

1 **SCHEDULING STATUS**

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4 **1. NAME OF THE MEDICINE**

5 **AMOROLFINE 5 % GLENMARK** nail lacquer

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7 **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

8 **AMOROLFINE 5 % GLENMARK:** Each mL contains 50 mg amorolfine (as amorolfine
9 hydrochloride).

10 For full list of excipients, see section 6.1.

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12 **3. PHARMACEUTICAL FORM**

13 Liquid.

14 **AMOROLFINE 5 % GLENMARK:** Clear, colourless to pale yellow liquid.

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16 **4. CLINICAL PARTICULARS**

17 **4.1 Therapeutic indications**

18 **AMOROLFINE 5 % GLENMARK** is indicated for onychomycoses caused by dermatophytes,
19 yeasts and moulds. Only little experience is available in cases where the nail matrix was involved.

20

21 **4.2 Posology and method of administration**

22 Posology:

23 **Onychomycoses**

24 Nail Lacquer: To be applied to affected finger or toenails once or twice weekly.

25

26 Method of administration

27 Topical

28

29 The patient should apply the nail lacquer as follows:

30 1. Before the first application of **AMOROLFINE 5 % GLENMARK**, it is essential that the
31 affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as
32 possible using a disposable nail file supplied. The surface of the nail should then be
33 cleansed and degreased using an alcohol-soaked swab (as supplied).

34 Before repeating application of **AMOROLFINE 5 % GLENMARK**, the affected nails should
35 be filed down again as required and must always first be cleansed with an alcohol-soaked
36 swab to remove any remaining lacquer.

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

38

39 2. With the applicator supplied, apply the nail lacquer to the entire surface of the affected
40 nails and allow it to dry for approximately 3-5 minutes. For each nail to be treated, dip the
41 applicator into the nail lacquer without wiping off any of the lacquer on the bottle neck.
42 After use, clean the applicator with the same pre-soaked swab used before for nail
43 cleansing. **Keep the bottle tightly closed.**

44

45 3. When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves
46 to protect the **AMOROLFINE 5 % GLENMARK** on the nails. Treatment should be
47 continued without interruption until the nail is regenerated and the affected areas are finally
48 cured. The required duration of treatment depends essentially on intensity and localisation
49 of the infection and on growth rate of the nails, but in general, it is six months for fingernails
50 and nine to twelve months for toenails.

51 Clinical experience indicates that cure is achieved after six months in approximately 50 %
52 of distal onychomycosis cases in which less than 80 % of the nail surface was affected.
53 Mycological cure was achieved in 60-80 % of cases.

54

55 **4.3 Contraindications**

AMOROLFINE 5 % GLENMARK is contra-indicated in:

- Individuals with known hypersensitivity to amorolfine hydrochloride or any of the excipients listed in section 6.1. These individuals should not reuse **AMOROLFINE 5 % GLENMARK**
- Pregnancy and lactation. No experience exists with pregnancy and breastfeeding while using **AMOROLFINE 5 % GLENMARK**
- Children.

4.4 Special warnings and precautions for use

AMOROLFINE 5 % GLENMARK should not be applied on the skin around the nail. Avoid contact of the lacquer with eyes, ears and mucous membranes.

Owing to the lack of clinical experience available to date, children (particularly young children and infants) should not be treated with **AMOROLFINE 5 % GLENMARK**.

Before repeat application of **AMOROLFINE 5 % GLENMARK**, cosmetic nail lacquer should be removed carefully. Use of cosmetic lacquers or artificial nails should be avoided during treatment with **AMOROLFINE 5 % GLENMARK**. After applying **AMOROLFINE 5 % GLENMARK**, an interval of at least 10 min should be respected before application of any cosmetic nail lacquer.

When organic solvents are used impermeable gloves shall be used otherwise **AMOROLFINE 5 % GLENMARK** will be removed.

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.

Remove the product carefully by using a nail remover solution.

The product should not be reapplied.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

Use of nail varnish or artificial nails should be avoided during treatment

4.6 Fertility, pregnancy and lactation

Pregnancy

Experience with amorolfine use during pregnancy and/or lactation 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; it is unknown whether amorolfine is excreted in human milk. Amorolfine should not be used during pregnancy and/ or lactation unless clearly necessary.

4.7 Effects on ability to drive and use machines

AMOROLFINE 5 % GLENMARK has no influence on the ability to drive and use machines.

4.8 Undesirable effects

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

Tabulated summary of adverse reactions

The adverse reactions are listed by system organ class and absolute frequency.

System Organ Class	Adverse Reactions	Frequency Category
<i>Immune system disorders</i>	Hypersensitivity (systemic allergic reaction)	Frequency unknown

112	Skin and subcutaneous tissue disorders	Nail disorder, nail discolouration, 113 onychoclasia (broken nails), onychorrhexis 114 (brittle nails). 115 However, these reactions can also be linked 116 to the onychomycosis itself.	Frequent
117		Skin burning sensation, contact dermatitis	Less frequent
118		Erythema, pruritis, urticaria, blister	Frequency 119 unknown

121 Reporting of suspected adverse reactions

122 Reporting suspected adverse reactions after authorisation of the medicine is important. It allows
 123 continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked
 124 to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions**
 125 **Reporting Form**”, found online under SAHPRA’s publications:

126 <https://www.sahpra.org.za/Publications/Index/8>

128 **4.9 Overdose**

129 No systemic signs of overdose are expected following topical application of **AMOROLFINE 5 %**
 130 **GLENMARK**. Should **AMOROLFINE 5 % GLENMARK** be ingested, treatment should be
 131 symptomatic and supportive.

133 **5. PHARMACOLOGICAL PROPERTIES**

134 **5.1 Pharmacodynamic properties**

135 Pharmacological classification: A 13.9.2 Fungicides

137 **AMOROLFINE 5 % GLENMARK** is a topical antimycotic. Amorolfine has both *in vitro* fungicidal
 138 and fungistatic properties based on an alteration of the fungal cell membrane targeted primarily

140 on sterol biosynthesis. The ergosterol content is reduced, and at the same time unusual sterically
141 nonplanar sterols accumulate.

142

143 Amorolfine has a broad spectrum of action *in vitro* against:

144 yeasts: **Candida, Malassezia or Pityrosporum,*

145 *Cryptococcus*

146 dermatophytes: **Trichophyton, *Microsporum,*

147 **Epidermophyton*

148 moulds: **Hendersonula, *Alternaria,*

149 **Scopulariopsis, Scytalidium*

150 dematiacea: **Cladosporium, Fonsecaea, Wangiella*

151 [** in onychomycosis*]

152 dimorphic fungi: *Coccidioides immitis, Histoplasma*

153 *capsulatum, Sporothrix schenckii*

154

155 In oral studies at high doses in animals, Amorolfine showed some additive effect *in vitro* and *in*
156 *vivo* with several antifungals, including ketoconazole, itraconazole, terbinafine and griseofulvin,
157 against dermatophytes. With the exception of Actinomyces, bacteria are not sensitive to
158 amorolfine. *Propionbacterium acnes* is only slightly sensitive.

159

160 5.2 Pharmacokinetic properties

161 Absorption

162 Amorolfine from the nail lacquer penetrates and diffuses through the nail plate and effective
163 concentrations accumulate in the nail bed where access to fungi is critical. Systemic absorption
164 of the active ingredient is very low with this type of application.

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166 Distribution

167

168 Following prolonged topical use of amorolfine nail lacquer there is no indication of accumulation
169 in the body.

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171 **6. PHARMACEUTICAL PARTICULARS**

172 **6.1 List of excipients**

173 Absolute Alcohol (Ethanol 99 % v/v), ammonio methacrylate copolymer (type A), ethyl acetate,
174 n-butyl acetate extra pure, triacetin (glycerol triacetate).

175

176 **6.2 Incompatibilities**

177 Not applicable

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179 **6.3 Shelf life**

180 24 months

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182 **6.4 Special precautions for storage**

183 Store at or below 25 °C.

184 Keep the bottle away from heat.

185 Keep the bottle tightly closed after use.

186 KEEP OUT OF THE REACH OF CHILDREN.

187

188 **6.5 Nature and contents of container**

189 **AMOROLFINE 5 % GLENMARK:** 2,5 mL amber glass (type I) bottle, closed with a white opaque,
190 tamper- evident HDPE closure and a PET liner fitted inside.

191 Supplied with:

192 10 LDPE reusable applicators

193 12 disposable nail files

194 12 swabs sachets (impregnated with 70 % isopropyl alcohol in foil packs).

195

196 Pack size: One (1) bottle including 10 applicators, 12 nail files and 12 swabs packed in an outer
197 carton.

198

199 **6.6 Special precautions for disposal and other handling**

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

202

203 **7. HOLDER OF CERTIFICATE OF REGISTRATION**

204 **Glenmark Pharmaceuticals South Africa (Pty) Ltd**

205 2nd Floor, Building D,

206 Stoneridge Office Park

207 8 Greenstone Place,

208 Greenstone, Edenvale,

209 Gauteng, 1609

210

211 **8. REGISTRATION NUMBER(S)**

212 To be allocated

213

214 **9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION**

215 To be allocated

216

217 **10. DATE OF REVISION OF TEXT**

218 To be allocated