BANOPHEN- diphenhydramine hydrochloride, zinc acetate cream
Major Pharmaceuticals

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.

Major Pharmaceuticals Banophen™ Drug Facts

Active ingredient

Diphenhydramine hydrochloride 2%

Zinc acetate 0.1%

Purpose

Topical analgesic

Skin protectant

Uses

- temporarily relieves pain and itching associated with:
- insect bites
- minor burns
- sunburn
- minor skin irritations
- minor cuts
- scrapes
- rashes due to poison ivy, poison oak and poison sumac
- dries the oozing and weeping of poison ivy, poison oak and poison sumac

Warnings

For external use only

Do not use

- on large areas of the body
- with any other product containing diphenhydramine, even one taken by mouth

Ask a doctor before use

- on chicken pox
- on measles

When using this product

- avoid contact with the eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

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

Directions

- do not use more than directed
- adults and children 2 years of age and older: apply to affected area no 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

cetyl alcohol, diazolidinyl urea, methylparaben, PEG-2 stearate, PEG-20 stearate, propylene glycol, propylparaben, purified water

Questions or comments?

1-800-616-2471

Principal Display Panel

EXTRA STRENGTH ITCH RELIEF

COMPARE TO Active Ingredients Of EXTRA STRENGTH BENADRYL® CREAM

EXTRA STRENGTH

Banophen™

Relieves Itches From Insect Bites And Skin Irritations

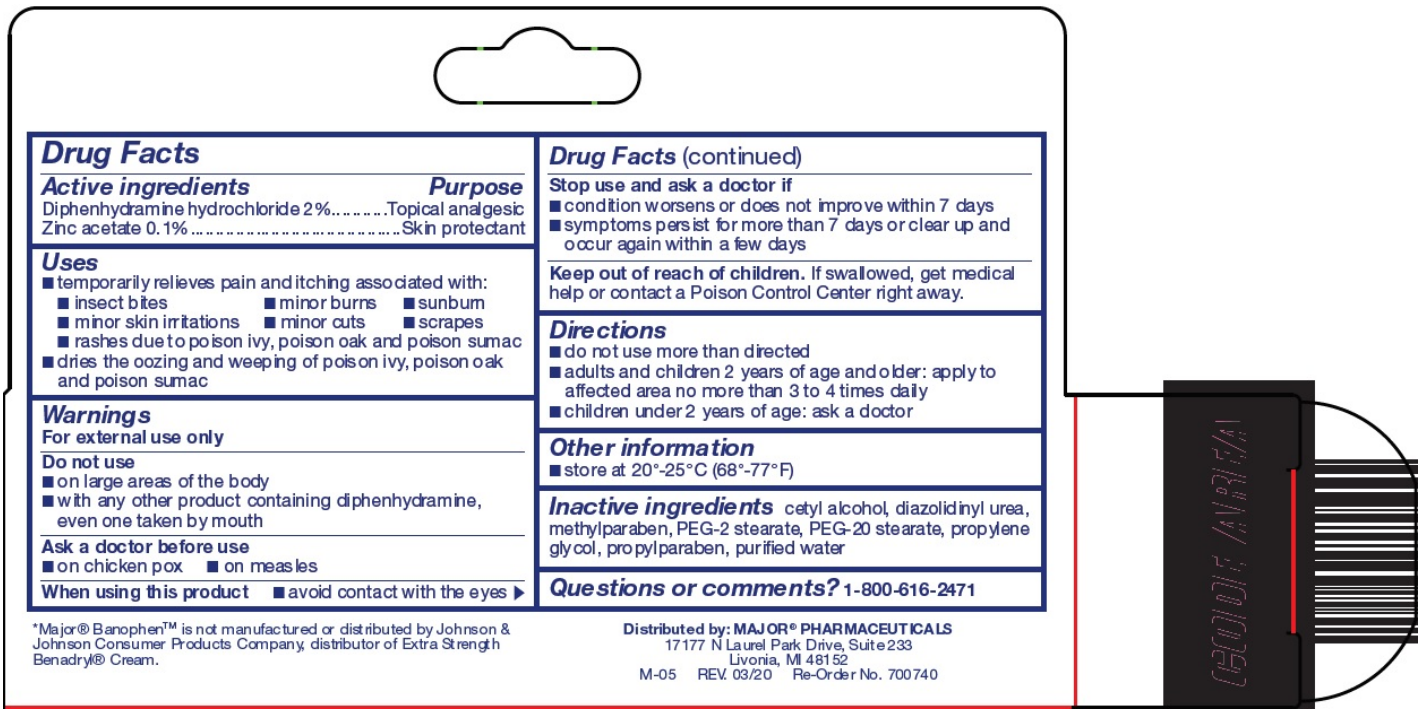
EXTRA STRENGTH

Banophen™

Anti-Itch Cream

Topical Analgesic / Skin Protectant

NET WT 1 OZ (28 g)



Drug Facts

Active ingredients — **Purpose**

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Zinc acetate 0.1%..... Skin protectant

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Drug Facts (continued)

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Questions or comments? 1-800-616-2471

*Major® Banophen™ is not manufactured or distributed by Johnson & Johnson Consumer Products Company, distributor of Extra Strength Benadryl® Cream.

Distributed by: MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
M-05 REV. 03/20 Re-Order No. 700740

BANOPHEN

diphenhydramine hydrochloride, zinc acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-5354
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	0.1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PEG-2 STEARATE (UNII: 94YQ11Y95F)	
PEG-20 STEARATE (UNII: NBX892EA57)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0904-5354-31	1 in 1 CARTON	06/19/2009	
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 not final	part348	06/19/2009	

Labeler - Major Pharmaceuticals (191427277)

Revised: 7/2020 Major Pharmaceuticals