

Patient leaflet according to pharmacists' regulations (preparations) 1986.

Maronil

החיות: השימוש עלול לפגום בכישרון הנהיגה
 אזהרה: الاستعمال قد يؤثر في قابلية السوافة
 Caution! Use may disturb driving ability

Maronil

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

Composition:

Each dragee of Maronil 25 contains: Clomipramine HCl 25 mg.
 Each sustained release tablet of Maronil 75 S.R. contains:
 Clomipramine HCl 75 mg.

Therapeutic activity:

Treatment of various types of depression and obsessive-compulsive disorders (OCD).

When should the preparation not be used?

Do not use this medicine if you are sensitive to any of its ingredients or to other tricyclic antidepressants.

Do not use this medicine concomitantly with a monoamine oxidase inhibitor (MAOI, for treating depression). 14 days should elapse between discontinuation of an MAOI and initiation of treatment with Maronil.

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

If you are pregnant or breastfeeding.

If you are suffering, or have suffered in the past, from impaired function of the respiratory system (e.g. asthma), the heart and/or vascular system, the eyes (e.g. glaucoma), the liver, the kidney/urinary tract, the digestive system (e.g. ulcer), the thyroid gland, the blood system (e.g. coagulation disorder), the prostate gland, diabetes (use of this medicine can alter (increase or decrease) the blood glucose levels), alcoholism and epilepsy.

If you are receiving an electroconvulsive therapy (ECT).

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.

Do not drink wine 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:

During treatment with this medicine, the following tests should be performed: blood and liver function. If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine. If you are about to undergo an operation (including a dental operation) or any action which involves anesthesia, please report the anesthetist that you are taking this medicine.

Do not take another antidepressant medicine concomitantly with Maronil.

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: affecting the central nervous system (e.g. sedatives, hypnotics, drugs for parkinsonism, epilepsy, antiallergics, anesthetics or narcotic analgesics), antihypertensives, cough and cold preparations, drugs for thyroid therapy, anticholinergic medicines and medicines with anticholinergic effect (e.g. stomach antispasmodic), cimetidine (for peptic ulcer), alcohol, clonidine (for

hypertension and migraine), sulfiram (Antabuse).

14 days should elapse between discontinuation of monoamine oxidase inhibitor (MAOI) and initiation of treatment with Maronil.

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, diarrhea, blurring of vision, nausea, drowsiness, headache, dizziness, sensitivity upon exposure to the sun, weakness, weight gain and unpleasant taste. If the symptoms are persisting or disturbing refer to your doctor.

Effects that require special attention:

Skin rash or irritation, high body temperature, difficulty of speaking or swallowing, tremor, constipation, paralytic ileus, sore throat, hallucinations, eye pain, slowed movements, urinary retention (rare): stop treatment and refer to 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.

Dosage:

Dosage is according to doctor's instructions only.

Do not exceed the recommended dosage.

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 specific time, take the dose as soon as you remember, but never take a double dose to compensate for a missed one.

Directions for use:

Do not chew! Swallow the medicine with a small amount of water.

How can you contribute to the success of the treatment?

Even if there is an improvement in your health, do not discontinue use of this medicine, before consulting your doctor and then reduce the dosage gradually. Few weeks of therapy may be required before the desired response is obtained.

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.

Do not induce vomiting unless explicitly instructed to do so by a doctor!

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.

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

Storage:

Store in a cool and dry place. 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.

Manufactured by TRIMA Ltd., Kibbutz MAABAROT

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