PSORIAFLORA- mahonia aquifolium root bark cream Schwabe Mexico, S.A. de C.V.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Psoriaflora

Active Ingredient

Berberis aquifolium 2X

Inactive Ingredients

Benzyl Alcohol

Cetyl Alcohol

Ethyl Alcohol

Glycol Stearate

Isopropyl Myristate

Mineral Oil

Potassium Hydroxide

Purified Water

Stearyl Heptanoate

Dosage & Administration

Directions:

Adults and Children 2 years of age and older: apply to affected area up to 4 times daily. Rub in gently.

Children under 2 years of age: consult a physician.

Patch test recommended on sensitive skin.

Indications & Usage

Temporarily relieves the dryness, itching, flaking, rash, redness and skin irritation associated with psoriasis.

Purpose

Temporarily relieves the dryness, itching, flaking, rash, redness and skin irritation

associated with psoriasis.

Warnings

For external use only.

Avoid contact with eyes or broken skin.

Do not use

Do not use if hypersensitive to any ingredients in this product. Breast-feeding women should not apply to breast area.

Stop Use

Stop use and ask a doctor if increased skin irritation, rash or other allergic reaction develops, condition worsens or does not improve within 7 days. These could be signs of a serious condition.

Pregnancy or Breast Feeding

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

Keep out of reach of children

Keep out of reach of children.

Overdosage

If swallowed, seek medical help or contact a Poison Control Center immediately.



Add image transcription here...

PSORIAFLORA mahonia aquifolium root bark cream Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68466-2005

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAHONIA AQUIFOLIUM ROOT BARK (UNII: VZJ9F3C3SB) (MAHONIA AQUIFOLIUM ROOT BARK - UNII:VZJ9F3C3SB)	MAHONIA AQUIFOLIUM ROOT BARK	2 [hp_X] in 28 g

Inactive Ingredients			
Ingredient Name	Strength		
BENZYL ALCOHOL (UNII: LKG8494WBH)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
ALCOHOL (UNII: 3K9958V90M)			
GLYCOL STEARATE (UNII: 0324G66D0E)			
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
MINERAL OIL (UNII: T5L8T28FGP)			
POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T)			
WATER (UNII: 059QF0KO0R)			
STEARYL HEPTANOATE (UNII: 2M4UGL1NCN)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:68466- 2005-4	1 in 1 CARTON	04/22/2022		
1	28 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/22/2022	

Labeler - Schwabe Mexico, S.A. de C.V. (812805901)

Establishment				
Name	Address	ID/FEI	Business Operations	
Schwabe Mexico, S.A. de C.V.		812805901	manufacture(68466-2005)	

Revised: 11/2023 Schwabe Mexico, S.A. de C.V.