FOOT SOAK- menthol, methyl salicylate crystal
Xtreme Tools International, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

FOOT SOAK

Active Ingredients

Menthol 5%

Methyl Salicylate 5%

Purpose

Topical Analgesic

Use

For the Temporary relief of minor pain.

Warning

For External use only.

If pregnant or breast-feeding, ask a health professional before use.

Allergy Alert:
If prone to allergic reaction from aspirin or salicylate, consult a doctor before use.

When using this product

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

Condition worsens or does not improve after regular use of this product.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Pour a desired amount of Foot Soak into pan or tub of warm water. Soak for as long as desired.

Inactive ingredients

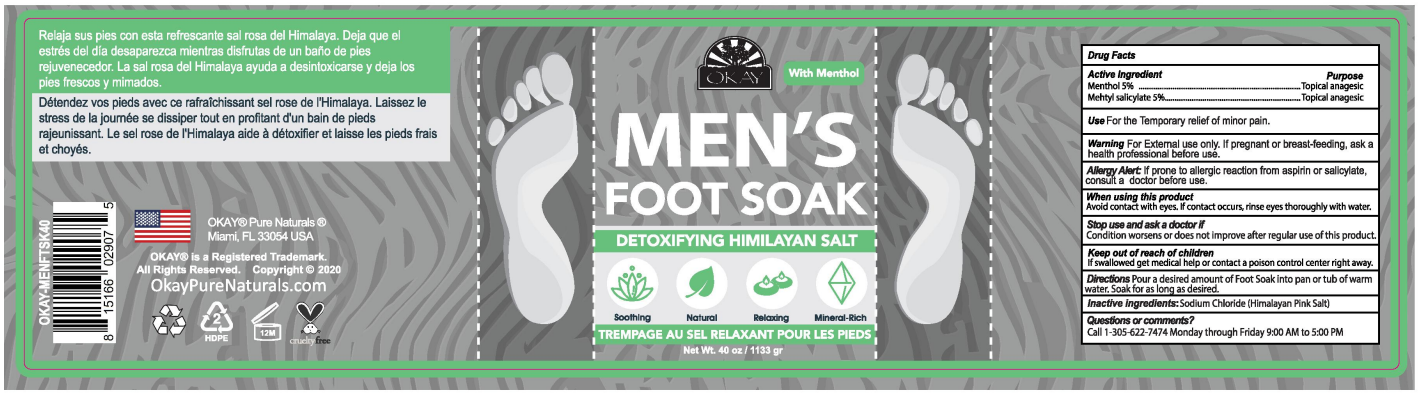
Sodium Chloride (Himalayan Pink Salt)

Questions or comments?

Call 1-305-622-7474 Monday through Friday 9:00 AM to 5:00 PM

Package Label

1133 gr in JAR; NDC 74553-005-01



FOOT SOAK

menthol, methyl salicylate crystal

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74553-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	5 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:74553-005-01	1133 g in 1 JAR; Type 0: Not a Combination Product	11/25/2020	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph not final	part348	11/25/2020	

Labeler - Xtreme Tools International, Inc (125398904)

Registrant - Xtreme Tools International, Inc (125398904)

Establishment

Name	Address	ID/FEI	Business Operations
Xtreme Tools International, Inc		125398904	manufacture(74553-005)