

**PROCTOSAN CREAM- ratanhia, aesculus hippocastanum, collinsonia canadensis, paeonia officinalis, negundo cream
Seroyal USA**

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.

PROCTOSAN CREAM

Active ingredients

This preparation contains:

Aesculus hippocastanum (Horse chestnut) Seeds MT 0.4%

Collinsonia canadensis (Stone root) Underground Parts MT 0.4%

Negundo (Box-elder) Bark MT 0.1%

Paeonia officinalis (Peony) Underground Parts MT 0.4%

Ratanhia (Rhatany) Root MT 2.0%

Uses

For the temporary relief of symptoms associated with hemorrhoids.

Warnings

For external and intrarectal use only.

Do not use this product with an applicator if the introduction of the applicator into the rectum causes additional pain. Consult a doctor promptly.

When using this product do not exceed the recommended daily dosage unless directed by a doctor.

Stop use and ask a doctor

In case of bleeding.

If condition worsens or does not improve within 7 days.

If pregnant or breastfeeding, 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.

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Other information

Do not use if inner seal is missing or broken.

Store in a cool, dry place.

Contents may not fill package in order to accommodate required labeling.

Please rely on stated quantity.

Inactive ingredients

Cetostearyl alcohol, glycerin, purified water

Directions

Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. Apply a small amount on affected area in the morning and at night and after each bowel movement, or as recommended by your healthcare practitioner.

FOR INTRARECTAL USE: Attach applicator to tube. Lubricate applicator well, then gently insert applicator into the rectum. Squeeze tube to release a small amount of cream into the rectum. Gently remove applicator and thoroughly cleanse applicator after each use. Children: Use under the direction of your healthcare practitioner.

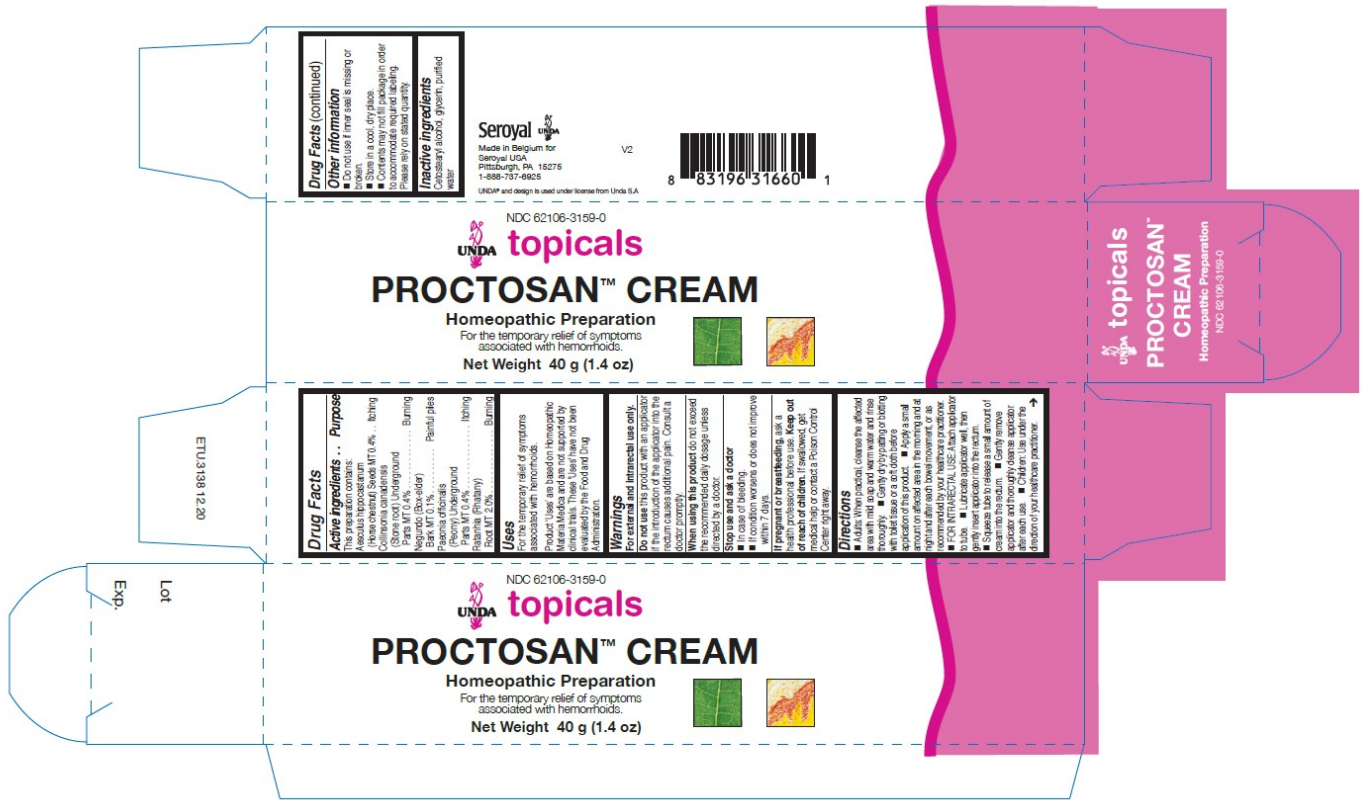
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NDC 62106-3159-0

UNDA topicals

PROCTOSAN CREAM

Homeopathic Preparation

For the temporary relief of symptoms associated with hemorrhoids.

Net Weight 1.4 oz (40 g)

PROCTOSAN CREAM

ratanhia, aesculus hippocastanum, collinsonia canadensis, paeonia officinalis, negundo cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62106-3159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
KRAMERIA LAPPACEA ROOT (UNII: P29ZH1A35Z) (KRAMERIA LAPPACEA ROOT - UNII:P29ZH1A35Z)	KRAMERIA LAPPACEA ROOT	1 [hp_X] in 40 g
COLLINSONIA CANADENSIS ROOT (UNII: O2630F3XDR) (COLLINSONIA CANADENSIS ROOT - UNII:O2630F3XDR)	COLLINSONIA CANADENSIS ROOT	1 [hp_X] in 40 g
PAEONIA OFFICINALIS ROOT (UNII: 8R564U2E1P) (PAEONIA OFFICINALIS ROOT - UNII:8R564U2E1P)	PAEONIA OFFICINALIS ROOT	1 [hp_X] in 40 g

HORSE CHESTNUT (UNII: 3C18L6RJAZ) (HORSE CHESTNUT - UNII:3C18L6RJAZ)	HORSE CHESTNUT	1 [hp_X] in 40 g
ACER NEGUNDO INNER BARK (UNII: 9GB215FRJX) (ACER NEGUNDO INNER BARK - UNII:9GB215FRJX)	ACER NEGUNDO INNER BARK	1 [hp_X] in 40 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62106-3159-0	1 in 1 CARTON	12/17/2015	
1		40 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		12/17/2015	

Labeler - Seroyal USA (018361118)

Establishment

Name	Address	ID/FEI	Business Operations
SAN'UP		401010287	manufacture(62106-3159)

Revised: 7/2021

Seroyal USA