FIRST DEGREE- calendula officinalis, echinacea angustifolia, cantharis vesicatoria tincture Welmedix LLC

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.

First°Degree® Burn Cream

Active ingredients

Calendula officinalis TINC HPUS

Cantharis vesicatoria 3X HPUS

Echinacea angustifolia TINC HPUS

The letters 'HPUS' indicate that the active ingredients are officially monographed in the Homeopathic Pharmacopoeia of the United States. TINC and 3X are homeopathic dilutions: see www.firstdegree.com for details.

Purposes

wound healing, superficial burns and scalds

burns, scalds, rawness, burning pain

itching, burning, irritation from insect bites

Uses

Temporarily relieves symptoms such as minor skin pain, rawness and itching due to:

- minor burns
- insect bites
- minor scrapes
- scalds

Product Uses are based on the Homeopathic Materia Medica, and have not been evaluated by the Food and Drug Administration.

Warnings

For external use only

Do not use

- if you have an allergy or hypersensitivity to any ingredients or if you have had a prior reaction to this product
- over large areas of the body
- on deep or puncture wounds
- on animal bites
- on serious burns, cuts or scrapes

When using this product

do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

If pregnant or breast feeding

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- for best results, apply immediately to affected area
- adults and children 2 years of age and older: apply to affected area 2-3 times a day, as needed, or as directed by your doctor
- children under 2 years of age: consult a doctor

Other information

store at 15-30°C (59-86°F)

Inactive ingredients

butyrospermum parkii (shea butter), C18-22 hydroxyalkyl hydroxypropyl guar, hydrogenated polydecene, isopropyl myristate, lanolin, methylparaben, propylparaben, purified water, sodium polyacryloyldimethyl taurate, trideceth-10

Questions or comments?

Call 1-888-565-2876 Monday through Friday, 9am-5pm

Principal Display Panel - First°Degree® Therapeutic Burn Cream

NEW

THERAPEUTIC BURN CREAM

First°Degree®

NDC 24330-0110-21

- Soothes the pain & cools the burn
 - Acts as an antiseptic for burns
 - Helps reduce the appearance of scars

Homeopathic

Burns Happen. Be Prepared.TM

NET WT. 3/4 OZ (21g)



Carton Label - First°Degree® Therapeutic Burn Cream

Principal Display Panel - First° Degree® Burn Cream

BURN CREAM

First°Degree[®]

- Helps reduce the appearance of scars
- Protects against infection
- Soothes the pain & cools the burn

NET WT 1/2 oz (14 g)

1 TUBE

Homeopathic



Carton Label - First°Degree® Burn Cream

$\textbf{Principal Display Panel-Firs} \, t^{\circ} \textbf{Degree}^{\circledR} \, \, \textbf{Multi-Symptom Burn Cream}$

INSTANTLY SOOTHING!

96% NATURAL

 $First^{\circ}Degree^{\circledR}$

MULTI-SYMPTOM BURN CREAM SOOTHES THE PAIN & COOLS THE BURN

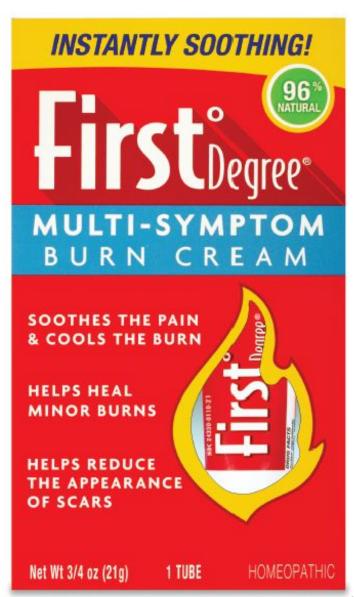
HELPS HEAL MINOR BURNS

HELPS REDUCE THE APPEARANCE OF SCARS

Net Wt 3/4 oz (21g)

1 TUBE

HOMEOPATHIC



Carton Label - First°Degree® Multi-Symptom Burn Cream

FIRST DEGREE

calendula officinalis, echinacea angustifolia, cantharis vesicatoria tincture

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24330-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18 E7415PXQ) (CALENI OFFICINALIS FLOWERING TOP - UNII: 18 E7415PXQ)		ALENDULA OFFICINALIS LOWERING TOP	1 [hp_Q] in 0.1 g	
ECHINACEA ANGUSTIFO LIA (UNII: VB06 AV5US8) (ECHINACEA ANGUSTIFO UNII: VB06 AV5US8)	DLIA - EO	CHINACEA ANGUSTIFOLIA	1 [hp_Q] in 0.1 g	
LYTTA VESICATORIA (UNII: 3Q034RO3BT) (LYTTA VESICATORIA - UNII:3Q034RO3BT)	L	YTTA VESICATORIA	3 [hp_X] in 0.1 g	

Inactive Ingredients			
Ingredient Name	Strength		
SHEA BUTTER (UNII: K49 155WL9 Y)			
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)			
LANOLIN (UNII: 7EV65EAW6H)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (UNII: Z8 IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
TRIDECETH-10 (UNII: G624N6MSBA)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24330-110-21	1 in 1 CARTON	0 1/0 1/20 0 7	
1		21 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:24330-110-14	1 in 1 CARTON	05/01/2014	
2		14 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:24330-110-22	1 in 1 CARTON	0 3/0 1/20 15	
3		21 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		0 1/0 1/20 0 7		

Labeler - Welmedix LLC (830387812)

Establishment				
Name	Address	ID/FEI	Business Operations	
Denison Pharmaceuticals, LLC		001207208	MANUFACTURE(24330-110)	

Revised: 8/2015 Welmedix LLC