KIDS RELIEF ARNICA- arnica montana, hypericum perforatum cream HOMEOLAB USA INC

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.

DRUG FACTS

ACTIVE INGREDIENTS HPUS

Arnica montana (Leopard's bane) 1X Hypericum perforatum (St John's Wort) 1X

PURPOSE

Pain, bruises, sprains, muscle aches

Bruises, strains

These claims have not been reviewed by the Food and Drug Administration. They are based on traditional homeopathic practice.

The letters "HPUS" indicate that the ingredients in this product are officially monographed in the Homoeopathic Pharmacopoeia of the United States.

USES

This homeopathic medecine is made from a combination of ingredients traditionally used to help relieve symptoms associated with:

- minor bruises
- strains
- sprains
- muscle aches

WARNINGS

For external use only.

Do not use on broken skin.

When using this product, avoid contact with eyes; if contact occurs, rinse abundantly with water to remove.

Stop use and ask a doctor

- if symptoms persist for more than 3 days or worsen

- if hypersensitivity and/or allergy occurs.

Keep out of reach of children. If ingested, get medical help or contact a Poison Control Center immediately.

DIRECTIONS

- Apply a thin layer to the affected area, rub in gently. Repeat 3 times a day or as needed.
- Children under 2 yrs: ask a doctor.

OTHER INFORMATION

- Store at room temperature (68 77°F)
- Do not use if tube seal is broken.

INACTIVE INGREDIENTS

Carbomer, ceteareth-12, cetearyl alcohol, cetyl alcohol, cetyl palmitate, DMDM hydantoin, glycerin, glyceryl cocoate, glyceryl stearate, iodopropynyl butylcarbamate, isopropyl myristate, isopropyl palmitate, octyldodecanol, PEG-20 glyceryl stearate, PEG-100 stearate, purified water, sodium hydroxide, sorbitan stearate.

CARTON



TUBE



KIDS 1	RELIEF	ARNICA
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arnica montana, hypericum perforatum cream

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source) NDC:60512-9086		-9086	
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingredient Name			Basis of	Strength	Strength
ARNICA MONTANA (UNII: 080TY208ZW) (ARNICA MONTANA - UNII:080TY208ZW)			ARNICA MO	NTANA	1 [hp_X] in 50 g

HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM -	HYPERICUM	1 [hp_X]
UNII:XK4IUX8MNB)	PERFORATUM	in 50 g

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE A (UNII: F68VH75CJC)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL COCOATE (UNII: WVK1CT5994)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PEG-20 GLYCERYL STEARATE (UNII: MJV0165YY8)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:60512-9086-1	1 in 1 CARTON		
1	50 g in 1 TUBE		
2 NDC:60512-9086-2	6 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		03/15/2012		

Labeler - HOMEOLAB USA INC (202032533)

Establishment					
Name	Address	ID/FEI	Business Operations		
HOMEOLAB USA INC		202032533	manufacture(60512-9086)		