

SPA SKILHA HELIOPROT AB SPF 40- bemotrizinol, octinoxate, avobenzone, titanium dioxide cream

SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS

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.

SPA SKILHA HELIOPROT AB SPF 40

Ethylhexyl methoxycinnamate, butyl methoxydibenzoylmethane, titanium dioxide and bis-ethylhexyl oxyphenol methoxyphenyl triazine offers total protection and wide spectrum against the UVA and UVB.

As dermoprotective solar screen, moisturizes and nourishes. Delays photo-aging and prevents skin cancer.

Keep out of reach of children

Use this product when you exposed to the sun. SPF 40 UVA / UVB

Avoid contact with eyes, do not use in the children under (6) six months of age.

- Apply generously before sun exposure.
- Reapply after (6) six hours.

Its composition is photo stable, perfectly adjusted to any state and any condition of the skin.

IMAGE OF THE LABEL



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66854-025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BEMOTRIZINOL (UNII: PWZ1720CBH) (BEMOTRIZINOL - UNII:PWZ1720CBH)	BEMOTRIZINOL	1.5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	4 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LM26O6933)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
HYDROLYSED BOVINE COLLAGEN (ENZYMATIC; 2000-5000 MW) (UNII: 5WE8P977RQ)	
WHEAT GERM OIL (UNII: 14C97E680P)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
DIMETHICONOL (41 MPA.S) (UNII: 343C7U75XW)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A218C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66854-025-01	9 g in 1 JAR		
2	NDC:66854-025-02	33 g in 1 JAR		
3	NDC:66854-025-03	60 g in 1 TUBE		
4	NDC:66854-025-05	20 in 1 BOX		
4	NDC:66854-025-04	15 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/30/2012	

Labeler - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Registrant - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Establishment

Name	Address	ID/FEI	Business Operations
SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS		880172184	analysis, label, manufacture, pack

