

H-FISSURES FORMULA - calendula officinalis, chamomilla oil
Healing Natural Oils 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.

Active Ingredients :

Calendula officinalis -12C HPUS
Chamomilla - 6C HPUS

Purpose

Calendula officinalis - 12C HPUS (healing agent),
Chamomilla - 6C HPUS (soreness of anus, painful fissures).

The letters 'HPUS' indicate that the components in this product are officially monographed in the Homoeopathic Pharmacopoeia of the United States

Inactive Ingredients :

Corylus avellana nut oil, Essential Oil Blend (Helichrysum italicum flower, Lavandula officinalis flower bud, Matricaria recutita flower)

Indications :

For the temporary relief of anal fissure symptoms such as burning, soreness and minor bleeding.

Directions :

Adults and Children 4 yrs and over: Wash hands before and after use.
Shake well and apply 1 or 2 drops to a cotton swab or your finger and apply directly to the affected area 3x per day.
Do not oversaturate or exceed dosage.

Warnings :

For external use only.

Perform skin test prior to initial use.

If pregnant or breastfeeding consult a doctor before use.

Keep out of reach of children.

Keep away from eyes and mucous membranes. If swallowed get medical help or contact a Poison Control

Center right away.

Discontinue use if irritation occurs.

Consult a doctor if symptoms worsen after 7 days.

Dist. by Healing Natural Oils 3830 Valley Ctr Dr, #705-526, San Diego, CA 92130, USA

Healing Natural Oils

H-Fissures

Formula

Homeopathic

For External Use Only

036

11ml (0.37 fl. oz)

amails.com

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61077-036
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	12 [hp_C] in 11 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	6 [hp_C] in 11 mL

Inactive Ingredients

Ingredient Name	Strength
EUROPEAN HAZELNUT OIL (UNII: 8RQ2839AVG)	
HELICHRYSUM ITALICUM FLOWER (UNII: P62Y550X24)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AHIRAF4M)	
CHAMOMILE (UNII: FGL3685T2X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61077-036-11	11 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	11/06/2013	
2	NDC:61077-036-33	33 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	11/06/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/06/2013	

Labeler - Healing Natural Oils LLC (113679703)

Establishment

Name	Address	ID/FEI	Business Operations
King Bio, Inc.		617901350	manufacture(61077-036)

Revised: 12/2017

Healing Natural Oils LLC