Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

ENTUMIN® 40 mg
Tablets

Active ingredient and its quantity:
Each tablet contains:
Clotiapine 40 mg

For the list of inactive ingredients see section 2 "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

For the treatment of severe mental and emotional disorders (neuroleptic).

Therapeutic group:
Antipsychotic

2. Before using this medicine

X Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient (clotiapine) or to any of the other ingredients in this medicine (see section 6).
- In states of unconsciousness or severe CNS depression.
- If you have a predisposition to seizures.
- If you have increased intraocular pressure (narrow angle glaucoma).
- If you are breastfeeding.
- In children below the age of 16 years.

Special warnings about using this medicine
! Before using Entumin, tell your doctor if:

- You suffer from any of the following problems: prostate disease, intestinal, renal, cardiac (including a disorder known as QT interval prolongation) or hepatic disorder, Parkinson's disease, low blood pressure (hypotension), dementia.
- Any of your family members has a history of blood clots, since blood clot formation has been already associated with such medicines.

Additional warnings:

- Immediately contact a doctor if you develop fever.

- The treatment must be stopped gradually.

Children and adolescents:
Entumin should not be administered to children below the age of 16 years.

Tests and follow up:
- During the treatment period with this medicine, blood pressure monitoring should be conducted in elderly patients.
- In patients with history of low white blood cell levels or drug induced leukopenia/neutropenia, the doctor will conduct frequent complete blood count monitoring in the first treatment months.
- In patients with neutropenia, the doctor will closely monitor fever or other infection symptoms.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- Substances affecting the CNS such as: alcohol, sedatives, analgesics, hypnotics, MAO inhibitors and antihistamines.
- Antihypertensive medicines.
- Lithium.
- Medicines prolonging the QT interval or causing electrolyte imbalance.

Using this medicine and alcohol consumption
Avoid drinking alcohol.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think that you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy
Immediately notify your doctor upon confirmation of pregnancy. The doctor is the most appropriate person to decide whether to prescribe Entumin during pregnancy.

The following symptoms may occur in neonates born to mothers who have taken Entumin during the last trimester (last 3 months of their pregnancy): tremor, muscle stiffness and/or muscle weakness, somnolence, agitation, respiratory distress and feeding difficulties. If your baby demonstrates any of the above symptoms, contact a doctor.

Breastfeeding
Do not use Entumin during breastfeeding. The metabolites of Entumin are excreted in breast milk.

Driving and using machines
Avoid driving or operating machines, especially at the beginning of treatment, since Entumin may cause somnolence and reduce your reaction capacity.

Important information about some of this medicine's ingredients

The tablets contain lactose. If you have been told in the past by a doctor that you have an intolerance to certain sugars, consult your doctor before starting treatment with this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

- Do not exceed the maximal daily dosage of 360 mg in divided doses.
- In underweight patients, patients with liver or kidney disease and in the elderly, treatment should be started at lower doses, and the dosage should be gradually increased.

Do not exceed the recommended dose.

- Do not chew!
- Swallow the medicine with some water.
- The tablet can be split at the score line and crushed.

If you have accidentally taken a higher dose, you may experience: somnolence or significant agitation, a comatose state, seizures, difficulties breathing, blood pressure drop, very rapid or irregular heart rate, tremor, muscle stiffness. If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forgot to take Entumin

Do not take a double dose to compensate for the forgotten dose.

If you stop taking Entumin

The treatment must be stopped gradually. Even if your health improves, do not stop taking this medicine without consulting your doctor.
Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects:

Like with all medicines, using Entumin may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Consult your doctor immediately if you notice any of the following symptoms:
- Venous blood clots, especially in the legs (the symptoms observed include swelling, pain and redness in the leg), which may move along the blood vessels to the lungs, causing chest pain and difficulties breathing.
- If fever develops.

The most common side effects, especially at the beginning of treatment, are dizziness (and sometimes incidents of loss of consciousness) with a sudden change in the body state, sensation of dry mouth, visual disturbances and constipation.
In rare cases (≥ 1/10,000; < 1/1,000) the following effects may occur: somnolence or agitation and confusion, tremor, muscle stiffness, restlessness, extremely rapid heart rate.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects following drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions

- Do not store above 25°C.
- Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Lactose, maize starch, cellulose microcrystalline, gelatin, colloidal anhydrous silica, paraffin liquid, talc, magnesium stearate.

What the medicine looks like and contents of the pack:
Round and flat white to yellowish tablets, with a slanted edge and a score line on one side, packed in a blister (tray) package.
Each pack contains 30 or 500 tablets.
Not all pack sizes may be marketed.

Registration holder's name and address:
Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761

Manufacturer's name and address:
DELPHARM L'AIGLE,
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Registration number of the medicine in the National Drug Registry of the Ministry of Health:
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