Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 55.74 mg amorolfine hydrochloride (equivalent to 50 mg amorolfine).
Excipient(s) with known effect:
Alcohol (ethanol) 55.4 %w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated nail lacquer.
A clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of mild cases of distal and lateral subungual Onychomycoses caused by dermatophytes, yeasts and moulds limited up to 2 nails in adults.

4.2 Posology and method of administration

Posology

The nail lacquer should be applied to the affected finger or toe nails once weekly.

Special populations

Elderly
There are no specific dosage recommendations for use in elderly patients.

Paediatric populations

Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacqueris not recommended for use in children and adolescents below 18 years due to a lack of data on safety or efficacy.

Method of administration

1. Before the first application of Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as possible using the nail file supplied. The surface of the nail should then be cleansed and degreased using an alcohol swab (as supplied).
Cosmetic nail lacquer may be applied at least 10 min after Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer application.
Before repeat application of Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer, any remaining nail lacquer, and cosmetic nail lacquer if any, should be removed carefully, then the affected nails should be filed down again as required, following cleansing with a cleaning swab .

Caution: Nail files used for affected nails must not be used for healthy nails.

2. With one of the reusable applicators supplied, apply the nail lacquer to the entire surface of the affected nails. Allow the nail lacquer to dry for 3-5 minutes. After use, clean the applicatorwith the same cleansing swab used before for nail cleaning. Keep the bottle tightly closed.

For each nail to be treated, dip the applicator into the nail lacquer without wiping off any of the lacquer on the bottle neck.

Treatment should be continued without interruptionuntil the nail is regenerated and the affected areas are finally cured. The required duration of treatment depends essentially on intensity and localisation of the infection. In general, it is six months (finger nails) and nine to twelve months (toe nails).A review of the treatment is recommended at intervals of approximately three months.

Co-existent tinea pedis should be treated with an appropriate antimycotic cream.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer should not be applied on the skin around thenail.

Avoid contact of the lacquer with eyes, ears and mucous membranes.

Patients with underlying conditions predisposing to fungal nail infections should be referred to a doctor. Such conditions include peripheral circulatory disorders, diabetes mellitus, and immunosuppression.

Patients with nail dystrophy and destroyed nail plate should be referred to their doctor.

Owing to the lack of clinical experienceavailable to date, children should not be treated with Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer.

When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect the amorolfine lacquer on the nails.

During the application of amorolfine no artificial nails shall be used.

During the application of amorolfine no cosmetic nail lacquer or artificial nails shall be used.

After applying Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer, an interval of at least 10 min should be respected before application of any cosmetic nail lacquer. Before repeat application of Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer, the cosmetic nail lacquer should be removed carefully.

A systemic or local allergic reaction could possibly occur after use of this product. If this happens, the product should be stopped immediately and medical advice should be sought.

This medicine contains 55.4%w/w alcohol (ethanol).

It may cause burning sensation on damaged skin.

Remove the product carefully by using a nail remover solution.

The product should not be reapplied.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
Experience with amorolfine use during pregnancy is limited. Only a few cases of exposure to topical amorolfine use in pregnant women have been reported in the post-authorisation setting, therefore the potential risk is unknown.

Studies in animals have shown reproductive toxicity at high oral doses. Amorolfine should not be used during pregnancy unless clearly necessary.

Breast-feeding
Experience with amorolfine use during lactation is limited. It is unknown whether amorolfine is excreted in human milk.
Amorolfine should not be used during lactation unless clearly necessary.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Adverse drug reactions are rare. Nail disorders (e.g. nail discoloration, broken nails, brittle nails) may occur. These reactions can also be linked to the onychomycosis itself.

System Organ Class	Frequency	Adverse drug reaction
Immune system disorders	Unknown frequency*	Hypersensitivity (systemic allergic reaction)*
Skin and subcutaneous tissue disorders	Rare (≥1/10,000 to <1/1,000)	Nail disorder, nail discoloration, onychoclasis (broken nails), onychorrhexis (brittle nails)
	Very rare (<1/10,000)	Skin burning sensation
	Unknown frequency	Erythema*, pruritus*, contact dermatitis*, urticarial*, blister*

*post-marketing experience

Reporting of suspected adverse reactions
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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No systemic signs of overdose are expected following topical application of amorolfine 5% nail lacquer.
In case of accidental oral ingestion, an appropriate symptomatic measures should be taken if needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Other antifungals for topical use ATC code: D01AE16

Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacqueris a topical antimycotic. Amorolfine belongs to a new chemical class, and its fungicidal action is based on an alteration of the fungal cell membrane targeted primarily on sterol biosynthesis. The ergosterol content is reduced, and at the same time unusual sterically nonplanar sterols accumulate.

Amorolfine is a broad spectrum antimycotic. It is highly active (MIC < 2mcg/ml) *in vitro* against
yeasts: Candida, Cryptococcus, Malassezia
dermatophytes: Trichophyton, Microsporum, Epidermophyton
moulds: Hendersonula, Alternaria, Scopulariopsis
dematiacea: Cladosporium, Fonsecaea, Wangiella
dimorphic fungi: Coccidioides, Histoplasma, Sporothrix

With the exception of *Actinomyces*, bacteria are not sensitive to amorolfine. *Propionibacterium acnes* is only slightly sensitive.

5.2 Pharmacokinetic properties

Amorolfine from nail lacquer penetrates into and diffuses through the nail plate and is thus able to eradicate poorly accessible fungi in the nail bed. Systemic absorption of the active ingredient is very low with this type of application.

Following prolonged use of Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer, there is no indication of drug accumulation in the body.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonio methacrylate copolymer type A (Eudragit RL 100)
Triacetin
Butyl acetate
Ethyl acetate
Ethanol, anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquershould be stored below 30°C. Protect from heat. Keep the bottle upright and tightly closed after use.

6.5 Nature and contents of container

Amber glass bottle (Type I or Type III) and a HDPE cap with PTFE liner and tamper evident ring.

The pack is available in sizes of 2.5 ml and 3 ml

Each 2.5 ml and 3 ml pack consists of 1 bottle filled with Schollmed Once Weekly Fungal Nail Treatment 5% w/v Medicated Nail Lacquer.
Each pack also contains 30 cleansing swabs, 10 re-usable applicators and 30 nail files.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/070/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th May 2018

10 DATE OF REVISION OF THE TEXT

June 2022