

**PATIENT LEAFLET IN  
ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS  
(PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

# Medosil

## Tablets

### Composition

Each tablet contains Terbinafine (as hydrochloride) 250 mg For information about inactive ingredients see section 6 – "Additional information".

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. 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?

For treatment of fungal infections of the skin and nails.

#### Therapeutic class

An oral antifungal agent.

Medosil tablets are used for the treatment of fungal infections of the fingernails and toenails, fungal infection of the hair and scalp (tinea capitis), of the groin and other areas of the body and of the feet (athlete's foot), as well as yeast infections of the skin. When taken orally, Medosil reaches the site of infection in sufficiently strong concentrations to eradicate the fungus or halt its growth.

### 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You have or have had a liver disease.
- You are breastfeeding.

#### Special warnings regarding the use of the medicine

Before treatment with Medosil, you should check whether the following conditions apply to you. If they do, inform the doctor or pharmacist, as Medosil may not be the right medicine for you:

- You are pregnant or trying to become pregnant.
- You have any kidney or liver function problems.
- You have psoriasis.
- You have lupus.
- You have a rash due to high level of white blood cells.

#### Children and adolescents

This medicine is usually not intended for children.

#### Tests and follow-up

Blood tests should be performed before and during treatment with Medosil to monitor your liver function.

#### Drug interactions

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

- Rifampicin, for treatment of bacterial infections
- Cimetidine, for treatment of digestive system problems such as an ulcer
- Antidepressants, including tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRI) or monoamine oxidase inhibitors (MAOI)
- Oral contraceptives (may cause irregular menstrual periods and bleeding between periods in some patients)
- Beta blockers or antiarrhythmic agents, for treatment of heart problems
- Warfarin, a blood thinner
- Medicines for treatment of heart problems (such as: propafenone, amiodarone)
- Cyclosporine, which is given following transplantation
- Other medicines for treatment of fungal infections (such as: fluconazole, ketoconazole)
- Cough medicines (such as: dextromethorphan)
- Caffeine

#### Pregnancy and breastfeeding

##### Pregnancy

If you are pregnant or planning to become pregnant, consult a doctor before using the medicine.

##### Breastfeeding

Do not use the medicine while breastfeeding.

#### Driving and operating machinery

Some patients have reported dizziness while using Medosil. If you feel dizzy, do not drive or operate machinery.

**Important information about some of the ingredients of the medicine** This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.

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

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine. The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is: one tablet of 250 mg per day.

**Do not exceed the recommended dose.**

#### When should Medosil be taken?

Taking the medicine at the same time every day will help you remember when to take it. The tablets may be taken on an empty stomach or after a meal.

#### Duration of treatment

The duration of treatment depends on the type of infection, its severity and the affected body part. The doctor will tell you for exactly how long you should use the medicine.

The standard duration of treatment is:

**For fungal infection of the feet (athlete's foot):** the medicine is usually taken for 2-6 weeks.

**For fungal and yeast infections of the groin and other areas of the body:** the medicine is usually taken for 2-4 weeks.

It is important to take the tablet or tablets every day, and continue the treatment for the duration prescribed by the doctor. This will ensure that the infection will resolve completely and reduce the odds of it returning after you stop taking the tablets.

**For hair and scalp infections:** the standard duration of treatment is 4 weeks.

**For nail infections:** fungal infections of the nails usually take longer to resolve than fungal infections of the skin. For most nail infections, Medosil tablets should be taken for 6 to 12 weeks.

**For fingernail infections:** a treatment duration of 6 weeks is sufficient in most cases.

**For toenail infections:** a treatment duration of 12 weeks is sufficient in most cases.

Certain patients with slow nail growth may require a longer duration of treatment. The doctor will discuss this with you.

#### How to take the medicine

The tablet should be taken whole with a full glass of water.

To help swallowing, the tablet may be halved if necessary and then used immediately. Once the tablet is halved, both its halves should be swallowed together immediately.

#### If you accidentally took a higher dosage

If you took an overdose or if a child accidentally swallowed this medicine, go immediately to a hospital emergency room and take the package of the medicine with you.

#### If you forgot to take the medicine

If you missed a dose of Medosil, take a tablet as soon as you remember. Take the next dose at the scheduled time, and then continue as usual until you finish the entire treatment. Follow the treatment as recommended by the doctor.

It is important to finish the entire treatment according to the doctor's instructions, unless the doctor has instructed you to stop the treatment.

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

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

### 4. SIDE EFFECTS

As with any medicine, using Medosil may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

#### Severe side effects

**Stop taking the medicine and inform the doctor immediately if you notice any of the following rare symptoms:**

- Yellowing of the skin or of the eyes. Urine that is darker than usual or light-colored stool, prolonged and unexplained nausea, stomach problems, decreased appetite, unusual tiredness or weakness (possible sign of liver problems), increase in liver enzymes which is observed in blood test results.
- Severe skin reactions, including rash, sensitivity to light, blisters or bruises.
- Weakness, abnormal bleeding, hematomas, abnormal pallor of the skin, abnormal tiredness or weakness or shortness of breath on exertion or frequent infections (possible signs of blood problems).
- Breathing difficulties, dizziness, swelling, mostly of the face and throat, flushing, stomach spasms, stiffness, rash, fever or swollen/enlarged lymph nodes (possible signs of severe allergic reactions).
- Symptoms such as rash, fever, itch, tiredness or if you notice purplish spots under your skin (possible signs of blood vessel inflammation).
- Severe abdominal pain radiating to the back (possible sign of inflammation of the pancreas).

- Unexplained muscle pain or weakness or dark (red-brown) urine (possible signs of muscle breakdown).

#### Additional side effects:

**Very common side effects (effects that occur in more than one out of ten users):**

- Headache
- Gastrointestinal problems such as loss of appetite, pain, digestive difficulties, bloated feeling or nausea
- Diarrhea
- Itch, rash or swelling
- Muscle and joint pain

**Uncommon side effects that have been reported (effects that occur in less than one user out of 100):**

Alteration or loss of the sense of taste. This effect usually resolves within several weeks of discontinuation of the treatment. However, a very small number of people (less than 1 out of 10,000) have reported that the disturbance in the sense of taste lasted longer, and as a result they were eating less and losing weight. Moreover, there are reports of some patients who have experienced anxiety or symptoms of depression as a result of this side effect.

**Rare side effects (effects that occur in less than one user out of 1,000):**

- You feel unwell, dizziness
- Numbness or tingling

**Very rare side effects (effects that occur in less than one user out of 10,000):**

- Tiredness
- A decrease in the number of certain blood cells. You may notice that bleeding or bruises develop more easily than usual, or you may get infectious diseases more easily and they may be more severe than usual.
- Eruption of a psoriasis-like skin condition, or worsening of psoriasis including rash or eruption of small, pus-filled blisters
- Vertigo
- Hair loss
- Eruption or worsening of lupus (a chronic disease whose symptoms include skin rash and muscle and joint pain)

The following have also been reported: Symptoms of blood system disturbances: weakness, abnormal bleeding, bruising or frequent infections. Potentially irreversible disturbances in the sense of smell, impaired hearing, beeping and/or ringing in the ears, flu-like symptoms, elevation in blood levels of a muscle enzyme called creatine phosphokinase (can be detected in a blood test), vision impairment or blurred vision.

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

#### Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

### 5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25°C.
- Do not discard medicines in wastewater or domestic trash. 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, the medicine also contains:**

Sodium starch glycolate, microcrystalline cellulose, hypromellose, magnesium stearate, silica colloidal anhydrous, purified water.

**What does the medicine look like and what are the contents of the package?**

White to off-white round tablets, one side has a score line with the "Remedica" logo, and the other side is debossed with the letter "T". Each pack contains 14 tablets packed in blisters.

#### Name and address of the license holder:

Medomie Pharma Ltd., 5358305, P.O.B. 816, Givatayim

#### Name and address of the manufacturer

Remedica Ltd  
Aharon Str., Limassol Industrial Estate.  
3056 Limassol, Cyprus.

This leaflet was revised in October 2024 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 177-23-37306