

2024-09-27



Athlete's Foot Treatments Monograph

Health Products and Food Branch

FOREWORD

This monograph is intended to replace the existing Athlete's Foot Treatments Monograph of December 07, 2018. This monograph describes the requirements necessary to receive market authorization [i.e. a Drug Identification Number (DIN) or a Natural Product Number (NPN)], for athlete's foot treatment products. The monograph identifies the permitted medicinal and non-medicinal ingredients, concentrations, indications, directions and conditions of use for these products to be market authorized without the submission to Health Canada of additional evidence. Products which do not meet the criteria outlined in this document can apply for market authorization outside of the monograph stream.

Applicants are reminded that athlete's foot treatments products, like other non-prescription drugs or natural health products, are subject to the *Food and Drug Regulations* or the *Natural Health Products Regulations* administered by the Natural and Non-prescription Health Products Directorate (NNHPD). This includes requirements related to labelling, manufacturing and product specifications. Additional information on labels, outside of those specified in the monograph, such as additional directions for use and/or non-therapeutic claims are acceptable as long as they meet the [Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims](#), the [Guidelines for Consumer Advertising of Health products for Nonprescription drugs, Natural Health Products, Vaccines and Medical Devices](#), and are not false, misleading or counterintuitive to the use of the product.

Notes:

- Text in parentheses is additional optional information which can be included on the label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant on the label.

Medicinal Ingredients

Athlete's foot treatment products are classified as natural health products (NHPs) if they contain only one or several ingredients from Table 1. Applicants applying for an NPN can access the appropriate forms and guidance at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html>.

Athlete's foot treatment products are classified as non-prescription drugs (NPDs) if they contain an ingredient from Table 2. Applicants applying for a DIN can access the appropriate forms and guidance at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents.html>.

Proper name(s), Common name(s), Source information

Table 1: NHP medicinal ingredients

Proper name(s) ¹	Common name(s) ¹	Source information ¹	Quantity ²
		Source ingredient(s)	
10-Undecenoic acid	<ul style="list-style-type: none"> Undecenoic acid Undecylenic acid 	Undecenoic acid	10 – 25%
10-Undecenoic acid, calcium(2+) salt	Calcium undecylenate	Calcium undecylenate	10 – 25%
10-Undecenoic acid, copper(2+) salt	Copper undecylenate	Copper undecylenate	10 – 25%
10-Undecenoic acid, zinc(2+) salt	Zinc undecylenate	Zinc undecylenate	10 – 25%
<ul style="list-style-type: none"> 1-Ethenyl-2-pyrrolidinone homopolymer compound with iodine 1-Vinyl-2-pyrrolidinone polymers, iodine complex 	Povidone-iodine	Povidone-Iodine	10%

¹At least one of the following references was consulted per proper name, common name, and source information: NHPID 2024; RSC 2023; US FDA 2021; Sweetman 2017.

²Quantities are expressed as percentage weight by volume (% w/v). The following reference was consulted for the quantity: US FDA 2021.

Table 2: NPD medicinal ingredients

Proper name(s)	Common name(s)	Quantity
<ul style="list-style-type: none"> 3-(4-Chlorophenoxy)-1,2-propanediol p-Chlorophenyl alpha-glyceryl ether 	Chlorphenesin	0.5 – 1%
5-Chloro-7-iodo-8-quinolinol	<ul style="list-style-type: none"> Clioquinol Iodochlorhydroxyquin 	3%
<ul style="list-style-type: none"> 1,2,4-Trichloro-5-[(3-iodo-2-propynyl)oxy]benzene 	Haloprogin	1%

Proper name(s)	Common name(s)	Quantity
<ul style="list-style-type: none"> • 2,4,5-Trichlorophenyl gamma-iodopropargyl ether • 3-Iodo-2-propynyl 2,4,5-trichlorophenyl ether 		
<ul style="list-style-type: none"> • Methyl(3-methylphenyl)carbamothioic acid O-2-naphthalenyl ester • O-2-Naphthyl m,N-dimethylthiocarbamate 	Tolnaftate	1%

Route of administration

Topical

Dosage form(s)

Acceptable dosage forms for NHPs

- Aerosol; Aerosol, metered dose; Aerosol, spray; Cream; Gel; Liquid; Lotion; Ointment; Paste; Powder; Solution; Spray; Spray, bag-on-valve; Spray, metered dose; Spray, suspension; Swab, medicated; Topical liquid; Wipe.

Acceptable dosage forms for NPDs

- Aerosol; Aerosol Foam; Cream; Gel; Lotion; Ointment; Paste; Powder; Solution; Spray; Spray, bag-on-valve; Spray, metered dose; Swab; Wipe.

Use(s) or Purpose(s)

All products (Self-Care Framework Category I)

- For the treatment of athlete's foot (US FDA 2021).
- Cures athlete's foot (US FDA 2021).
- Kills athlete's foot fungus (US FDA 2021).
- Relieves (itching, scaling, burning, cracking, redness, soreness, irritation of) athlete's foot (US FDA 2021).

Products containing tolinaftate

- With daily use, for the prevention of athlete's foot, for individuals with recurring problems (US FDA 2021).

Dose(s)

Subpopulation(s)

Children 2 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older.

Quantity(ies)

See Tables 1 and 2.

Permitted combinations

Two or more of the following ingredients from Table 1 may be combined, provided that the combined ingredients provide a total undecylenate concentration of 10 – 25%:

- undecylenic acid
- calcium undecylenate
- copper undecylenate
- zinc undecylenate

Direction(s) for use

All products except products with a claim for the prevention of athlete's foot only

- Clean skin with soap and water and dry thoroughly (US FDA 2021).
- Apply a thin layer over affected area morning and night for full treatment period of 4 weeks (US FDA 2021).
- Pay special attention to spaces between toes (US FDA 2021).
- Wear well fitting, ventilated shoes and cotton socks (US FDA 2021).
- Supervise children when they use this product (US FDA 2021).

Products containing tolnaftate with a claim for the prevention of athlete's foot

- Clean skin with soap and water and dry thoroughly (US FDA 2021).
- For prevention, apply a thin layer to the feet once or twice daily (US FDA 2021).
- Pay special attention to spaces between toes (US FDA 2021).
- Wear well fitting, ventilated shoes and cotton socks (US FDA 2021).
- Supervise children when they use this product (US FDA 2021).

Aerosols, sprays and powders

Avoid inhaling or exposing others to (the) spray/powder.

Duration(s) of use

No statement required.

Risk information

Caution(s) and Warning(s)

All products

- **For external use only** (US FDA 2021).
- **When using this product** avoid contact with eyes. If contact occurs, rinse thoroughly with water (US FDA 2021).
- **Stop use and ask a doctor/physician/health care practitioner/health care provider/health care professional** if symptoms worsen or last for more than 4 weeks (US FDA 2021).
- **Keep out of reach of children.** If swallowed, call a poison control centre or get medical help right away.

Products containing povidone-iodine

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a thyroid disease (US FDA 2013).

Contraindication(s)

All products

Do not use for infections of the nails (US FDA 2021).

Products containing povidone-iodine

Do not use if you are pregnant or breastfeeding (US FDA 2013).

Known adverse reaction(s)

Products containing povidone-iodine

Rare anaphylactic reactions have been known to occur (Gray et al. 2013; Palobart et al. 2009; Yoshida et al. 2008).

Non-medicinal ingredients

Ingredients must be chosen from the current [Natural Health Products Ingredients Database](#) (NHPID) and must meet the limitations outlined in that database, the *Food and Drug Regulations* , and the current [Cosmetic Ingredient Hotlist](#), when relevant.

Storage conditions

- Must be established in accordance with the requirements described in the *Natural Health Products Regulations* or the *Food and Drug Regulations*.
- If the product is flammable or the if the container is under pressure, storage condition and warnings are required by the [Consumer Chemicals and Containers Regulations](#).

Specifications

This monograph describes those requirements that are specific to this class of non-prescription drugs and to natural health products. Any change to the manufacturing process that impacts the safety and efficacy of the ingredients, such as the use of novel technology (e.g. nanotechnology), requires supporting data and will be reviewed outside the monograph.

For products containing a Table 1 NHP medicinal ingredient

The finished product specifications must be established in accordance with the requirements described in the NNHPD [Quality of Natural Health Products Guide](#). The medicinal ingredient must comply with the requirements outlined in the [NHPID](#).

For products containing a Table 2 NPD medicinal ingredient:

Requirements described in the Regulations to the Food and Drugs Act must be met.

For products containing a Table 1 NHP medicinal ingredient:

EXAMPLE OF PRODUCT FACTS TABLE:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts	
Medicinal ingredients (w/v)	
Undecylenic acid	XX %
Zinc undecylenate	YY %
Uses	
<ul style="list-style-type: none"> • For the treatment of athlete's foot • Kills athlete's foot fungus. • Relieves itching, scaling, burning, cracking, redness, soreness, and irritation of athlete's foot. 	
Warnings	
For external use only.	
Do not use for infections of the nails.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a health care practitioner if symptoms worsen or last for more than 4 weeks.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions	
Adults and children 2 years and older: • Clean skin with soap and water and dry thoroughly • Apply a thin layer over affected area morning and night for full treatment period of 4 weeks • Avoid inhaling or exposing other to the spray ¹ • Pay special attention to spaces between toes • Wear well fitting, ventilated shoes and cotton socks • Supervise children when they use this product.	
Other information	
(Add storage information)	
Non-medicinal ingredients	
List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	

¹For products in a spray, aerosol or powder format

For products containing a Table 2 NPD medicinal ingredient:

DRUG FACTS TABLES (Format Optional for Self-Care Category I)

Drug Facts	
Active ingredient (w/w)	Purpose
Chlorphenesin XX %	Athlete's foot treatment
Uses	
<ul style="list-style-type: none"> • For the treatment of athlete's foot • Cures athlete's foot • Kills athlete's foot fungus • Relieves itching, scaling, burning, cracking, redness, soreness, irritation of athlete's foot. 	
Warnings	
For external use only	
Do not use for infections of the nails.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a doctor if symptoms worsen or last for more than 4 weeks.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions	
Adults and children 2 years and older: <ul style="list-style-type: none"> • Clean skin with soap and water and dry thoroughly • Apply/Spray a thin layer over affected area morning and night for full treatment period of 4 weeks • (When applying medication) Pay special attention to spaces between toes • Wear well fitting, ventilated shoes and cotton socks • Supervise children when they use this product [For aerosols and sprays] • Avoid inhaling or exposing others to spray. 	
Other information	
[If no other information, delete this section]	
Inactive ingredients	
List NMIs	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

Drug Facts	
Active ingredient (w/w) Clioquinol XX %	Purpose Athlete's foot treatment
Uses • For the treatment of athlete's foot • Cures athlete's foot • Kills athlete's foot fungus • Relieves (itching, scaling, burning, cracking, redness, soreness, irritation of) athlete's foot.	
Warnings For external use only	
Do not use for infections of the nails.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a doctor if symptoms worsen or last for more than 4 weeks.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults and children 2 years and older: • Clean skin with soap and water and dry thoroughly • Apply a thin layer over affected area morning and night for full treatment period of 4 weeks • (When applying medication) Pay special attention to spaces between toes • Wear well fitting, ventilated shoes and cotton socks • Supervise children when they use this product [For aerosols and sprays] • Avoid inhaling or exposing others to spray.	
Other information [If no other information, delete this section]	
Inactive ingredients List NMI's	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

Drug Facts	
Active ingredient (w/w) Haloprogin XX %	Purpose Athlete's foot treatment
Uses • For the treatment of athlete's foot • Cures athlete's foot • Kills athlete's foot fungus • Relieves (itching, scaling, burning, cracking, redness, soreness, irritation of) athlete's foot.	
Warnings For external use only	
Do not use for infections of the nails.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a doctor if symptoms worsen or last for more than 4 weeks.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults and children 2 years and older: • Clean skin with soap and water and dry thoroughly • Apply a thin layer over affected area morning and night for full treatment period of 4 weeks • Pay special attention to spaces between toes • Wear well fitting, ventilated shoes and cotton socks • Supervise children when they use this product [For aerosols and sprays] • Avoid inhaling or exposing others to spray.	
Other information [If no other information, delete this section]	
Inactive ingredients List NMI's	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

Drug Facts	
Active ingredient (w/w) Tolnaftate XX %	Purpose Athlete's foot treatment
Uses • For the treatment of athlete's foot • Cures athlete's foot • Kills athlete's foot fungus • Relieves (itching, scaling, burning, cracking, redness, soreness, irritation of) athlete's foot • With daily use, for the prevention of athlete's foot, for individuals with recurring problems	
Warnings For external use only	
Do not use for infections of the nails.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a doctor if symptoms worsen or last for more than 4 weeks.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults and children 2 years and older: • Clean skin with soap and water and dry thoroughly • Apply a thin layer over affected area morning and night for full treatment period of 4 weeks • For prevention, apply a thin layer to the feet once or twice daily • Pay special attention to spaces between toes • Wear well fitting, ventilated shoes and cotton socks • Supervise children when they use this product [For aerosols and sprays] • Avoid inhaling or exposing others to spray.	
Other information [If no other information, delete this section]	
Inactive ingredients List NMI's	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

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