

## **MAXIMUM-H- hydrocortisone cream**

**New GPC, Inc.**

*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.*

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### **maximum-H**

#### **Active Ingredient**

Hydrocortisone 1%

#### **Purpose**

Anti-itch ointment

#### **Uses**

For the temporary relief of external itching.

For temporary relief of itching associated with minor skin irritation and rashes.

#### **Inactive ingredients**

Water, Petrolatum, Hydrogenated Didecene Cetearyl Alcohol, Ceteareth-20, Lanolin, Mineral Oil, Glycerin, Sorbitan Stearate, Dimethicone, Methylpropanediol, PEG-40 Stearate, Lanolin Alcohol, Esculin, Disodium EDTA, Magnesium Aluminum Silicate, Acrylates/10-30 Alkyl Acrylate, Grosspolymer, 1,2-Hexanediol, Caprylyl Glycol, BHT, Soy, Isoflavones, Sodium Hydroxide, Phenoxyethanol, Sorbic Acid, Menthol, Tricaprylin, Polymethyl Methacrylate, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Citric Acid.

#### **Questions or Comments?**

MossPharmaceutical, P.O. Box 1426, Port Washington, NY 11050

[www.maximum-H.com](http://www.maximum-H.com)

#### **WARNINGS**

##### **For external use only.**

Avoid contact with eyes.

If condition worsens or if symptoms persist for more than 7 days, or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you consult a doctor.

Do not use for the treatment of diaper rash.

Keep out of the reach of children. If swallowed get help or contact a Poison control center right away.

#### **Directions**

Adults and Children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: Do not use, consult a Doctor.

For hemorrhoids - clean affected area with a cleansing wipe, then dry with a soft cloth. Apply externally to lower part of anal canal only. Apply up to 3 times daily at night and after every bowel movement.

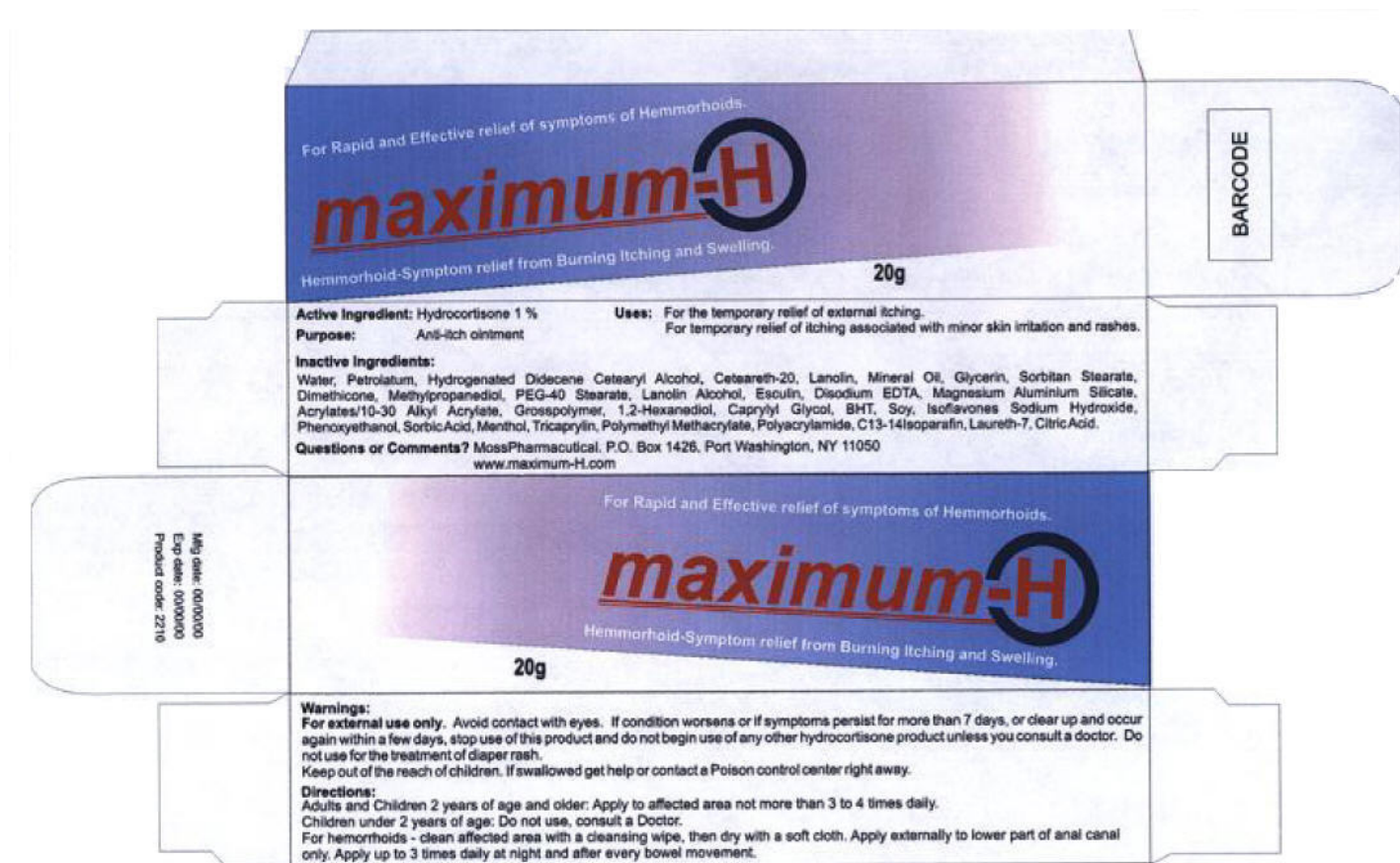
## PRINCIPAL DISPLAY PANEL - 20g Tube Carton

For Rapid and Effective relief of symptoms of Hemmorhoids.

### **maximum-H**

Hemmorhoid-Symptom relief from Burning Itching and Swelling.

20g



## MAXIMUM-H

hydrocortisone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65588-2210
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PETROLATUM (UNII: 4T6H12BN9U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MINERAL OIL (UNII: T5L8T28FGP)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
LANOLIN (UNII: 7EV65EAW6H)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
SOY ISOFLAVONES (UNII: 71B37NR06D)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBIC ACID (UNII: X045WJ989B)	
MENTHOL (UNII: L7T10EIP3A)	
TRICAPRYLIN (UNII: 6P92858988)	
ESCULIN (UNII: 1Y1L18LQAF)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65588-2210-1	1 in 1 CARTON		
1		20 g in 1 TUBE		
2	NDC:65588-2210-2	1 in 1 CARTON		
2		40 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	12/01/2009	

**Labeler** - New GPC, Inc. (895025443)

## Establishment

Name	Address	ID/FEI	Business Operations
New GPC, Inc.		895025443	MANUFACTURE

