

AMOROPHEN HYDROCHLORIDE LINIMENT- amorolfine hydrochloride liquid
Zhejiang Longmed Medical Technology Co., Ltd.

Amorophen hydrochloride liniment

amorolfine hydrochloride 5%

antifungal

KEEP OUT OF REACH OF CHILDREN SECTION

This product is dermatological drug category, over-the-counter drugs.

This product is indicated for the treatment of nail (including toenail) infections caused by susceptible fungi.

1. The first time you use this product, please consult a professional doctor and confirm the diagnosis of nail fungal infection suitable for this product.
2. Patients with extensive fungal infections, such as those with more than two fingernails (or toenails) affected or a single toenail infection covering more than half of the nail area, require comprehensive treatment. Consultation with a specialist is recommended before using this product.
3. Please read the instructions carefully before using this product, and use it in strict accordance with the instructions.
4. This product should not be inhaled and should avoid contact with mucous membranes (such as mouth, nose) and skin folds.
5. If the liniment accidentally gets into the eyes or ears, rinse with water immediately, and immediately go to the nearest hospital to consult a doctor or pharmacist.
6. If you take this product by mistake, go to the nearest hospital immediately to consult a doctor or pharmacist.
7. Lactating women should avoid using this product.
8. It is not recommended for children due to the lack of relevant clinical research data.

1. File down (toenails)
2. Clean your nails
3. Remove the liniment from the vial
4. Apply liniment
5. Drying
6. Cleaning the Medicine Shovel (Medicine spatula)
7. Before using this product for the second time, remove the old ointment with a medical cotton swab.

Please read the instructions carefully before using this product, and use it in strict accordance with the instructions.

Shelf life 3-Year

WATER

alcohol

Sorbitol

propylene glycol

root of Dahurian angelica

keratin

tolnaftate

Drug Facts	
Active ingredients amorolfine hydrochloride 5%	Purpose antifungal
Uses <ul style="list-style-type: none"> This product is a dermatological drug category, over-the-counter drugs. This product is indicated for the treatment of nail (including toenail) infections caused by susceptible fungi. 	
Warnings 1. The first time you use this product, please consult a professional doctor and confirm the diagnosis of nail fungal infection suitable for this product. 2. Patients with extensive fungal infections, such as those with more than two fingernails (or toenails) affected or a single toenail infection covering more than half of the nail area, require comprehensive treatment. Consultation with a specialist is recommended before using this product. 3. Please read the instructions carefully before using this product, and use it in strict accordance with the instructions. 4. This product should not be inhaled and should avoid contact with mucous membranes (such as mouth, nose) and skin folds. 5. If the liniment accidentally gets into the eyes or ears, rinse with water immediately, and immediately go to the nearest hospital to consult a doctor or pharmacist. 6. If you take this product by mistake, go to the nearest hospital immediately to consult a doctor or pharmacist.	
7. Lactating women should avoid using this product. 8. It is not recommended for children due to the lack of relevant clinical research data.	
Directions 1. File down (toenails) 2. Clean your nails 3. Remove the liniment from the vial 4. Apply liniment 5. Drying 6. Cleaning the Medicine Shovel (Medicine Spatula) 7. Before using this product for the second time, remove the old ointment with a medical cotton swab. <ul style="list-style-type: none"> Please read the instructions carefully before using this product, and use it in strict accordance with the instructions. 	
Inactive ingredients water, alcohol, Sorbitol, propylene glycol, root of Dahurian angelica, keratin, tolnaftate.	
Manufacturer Zhejiang Longmed Medical Technology Co., Ltd.	
Shelf life 3-Year	
MADE IN CHINA	
NET CONTENTS: LOT: EXP:	

AMOROPHEN HYDROCHLORIDE LINIMENT

amorolfine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84534-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMOROLFINE HYDROCHLORIDE (UNII: 741YH7379H) (AMOROLFINE - UNII:AB0BHP2FH0)	AMOROLFINE HYDROCHLORIDE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
KERATIN, TYPE I CYTOSKELETAL 18 (UNII: ZS6J3E8DAS)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TOLNAFTATE (UNII: 06KB629TKV)	
ANGELICA ACUTILOBA WHOLE (UNII: 61617L0028)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84534-002-01	1.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	
2	NDC:84534-002-02	2 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	
3	NDC:84534-002-03	2.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	
4	NDC:84534-002-04	3 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	
5	NDC:84534-002-05	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	
6	NDC:84534-002-06	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	10/31/2024	

Labeler - Zhejiang Longmed Medical Technology Co., Ltd. (554468373)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Longmed Medical Technology Co., Ltd.		554468373	manufacture(84534-002)

Revised: 10/2024

Zhejiang Longmed Medical Technology Co., Ltd.