"פורמט עלון זה נקבע ע"י משרד הבריאות ותוכנו נבדק ואושר על ידו"

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MYCOSTER 8 % NAIL LACQUER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Mycoster 8% nail lacquer contains 80 mg (80 mg/g) of Ciclopirox
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-forming solution for topical application
Colourless, transparent solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of fungal infections of the nails.

4.2 Posology and method of administration

Method of administration:

Unless advised otherwise, Mycoster 8 % nail lacquer should be applied as a thin layer on all affected nails once daily, preferably in the evening.

The medicated lacquer must be applied over the entire nail plate. Keep the bottle tightly closed after use.

Before initiating treatment, it is recommended to remove the loose parts of affected nails using nail clippers, a nail file or scissors.

The film-forming layer at the nail surface, which in the long-term could interfere with penetration of the active substance, should be removed once a week using cosmetic nail lacquer remover, throughout the duration of treatment. It is recommended to remove the loose parts of affected nails at the same time.

Treatment should be continued until full mycological and clinical recovery and healthy nail growth are observed.

The duration of treatment is a function of the area affected and the extent of the attack:
Treatment usually lasts 3 (onychomycosis of the fingernails) to 6 months (onychomycosis of the toenails). However, treatment duration should not exceed 6 months.

Pediatric Patients
Based on the safety profile in adults, Mycoster 8% nail lacquer is considered safe for use in children twelve years and older. No clinical trials have been conducted in the pediatric population.

4.3 Contra-indications

Hypersensitivity to ciclopirox or to any of the excipients of MYCOSTER.
Because of a lack of clinical experience, MYCOSTER is not indicated in children under 12 years old.

4.4 Special warnings and special precautions for use

Contact with eyes and mucous membranes should be avoided.
MYCOSTER film-forming solution is for external use only.

In case of sensitisation, treatment should be discontinued and appropriate therapy instituted.

The risk of removal of the unattached, infected nail, by the health care professional or during cleaning by the patient should be carefully considered for patients with a history of insulin dependent diabetes mellitus or diabetic neuropathy.

Do not apply ordinary nail lacquer or any other cosmetic lacquer on the treated nails.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed

4.6 Pregnancy and lactation

There are no adequate or well-controlled studies of topically applied ciclopirox in pregnant women. Ciclopirox Topical Solution, 8% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
It is not known whether this drug is excreted in human milk. Since many drugs are excreted in human milk, caution should be exercised when Ciclopirox Topical Solution, 8% is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

MYCOSTER has no effects on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects are ranged by system organ class and frequency.
The frequencies are defined as follows:
very common (≥ 1/10),
common (≥ 1/100 to < 1/10),
uncommon (≥ 1/1,000 to < 1/100),
rare (≥ 1/10,000 to < 1/1,000),
very rare (<1/10,000),
not known (cannot be estimated from the available data).

System organ class and frequency (MedDRA classification)	Undesirable effect
Skin and subcutaneous tissue disorders Not known (cannot be estimated from the available data)	Allergic contact dermatitis

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: OTHER ANTIFUNGALS FOR TOPICAL USE

ATC code: D01AE14

The active substance in MYCOSTER is Ciclopirox, an antifungal agent belonging to the pyridone group.

Ciclopirox is a broad-spectrum antimycotic agent which is active against dermatophytes (*Trichophytons, Microsporum canis, Epidermophytons*), yeasts (*Candida, Torulopsis, Trichosporum, Geotrichum*), moulds (*Scopulariopsis, Aspergillus*) and actinomycetes, together with a few gram-positive and gram-negative bacteria.

Any fungus species that does not belong to aforementioned genera should be studied in vitro in order to determine its level of susceptibility.

MYCOSTER is a formulation containing 8 per cent ciclopirox in a lacquer base. Once applied to the nail, the solvents (ethyl acetate and isopropanol) and the film-forming agent (copolymer of methylvinyl ether and maleic acid monobutylester) evaporate and ensure that ciclopirox adheres to the nail.

The fungicidal activity of ciclopirox is based on the inhibition of absorption, by fungal cells, of certain substances (metal ions, phosphate and potassium ions).

Ciclopirox accumulates in the fungal cell, in which it binds irreversibly to certain structures such as the cell membrane, mitochondria, ribosomes and microsomes.

5.2 Pharmacokinetic properties

The fate of the medicinal product has been studied in situ in the healthy human (healthy nail).

Ciclopirox is rapidly diffused in the nail plate:
- Fungicide concentrations are detected from the 7th day of the daily application,
- The maximum concentrations detected in the distal part of the nail reflect saturation of the nail plate; these are obtained:
Between the 14th and 30th day of application for fingernails,
Between the 30th and the 45th day of application for toenails.

If treatment is stopped, the shtrudelresidual effect of ciclopirox is demonstrated by active concentrations that persist for 7 to 14 days.

5.3 Preclinical safety data

Acute toxicity studies conducted with ciclopirox and/or ciclopirox olamine in rats and mice following oral or subcutaneous administration demonstrate similar and moderate toxicity (LD50 between 1740 mg/kg and 2500 mg/kg). By intraperitoneal or intravenous administration, ciclopiroxolamine toxicity increases slightly (LD50 between 70 mg/kg and 170 mg/kg).
Chronic and subchronic toxicity studies with ciclopirox olamine have not demonstrated any toxic effect.
Ciclopiroxolamine administered orally in rats does not induce any adverse effect on male or female fertility.
No embryotoxic or teratogenic effect has been observed after oral, topical or subcutaneous administration in animals. The studies were conducted on several animal species, mice, rats, rabbits and monkeys.
Ciclopiroxolamine administered orally in female rats does not induce any peri- or postnatal adverse effect, until ablactation of the whelps.
Local tolerance studies conducted in rabbits showed that the varnish was irritant for the skin. It also presents a low sensitisation potential.
In vitro and *in vivo* mutagenicity studies conducted with ciclopirox and ciclopirox olamine, their calcium and iron salts or a nail lacquer formulated with an 8% ciclopirox concentration are negative.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Ethyl acetate, isopropanol, copolymer of methylvinyl ether and maleic acid monobutylester.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years
After first opening: 90 days

6.4 Special precautions for storage

Store below 25ºC. Protect from light.
After first opening the container:
Keep the bottle tightly closed.

6.5 Nature and contents of container

Type III colourless glass bottle with a white screw cap fitted with a brush (LDPE).
Pack size: 1 bottle with 3 ml

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. LICENSE NUMBER
139 30 31564

8. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

PIERRE FABRE MEDICAMENTS
45, place Abel Gance
92100 Boulogne
France

9. LICENSE HOLDER
Perrigo Israel Agencies Ltd.,29 Lehi St.,Bnei-Brak

10. DATE OF TEXT REVISION: August 1st, 2016