CLEANOZ - sodium chloride solution
Laboratoires Gifrer Barbezat

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.

Uses

- Recommended for nasal rinsing in babies, children and adults.

Recommended for the following cases:

- Hygiene of nasal passage: Pollution, dry air, airconditioning, dust, pollen.
- Moisture efficiency.
- Nasal drainage. For babies and infants, this can be assisted with the use of Cleanoz® nasal aspirator kit™

Warning

For external use only, do not inject

- Do not use if solution changes color or becomes cloudy.

When using this product

- Use only if applicator is intact.
- To avoid contamination, do not touch tip of the container to any surface.
- Do not reuse. Once opened, discard.
- Do not use the same applicator on different people.

Keep out of reach of children.

Direction

- Twist and pull tab to remove.
- Tilt on the applicator to obtain the necessary dosage.
- Directions for use for babies and infants: Place the baby with its head leaning to the side. Place carefully the tip of the applicator in one nostril. Tilt to obtain the necessary dosage. Repeat on the other nostril.
- Use as often as needed for any length of time or as directed by physician. Non habit forming.

Other information

- Store at 68-77°F (20-25°C).
- Retain this carton for future reference.
- Use before expiration date marked on the carton or containers.

Inactive ingredients

Purified water, 0.9% Sodium Chloride

Questions? 1-866-5-UBIMED info@ubimed.com

Principal Display Panel

Cleanoz(R)

Saline solution

Natural relief for dry or stuffy noses

Convenient and hygienic

Newborns to adults

The #1 Choice of Healthcare Professionals

Preservative-free vials

Ubimed

3/5/10/20/30/40 Count

3/5/10/20/30/40 Sterile Single-Use Applicators

5mL (0.169 FL OZ) Each

HEIGHT: 9cm = 3.5433071 inches ~ 3.5 inches

WIDTH: 7.5cm = 2.9527559 inches ~ 3 inches

DEEP: 6cm = 2.3622047 inches ~ 2.4 inches

CLEANOZ

sodium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:44929-002

Route of Administration	NASAL, OPHTHALMIC

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
sodium chloride (UNII: 451W47IQ8X) (sodium cation - UNII:LYR4M0NH37)	sodium chloride	900 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44929-002-02	20 in 1 CARTON		
1	NDC:44929-002-01	5 mL in 1 AMPULE		
2	NDC:44929-002-03	3 in 1 CARTON		
2	NDC:44929-002-01	5 mL in 1 AMPULE		
3	NDC:44929-002-04	5 in 1 CARTON		
3	NDC:44929-002-01	5 mL in 1 AMPULE		
4	NDC:44929-002-05	40 in 1 CARTON		
4	NDC:44929-002-01	5 mL in 1 AMPULE		
5	NDC:44929-002-06	10 in 1 CARTON		
5	NDC:44929-002-01	5 mL in 1 AMPULE		
6	NDC:44929-002-07	30 in 1 CARTON		
6	NDC:44929-002-01	5 mL in 1 AMPULE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part341	11/25/2008	

Labeler - Laboratoires Gifrer Barbezat (278133806)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Gifrer Barbezat		278133806	manufacture

Revised: 3/2010 Laboratoires Gifrer Barbezat