are using medicines that can change the electrical activity of the heart.
  Do not use this medicine if you have lower than usual mineral (electrolyte) levels in your blood. Your doctor will advise you in this matter.
  Do not take Orap Forte together with:
  certain azole antifungals (for instance: ketoconazole, itraconazole, miconazole or fluconazole) or with certain antibiotics from the macrolide group, such as: erythromycin, azithromycin, clarithromycin, clar

- antialiergics, such as asternizole and terrenatine.
  cisapride a medicine for treating digestive disturbances.
  halofantrine a medicine for treating malaria.
  sparfloxacin an antibacterial medicine.
  certain medicines that can affect the mineral balance in your body, such as diuretics.
  In case of doubt, contact a doctor.
  Do not drink grapefruit juice during treatment with Orap Forte.

# Do not take this medicine without consulting a doctor before starting treatment:

If you are pregnant or are planning to become pregnant. In women taking Orap Forte in the last trimester of their pregnancy the following effects may occur in the newborn: shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, difficulties is fording the newborn

If you are suffering, from epilepsy or other problems that can cause function of the liver, from epilepsy or other problems that can cause fits (convulsions).

fits (convulsions). If you are an elderly patient suffering from dementia, which is a disease that causes mental decline with symptoms such as loss of memory, reduced attention and speech difficulties, taking **Orap Forte** can be associated with other risks. The doctor will speak to you about this.

### How will this medicine affect your daily life?

Use of this medicine may cause drowsiness in the early stages of treatment and therefore, may impair alertness when driving a car, operating dangerous machinery and in any other activity which requires alertness. Therefore, driving or operating machinery is permitted only with a physician's consent.

Do not drink wine or alcoholic beverages while under treatment with this medicine.

### Warnings

Warnings: If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

### Drug interactions:

Drug interactions: If you are taking another drug, including non-prescription medicines and food supplements, or if you have just finished treatment with another medicine, inform the attending doctor before commencing treatment with Orap Forte, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for the following medicine. medicines

Medicines for treatment of parkinsonism

- Medicines for treatment of parkinsonism. Do not take Orap Forte together with: certain azole antifungals (for instance: ketoconazole, itraconazole, miconazole or fluconazole) or with certain antibiotics from the macrolide group, such as: erythromycin, azithromycin, clarithromycin or troleandomycin. Use of medicines from these groups which are intended for external use (for instance: creams, lotions or vaginal capsuled is allowed. intended for external use (for instance: creatins, roughts or vaginal capsules) is allowed. certain medicines for treating AIDS, such as: ritonavir, indinavir, sequinavir. certain antidepressants, such as: nefazodone, amitriptyline, maprotiline, sertraline, paroxetine, citalopram and escitalopram. certain medicines for treating mental illnesses, such as: chlorpromazine and certipdole

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· certain medicines that can affect the mineral balance in your body, such as diuretic

In addition, avoid drinking grapefruit juice during treatment with Orap Forte.

### Side effects:

In addition to the desired effect of the medicine, adverse reactions may Very common side effects (reported in at least one user in every 10): Excessive sweating, excessive nighttime urination, dizziness,

sleepiness. Common side effects (reported in at least one user in 100 but in less than one user in 10):

Agitation, restlessness, depression, difficulty sleeping, tiredness and lack of energy, loss of appetite, dry mouth, vomiting, constipation, headache, blurred vision, oily skin, frequent urination, erection problems in men. Uncommon side effects (reported in at least one user in 1,000 but in less than one user in 100): In women, absence of monthly period, swelling of the face. Very rare side effects (reported in less than one user in 10,000): High blood sugar levels in diabetes patients, sugar in the urine; insufficient blood sodium levels; abnormalities in the heart tracing (electrocardiogram, "ECG") and abnormalities in the test of electrical activities of your brain (EEG). Other side effects: Epileptic fits/convulsions.

Hormonal changes that may lead to unexpected production of milk in women, swelling of the breasts in men, loss of sexual desire. Changes in body temperature

Changes in body temperature
Side effects that require special attention:
Refer to the doctor if you experience hormonal changes that can cause sudden production of milk in women, enlargement of breasts (also in men), erectile problems in men, in wornen: abnormal menstrual cycle, light periods or absence of periods.
Stop treatment and refer to the doctor immediately if you encounter the following effects:
Severe allergic reaction whose signs are rash, hives, acute irritation of the skin, itching, swelling of the face, mouth and tongue, difficulty breathing and swallowing.
Neuroleptic malignant syndrome whose signs are rapid pulse, changes in blood pressure and sweating accompanied by fever, rapid breathing, muscle stiffness, reduced consciousness and coma, elevated blood levels of the enzyme creatine phosphokinase.
Heart problems: rhythm disorders, fibrillations, more rapid pulse than usual.

- usual
- usual. 4. Involuntary movements and problems such as slowness, muscle stiffness or spasms, tremor, chills, restlessness and stiff neck. Excessive salivation, involuntary movements and spasms of the tongue, the face, the mouth, the jaw or the throat, speech difficulties, rolling of the eyes you may need to receive an additional medicine.

Overdosage: Refer to the doctor immediately if you have taken an overdose. You may experience one of the following signs: muscle stiffness, inability to move or inability to sit still and irregular heartbeat.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

### Dosage:

Dosage is according to doctor's instructions only. Do not exceed the recommended dosage. This medicine is not usually intended for use in children under 12

This medicine is not usually intended for use in children under 12 years of age. Take Orap Forte once a day, preferably in the morning at the dose determined by the doctor. It is possible that some time will pass before you feel the full effect of the medicine. Do not stop taking this medicine without explicit instructions from the doctor. If you stop taking **Orap Forte** too early, without the doctor's consent, your problem may recur. If the doctor instructs you to stop treatment, this will have to be done gradually, especially if you have been taking high dosages. If you stop treatment abruptly you may experience one of the following symptoms: Nausea, vomiting, difficulty sleeping and temporary jerky movements.

Nausea, vomiting, difficulty sleeping and temporary jerky movements. Therefore, remain in contact with your doctor from the moment you

I herefore, remain in contact with your doctor from the moment you stop treatment. The doctor may change the dosage of the medicine until the most suitable dose for you is found. This medicine is to be taken at specific time intervals as determined by the attending doctor. If you forget to take this medicine at the specified time, take the dose as soon as you remember; but never take two doses together!

### Attention!

Avoid drinking grapefruit juice while under treatment with Orap Forte.

# Directions for use: Do not chew! Swallow the medicine with water.

How can you contribute to the success of the treatment?

Even if there is an improvement in your health, or alternatively, if you feel that the medicine is not helping you, do not discontinue treatment with this medicine without consulting your doctor.

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. <u>Do not induce vomiting</u> unless explicitly instructed to do so by a doctor! This medicine has been prescribed for the treatment of your allment in

This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm. Do not give this medicine to your relatives, neighbours or acquaintances.

<u>Do not take medicines in the dark!</u> Check the label and the dose each time you take your medicine. Wear glasses if you need them.

## Storage:

Storage: Store below 25°C. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medications in the same package.

## Drug Registration No.: 139-76-20863

Manufacturer: Lusomedicamenta, Sociedade Técnica Farmacêutica, Portugal,

License Holder: J-C Health Care Ltd., Kibbutz Shefayim 60990, Israel.