OPAHL- benzocaine spray, metered Dharma Research, inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Active Ingredient

Benzocaine 20%......Oral Anesthetic

Uses

For the temporary relief of occasional minor irritation and pain associated with canker sores and minor dental procedures.

Warnings

- Keep out of reach of children
- If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center immediately.
- Do not use if you have a history of allergy to local anesthetic such a procaine, butacaine, benzocaine or other "caine" anesthetics.
- Flammable. Do not use near fire or flame. Avoid smoking during use.
- Avoid spraying in eyes.

Dosage

A single metered spray dispenses 50mg of Opahl-S Topical Anesthetic.

Directions

- Do not exceed recommended dosage
- Firmly insert extension tube into spray can valve and ensure it fits securely into the actuator opening
- position the extension tube 1-2 inches from the affected area.
- Spray 1/2 second (press and immediately release the actuator)
- Anesthesia is accomplished in approximately 20 seconds.

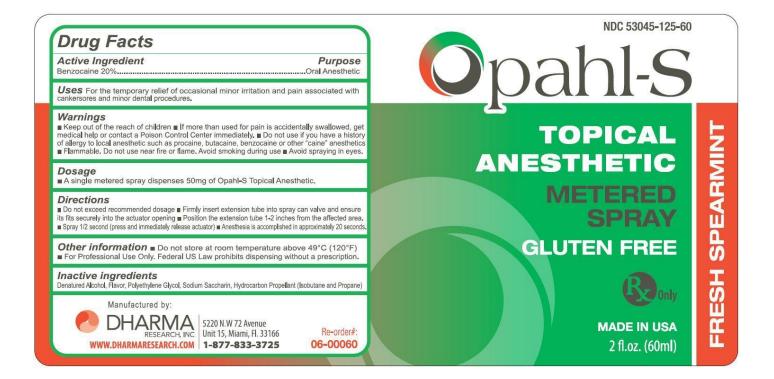
Other Information

- Do not store at room temperature above 49oC (120oF)
- For professional use only. Federal US Law prohibits dispensing without a prescription

Inactive ingredients

Denatured Alcohol, Flavor, Polyethylene Glycol, Sodium Saccharin, Hydrocarbon Propellant (Isobutane and Propane)

Label



OPAHL

benzocaine spray, metered

Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-125		
Route of Administration	ORAL, TOPICAL, DENTAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	12 g in 60 g		

Inactive Ingredients				
Ingredient Name	Strength			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
ALCOHOL (UNII: 3K9958V90M)				
PROPANE (UNII: T75W9911L6)				
ISOBUTANE (UNII: BXR49TP611)				

Product Characteristics					
Color		Score			
Shape		Size			
Flavor	SPEARMINT	Imprint Code			
Contains					

Packaging							
#	Item Code	Package Description	Marketing S	Start Date	Ma	arketing End Da	te
1 N	OC:53045-125-60	60 g in 1 BOTTLE					
Ma	rketing Infor	mation					
	rketing Infor	mation Application Number or Monogra	nph Citation M	Marketing Start	: Date	Marketing End	Date

Labeler - Dharma Research, inc. (078444642)

Registrant - Dharma Research, inc. (078444642)

Establishment						
Name	Address	ID/FEI	Business Operations			
Dharma Research, inc.		078444642	manufacture(53045-125)			

Revised: 1/2013 Dharma Research, inc.