DIBUCAINE- dibucaine ointment
Padagis Israel Pharmaceuticals Ltd

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.

Perrigo Dibucaine Ointment 1% Drug Facts

Active ingredient

Dibucaine 1%

Purpose

Hemorrhoidal/topical analgesic

Uses

for hemorrhoidal:

- for the temporary relief of pain, itching and burning due to hemorrhoids and other anorectal disorders for topical analgesic:
- for the temporary relief of pain and itching caused by sunburn, minor burns, minor cuts, scrapes, insect bites or minor skin irritation

Warnings

For external use only

Allergy warning: Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and ask a doctor.

Do not use

- in or near the eyes
- in infants under 2 years of age or weighing less than 35 pounds

When using this product

for hemorrhoidal:

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or applicator

for topical analgesic:

- do not use in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask a doctor if

for hemorrhoidal:

- condition worsens or does not improve within 7 days
- bleeding occurs

for topical analgesic:

- condition worsens or if symptoms persist for 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 hemorrhoidal:

- adults and children 12 years & older: when practical, clean 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 applying.
- apply externally to the affected area up to 3 or 4 times daily
- children under 12 years of age: ask a doctor

for topical analgesic:

- adults and children 2 years of age and over: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Other information

store at 20°-25°C (68°-77°F)

Inactive ingredients

acetone sodium bisulfite, lanolin, white petrolatum

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Child Resistant Packaging

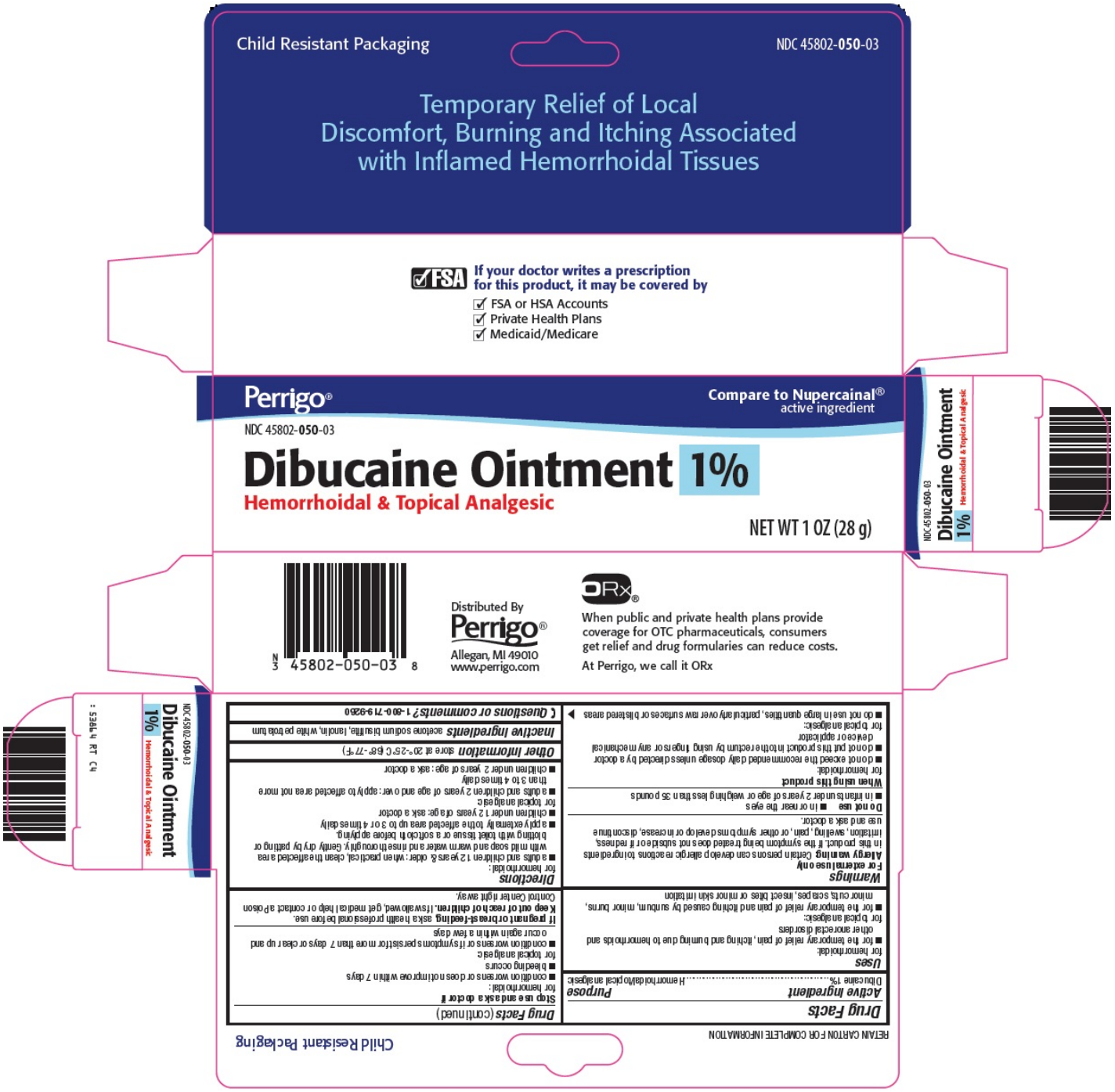
Temporary Relief of Local Discomfort, Burning and Itching Associated with Inflamed Hemorrhoidal Tissues

Compare to Nupercainal® active ingredient

Dibucaine Ointment 1%

Hemorrhoidal & Topical Analgesic

NET WT 1 OZ (28 g)



DIBUCAINE

dibucaine ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:45802-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIBUCAINE (UNII: L6JW2TJG99) (DIBUCAINE - UNII:L6JW2TJG99)	DIBUCAINE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ACETONE SODIUM BISULFITE (UNII: 47VY054OXY)	
LANOLIN (UNII: 7EV65EAW6H)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45802-050-03	1 in 1 CARTON	06/20/2011	
1		28 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
OTC monograph final	part346	06/20/2011	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 11/2021

Padagis Israel Pharmaceuticals Ltd