

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

The medicine is dispensed with a doctor's prescription only

# MARONIL 25

## Tablets

### Composition:

Each **Maronil 25** tablet contains: Clomipramine Hydrochloride 25 mg Inactive and allergenic ingredients in the preparation – see section 2, “Important information about some of the ingredients of the medicine” and section 6 “Further information”.

### Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

#### Depression of various origins

The use of **Maronil 25** to treat states of depression of various causes and symptoms in children and adolescents (of ages 0-17 years) is not recommended as there is insufficient information on the safety and efficacy of **Maronil 25** for treatment of this indication in children and adolescents.

#### Obsessive-compulsive disorder (OCD)

There is no experience in children younger than 5 years of age.

#### Therapeutic group

Tricyclic antidepressants, nonselective monoamine reuptake inhibitors. **Maronil 25** is used in adults to treat different types of depression and obsessive compulsive disorders associated with compulsive behavior and thoughts. Mood, as well as physical symptoms, such as sleeplessness, dizziness, heart palpitations and other disturbances, improve.

**Maronil 25** is also used to treat obsessive compulsive disorders in children and adolescents over the age of 5.

**Maronil 25** seems to act by increasing the amount of natural chemical transmitters (noradrenaline and serotonin) in the brain or by extending the duration of their effect.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine:

- If you have or have had hypersensitivity (an allergic reaction) to clomipramine or to any of the additional ingredients listed in section 6 “Further information” and in section 2 “Important information about some of the ingredients of the medicine” or to another medicine from the tricyclic antidepressants group.
- In combination with certain medicines to treat depression, such as monoamine oxidase (MAO) inhibitors or during the 14 days before or 14 days after treatment with MAO inhibitors.
- In combination with antiarrhythmics, such as quinidine and propafenone.
- If you have recently had a heart attack or if you suffer from a serious heart disease (congenital prolonged QT interval syndrome).
- In the following cases:
  - Severe intoxication from central nervous system depressants (e.g., hypnotics, analgesics or psychotropics) or from alcohol
  - Severe urinary retention
  - Severe confusion (delirium)
  - Untreated narrow-angle glaucoma (increased intraocular pressure)
  - Prostatic hyperplasia with urinary retention

<ul style="list-style-type: none"><li>Pyloric (the passage between the stomach and the duodenum) stenosis</li><li>Paralytic ileus</li></ul>
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#### Special warnings regarding use of the medicine

In certain circumstances, **Maronil 25** should not be taken or should only be taken after a thorough medical evaluation.

Therefore, inform the doctor if you suffer from or have suffered from any of the following disturbances or diseases:

- Tendency for epileptic seizures
- Heart rhythm disorders or other heart or blood vessel problems
- Other mental conditions
- Increased intraocular pressure (glaucoma)
- Liver or kidney disease
- Changes in blood cell count
- Intoxication (e.g., from medicines)
- Gastric emptying disorders
- Difficulties passing urine or an enlarged prostate
- Overactive thyroid gland or taking thyroid medication at the same time with **Maronil 25**
- Alcohol addiction
- Frequent constipation or bowel blockage
- Fainting
- Change in mood from depression to extreme euphoria
- If you have suicidal thoughts
- If you suffer from schizophrenia
- If you are about to undergo electroconvulsive therapy (ECT)
- If you take certain medicines to treat depression, e.g., selective serotonin reuptake inhibitors (SSRIs) (such as: fluoxetine) or serotonin and noradrenaline reuptake inhibitors (SNARIs), other tricyclic antidepressants and lithium
- If you are suffering from hypokalemia (low concentrations of potassium in the blood)

#### Further safety measures

- It is important that you and your family or caregivers discuss with the doctor any change in mood during the course of treatment with **Maronil 25**.
- If you wear contact lenses and suffer from eye irritation, inform your doctor.
- Before every surgical procedure or before starting dental treatment, inform the doctor or the dentist that you are taking **Maronil 25**.
- Maronil 25** may cause your skin to be more sensitive to sunlight. Therefore, avoid direct exposure to sunlight, wear sunglasses and protect the skin with appropriate clothing.
- Tell your doctor or pharmacist if you experience fainting or any other disease, any allergies, sugar intolerance (e.g., lactose, sucrose) or are taking any other medicine (including non-prescription) or applying any medicines externally.

#### Children and adolescents

The medicine is not intended for children and adolescents under the age of 18 for the indication of depression of varying origins.

The medicine is not intended for children under the age of 5 for the indication of obsessive-compulsive disorder (OCD).

#### Tests and follow-up

It is important that your doctor regularly monitor the progress of your treatment so that he can adjust the dosage and consequently reduce the side effects.

Your doctor may also perform blood tests, measure your blood pressure and check your heart and liver functions.

**Maronil 25** may cause dry mouth, which may increase the risk of caries. Therefore, during prolonged treatment, dental examinations should be performed regularly.

#### Information for families and caregivers

When **Maronil 25** is given to children and adolescents, behavioral changes should be looked out for.

The symptoms of depression, particularly suicidal behavior, may get worse during the course of treatment with **Maronil 25**. If they worsen,

contact the doctor immediately.

There have been reports of an increase in the frequency of behavioral disorders, including increased risk of suicidal thoughts, self-harm and suicide, in children, adolescents and young adults (up to the age of 25) with depression or other psychiatric diagnoses, who are being treated with antidepressants. This was observed in data from clinical trials.

Treatment must not be stopped suddenly, rather, only in consultation with the doctor, since withdrawal symptoms may occur.

#### Elderly patients

Elderly patients generally need lower dosages than young and middle-aged patients. Side effects are more likely to occur in elderly patients. The doctor will provide any special information about dosage precautions and the need for close monitoring.

#### Pregnancy and breastfeeding

Inform the doctor if you are pregnant, are planning to become pregnant or are breastfeeding.

Do not take **Maronil 25** during pregnancy, unless specifically prescribed by the doctor.

The doctor will weigh the risk to the unborn baby versus the medical benefit to the mother and make a decision regarding use of **Maronil 25**. The active ingredient of **Maronil 25** passes into breast milk and mothers taking **Maronil 25** are therefore advised not to breastfeed.

#### Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Medicines for the heart or blood pressure
- Medicines that affect the central nervous system (such as: barbiturates, benzodiazepines, surgical anesthetics)
- Other antidepressants (such as: SSRIs or SNARIs)
- Sedatives
- Epilepsy medicines (such as: barbiturates, valproic acid, carbamazepine and phenytoin)
- Hypnotics (such as: benzodiazepines)
- Strong analgesics (opiates)
- Medicines for preventing blood clotting (anticoagulants)
- Medicines for asthma or allergies
- Medicines for Parkinson's disease
- Thyroid medicines
- Medicines with the active ingredient cimetidine, for excessive secretion of gastric acid or gastric ulcers
- Hormonal contraceptives (birth control pills)
- Estrogens
- Methylphenidate (primarily used for attention deficit hyperactivity disorder [ADHD])
- Certain medicines to reduce blood lipids (ion-exchange resin)

Since many medicines may react with **Maronil 25**, it may be necessary to adjust the dosage or stop treatment with one of the medicines.

#### Use of the medicine and food

Grapefruit, grapefruit juice, cranberry juice – may affect how the medicine works.

#### Driving and operating machinery

This medicine may impair your responses, your ability to drive and your ability to use tools or machinery. **Maronil 25** may cause you to be sleepy, reduce your alertness or cause blurred vision. If this happens to you, avoid driving a vehicle, operating machinery or engaging in any activity that requires full alertness. These effects may be increased by other medicines or alcohol.

Children should be cautioned against riding a bicycle or playing near the road, and the like.

#### Use of the medicine and alcohol consumption

It is recommended to avoid drinking alcohol during the course of treatment, as **Maronil 25** may reduce alcohol tolerance.

#### Smoking

Inform your doctor of changes in smoking habits.

#### Important information about some of the ingredients of the medicine

**Maronil 25** contains lactose. If you have been told by the doctor that you have an intolerance to certain sugars, refer to the doctor before taking **Maronil 25**.

#### 3. HOW SHOULD YOU USE THIS MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

#### Dosage

The dosage and treatment regimen will be determined by the doctor only. **Do not exceed the recommended dose.**

#### Method of administration

**Maronil 25** can be taken with or without food.

Do not halve the tablet. There is no information about crushing or chewing the tablet.

#### If you accidentally took a higher dosage

The following symptoms of overdose usually appear within a few hours: heavy drowsiness; poor concentration; dulled senses; fast, slow, or irregular heartbeat; restlessness and agitation; loss of muscle coordination and muscle stiffness; shortness of breath; seizures; vomiting; fever.

If you accidentally took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Medical treatment may be necessary.

An overdose of this medicine is particularly dangerous in young children.

#### If you forgot to take the medicine

Use this medicine at set intervals, as determined by the attending doctor. If you forgot to take this medicine at the designated time, take the missed dose as soon as possible and return to the usual dosing schedule. If it is almost time to take the next dose, skip the missed dose and continue with the regular treatment program.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

#### If you stop taking the medicine

Treatment of depression and obsessive compulsive disorder requires long-term treatment with **Maronil 25**. The duration of treatment is determined by the doctor only.

The doctor may want to gradually lower the dosage before completely stopping treatment in order to avoid worsening of the condition and to reduce the risk of medicine withdrawal symptoms, such as: feeling sick, abdominal pains, diarrhea, difficulty falling asleep, anxiety or nervousness, headaches, nausea and generalized discomfort.

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

**If you have further questions regarding use of the medicine, consult a doctor or pharmacist.**

#### 4. SIDE EFFECTS

As with any medicine, use of **Maronil 25** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

#### Side effects requiring special attention

- Disturbances in body fluid quantities and salt levels, accompanied by symptoms such as confusion, hallucinations, seizures and brain edema (swelling due to accumulation of fluids in the brain) may occur. In such cases, refer to a doctor immediately.
- Very rarely, neuroleptic malignant syndrome may occur. The main symptoms are fever, irregular heartbeat, consciousness disturbances and muscle stiffness. In such cases, refer to a doctor immediately.
- Medicines such as **Maronil 25**, alone or in combination with other medicines, may cause serotonin syndrome. The typical symptoms of this syndrome are: fever, muscle spasms, seizures, restlessness, confusion and lack of consciousness. In such cases, refer to a doctor immediately.

#### Additional side effects

**Very common side effects – effects that occur in more than 1 user in 10**

- Lightheadedness
- Temporary tiredness
- Dizziness
- Tremor
- Restlessness
- Increased appetite
- Weight gain
- Dry mouth
- Disturbances in passing urine
- Muscle spasms
- Inability to focus vision
- Blurred vision
- Headache
- Sweating
- Constipation

**Common side effects – effects that occur in 1-10 in 100 users**

- Confusion with spatial disorientation and hallucinations
- Concentration disorders
- Speech disorders
- Sleep disturbances
- Anxiety
- Increased energy and elated mood
- Over-excitedness
- Aggressiveness
- Behavioral disorders
- Poor memory
- Yawning
- Insomnia
- Nightmares
- Numbness or a tingling sensation in the arms and legs
- Muscle weakness
- Muscle stiffness
- Hot flushes
- Dilated pupils
- Heart palpitations
- Low blood pressure combined with dizziness upon changing position
- Worsening depression
- Nausea
- Sensitivity to light
- Allergic skin reactions
- Itchy skin
- Increased laboratory test values
- Sexual function and drive (libido) disturbances
- Ringing in the ears

**Uncommon side effects – effects that occur in 1-10 in 1,000 users**

- Increased blood pressure
- Seizures
- Heart rhythm disorders
- Loss of appetite
- Movement and coordination disturbances
- Changes in perception and feelings
- Vomiting
- Gastrointestinal diseases
- Diarrhea
- Enlargement of the breast glands and increased milk secretion
- Unpleasant taste in the mouth

**Very rare side effects – effects that occur in less than one user in 10,000**

- High fever
- Decrease in the number of white blood cells (leukocytopenia), decrease in the number of blood platelets (thrombocytopenia), decrease in the number of neutrophil white blood cells (agranulocytosis) or increased number of eosinophil white blood cells (eosinophilia)
- Bleeding under the skin

- Hypersensitivity reaction (allergy), including shock, with reactions of the lungs and the entire body
- Movement disorders
- Glaucoma
- Conduction disorders of the heart
- Hepatitis with or without jaundice
- Edema (swelling of the joints, hands or other parts of the body)
- Hair loss
- Insufficient urine output
- EEG changes
- Pneumonia

**Side effects of unknown frequency (effects whose frequency has not yet been determined)**

- Inner restlessness and a constant urge to move
  - Repeated, involuntary and irregular movements
  - Muscle breakdown
  - Increase in the blood level of the hormone that produces milk (prolactin)
  - Delayed or no ejaculation (in men)
- Some of the side effects listed above go away during treatment, after the adjustment period to the preparation.
- If these effects continue or are bothersome, refer to a doctor.
- There have been reports of an increase in the frequency of behavioral disorders – including a greater risk of suicidal thoughts, self-harm and suicide – in children and adolescents with depression or other psychiatric diagnoses who are being treated with antidepressants.
  - An increased risk of bone fractures in patients aged 50 and older taking this type of medicine was observed.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.**

#### Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://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>

Additionally, you can report to “Unipharm Ltd.”.

#### 5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine should be kept in a safe 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

Store below 25°C, in a place protected from light.

#### 6. FURTHER INFORMATION

**In addition to the active ingredients, the medicine also contains:** Lactose monohydrate, Maize starch, Microcrystalline cellulose, Povidone, Carmellose sodium LS, Magnesium stearate, Colloidal silicon dioxide, Ethyl cellulose type B, Opadry 02B220022 (Yellow). Each **Maronil 25** tablet contains 30 mg lactose (monohydrate).

**What the medicine looks like and contents of the package** **Maronil 25** are yellow, round, biconvex tablets.

Each package contains 30, 50, 100 or 1000 tablets.

Not all package sizes may be marketed.

**Registration holder and address:** Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

**Manufacturer and address:** Unipharm Ltd., “Mevo Carmel” Industrial Park.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

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