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 was checked and approved

OXACATIN

Syrup

Composition: Each 5 ml contains:

Oxomemazine 1.65 mg
Potassium guaiacolsulphonate 33.30 mg
Sodium benzoate 33.30 mg
Each 5 ml contains approximately 3.0 gram sugar.

Inactive ingredients: Sugar, sorbitol, propylene glycol, sodium citrate, caramel flavour, citric acid, caramel color liquid, purified water.

Therapeutic group:

Oxomemazine - cough suppressant of phenothiazines group.

Potassium guaiacolsulphonate - expectorant.

Therapeutic activity: Antitussive syrup, expectorant. When should the preparation not be used?

Do not use this medicine if you are pregnant, two weeks before delivery and/or breastfeeding. Do not use this medicine if you are taking large doses of central nervous system (CNS) depressants. Do not use this medicine if you are sensitive to any of its ingredients.

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

If you are pregnant. If you are suffering, or have suffered in the past, from: Reye's syndrome, Parkinson's disease, bone marrow suppression, impaired function of: the respiratory system, the eyes (e.g. glaucoma), the heart and/or vascular system, the liver, the kidney/urinary tract, the digestive system (e.g. ulcer), the blood system, the prostate gland.

How will this medicine affect your daily life?

Use of this medicine may impair alertness and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery and in any other activity which requires alertness. Children should be cautioned against engaging in activities such as bicycle riding, playing near roads and the like.

<u>Do not drink wine</u> or alcoholic beverages while under treatment with this medicine.

This medicine may cause particular sensitivity upon exposure to the sun. Therefore, avoid exposing yourself to the sun and use appropriate protection (long clothes, a hat, sunscreen agents, etc.).

Warnings: Use of this medicine may cause blurring of vision.

Prolonged use may decrease salivary flow, and therefore could cause dental problems. This medicine may cause confusion, dizziness and sleepiness in the elderly.

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

Drug interactions: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups: drugs affecting the central nervous system (e.g.: sedatives, hypnotics, drugs for parkinsonism, epilepsy, general anesthetics and narcotic analgesics), anticholinergics or medications with anticholinergic activity (e.g.: tricyclic or monoamine

oxidase inhibitor antidepressants), antihypertensives and heart medications, antithyroid medications, epinephrine, alcohol-containing medications, appetite suppressants, hepatotoxic medications (especially for patients on prolonged therapy or with history of liver disease), antacids and absorbent antidiarrheals.

Side effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: dryness of the mouth, nose or throat, constipation, headache, nausea and loss of appetite, drowsiness, feeling of raised temperature, nasal congestion.

Side effects that require special attention:

Skin irritation, faintness, loss of balance, difficult or painful urination, unusual weakness, increased sweating, confusion, increased sensitivity of skin to sun (see above), disturbances in vision, restlessness, involuntary movements (rare): stop treatment and consult your doctor. 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.

Adverse reactions and drug interactions in children and infants: Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child!

See above for details of special side effects and drug interactions.

Dosage: Dosage is according to doctor's instructions only.

Do not exceed the recommended dosage. Do not use this medicine under 1 year of age.

This medicine is not usually recommended for administration to children under 2 years of age, children with acute illness (such as: chickenpox, measles, central nervous system infections, gastroenteritis) or dehydrated children.

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 a double dose to compensate for a missed one!

Directions for use: Swallow the medicine with a small amount of water. Take the medicine with a meal or with milk.

Do not retain this medicine in the mouth for a period longer than that required for swallowing.

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the doctor. Even if there is an improvement in your health, do not discontinue use of 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 ailment; in another patient it could cause harm. Do not give this medicine to relatives, neighbours or friends.

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

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.

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Manufacturer: Taro Pharmaceutical Industries Ltd.,

P.O.Box 10347, Haifa Bay 26110.