

NUMBING CREAM- pramoxine hydrochloride 1% cream
BLOOMWELL GARDENS LLC

Active Ingredient (w/w): Pramoxine Hydrochloride 1%External Analgesic

Inactive ingredients

Purified Water, Glycerin, Allantoin, Tocopheryl Acetate (Vitamin E), Carbomer, Propylene Glycol, Sodium Hydroxide, Phenoxyethanol, Ethylhexylglycerin

PurposeExternal analgesic

Uses

Temporarily helps reduce discomfort from:

Minor burns, Insect bites, Minor skin irritations, Post-shaving or grooming sensitivity

External itching or rash due to dry skin

Warnings (For external use only)

For external use only

Do not use on large areas of the body or on broken, blistered, or abraded skin

Avoid contact with eyes, mouth and mucous membranes

If pregnant or breast feeding, consult a healthcare provider before use

Stop use and ask a doctor if:

Condition worsens or symptoms persist for more than 7 days

Skin irritation, rash, or allergic reaction occurs

Keep out of reach of children.

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

Adults and children over 12 years:

Apply a thin layer to affected area

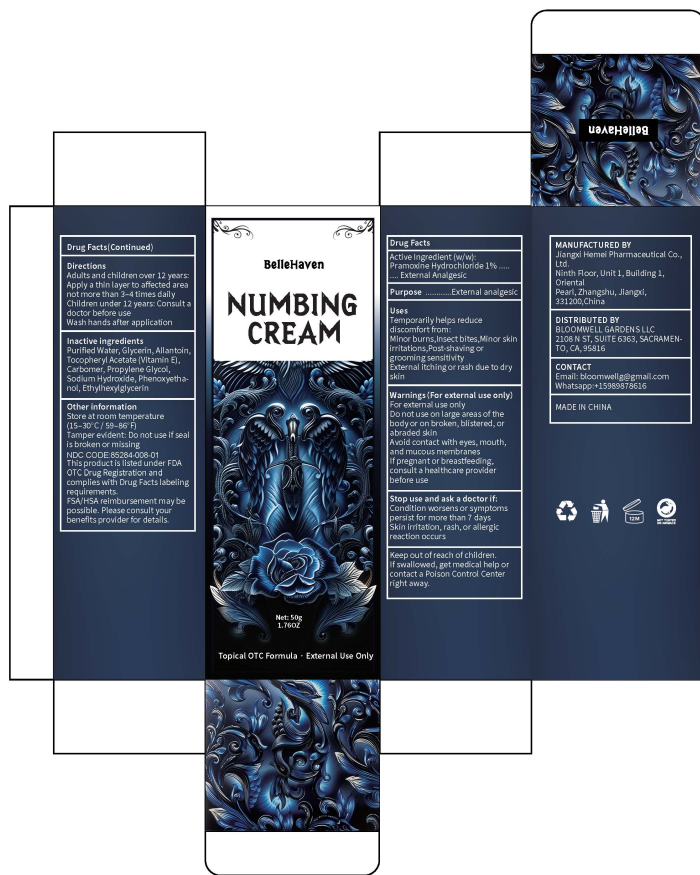
not more than 3-4 times daily

Children under 12 years: Consult a doctor before use

Wash hands after application

Store at room temperature (15-30°C/59-86°F)

Tamper evident: Do not use if seal is broken or missing



Drug Facts	
Active Ingredient (w/w): Pramoxine Hydrochloride 1%	External Analgesic
Purpose	External analgesic
Uses Temporarily helps reduce discomfort from: Minor burns, insect bites, minor skin irritations, Post-shaving or grooming sensitivity External itching or rash due to dry skin	
Warnings (For external use only) For external use only. Do not use on large areas of the body or on broken, irritated, or abraded skin. Avoid contact with eyes, mouth, and mucous membranes. If pregnant or breastfeeding, consult a healthcare provider before use.	
Stop use and ask a doctor if: Discomfort worsens or symptoms persist for more than 7 days. Skin irritation, rash, or allergic reaction occurs.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Other information Store at room temperature (15-30°C / 59-86°F). Tamper evident: Do not use if seal is broken or missing. NDC CODE 85284-008-01 This product is listed under FDA OTC Drug Registration and complies with Drug Facts labeling requirements. PSA/MSA reimbursement may be possible. Please consult your benefits provider for details.	
MADE IN CHINA	

NUMBING CREAM

pramoxine hydrochloride 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85284-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALLANTOIN (UNII: 344S277G0Z)	

WATER (UNII: 059QF0KO0R)	
CARBOMER (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
VITAMIN E POLYETHYLENE GLYCOL SUCCINATE (UNII: O03S90U1F2)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85284-008-01	50 g in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	08/13/2025	

Labeler - BLOOMWELL GARDENS LLC (124839891)

Establishment			
Name	Address	ID/FEI	Business Operations
Jiangxi Hemei Pharmaceutical Co., Ltd.		724892056	manufacture(85284-008)

Revised: 8/2025

BLOOMWELL GARDENS LLC