CURASORE- pramoxine hydrochloride liquid
S.S.S. Company

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.

DRUG FACTS

Active Ingredient:

Pramoxine Hydrochloride 1%

Purpose:

Local Anesthetic

Uses

For the temporary relief of pain and itching associated with fever blisters and cold sores

Warnings

For external use only

When using this product

- Do not swallow
- Avoid contact with the eyes
- Avoid contact with the nose

Stop use and consult a doctor If

- Redness
- Swelling
- Irritation or pain persists or increases, condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Keep out of the reach of children

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily; avoid moistening area for 2 to 3 minutes following application. Children under 2 years of age: consult a doctor.

Other Information

- **FLAMMABLE**
- Keep away from heat, sparks, and open flame
- Store in a cool place
- Keep lid tightly capped.
- To report an adverse event or obtain product information contact (404) 521-0857.

Inactive Ingredients

ethyl alcohol and ethyl ether

Principal Display Panel

NDC 12258-223-05

CURASORE®

Pain Relieving Anesthetic for

Fever Blisters • Cold Sores

Contains Ether

0.5 FL OZ (15mL)

Important: Begin application at the first sign of a fever blister or cold sore.

CURASORE®

Analgesic-Anesthetic-Antipruritic

for Relieving Pain & Itching of

Fever Blisters & Cold Sores

With

DISPOSABLE COTTON APPLICATORS

Other Packaging Content

Manufactured by S.S.S. Company, Atlanta, GA 30315, USA

ssspharmaceuticals.com

Rev. E

CURASORE

pramoxine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:12258-223
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 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	

ETHER (UNII: 0F5N573A2Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12258-223-05	1 in 1 CARTON	08/31/1995	
1		15 mL in 1 BOTTLE; 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	08/31/1995	

Labeler - S.S.S. Company (003288321)

Establishment

Name	Address	ID/FEI	Business Operations
S.S.S. Company		003288321	manufacture(12258-223) , pack(12258-223) , label(12258-223)

Revised: 10/2019 S.S.S. Company