CAPENT DIAPER RASH- zinc oxide lanolin ointment
Laboratorios Columbia S.A. de C.V.

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.

Active Ingredients

Zinc Oxide 25%

Lanolin 15.5%

Purpose

Skin protectant

Skin protectant

Uses ● Helps treat and prevent diaper rash ●Protects minor skin irritation associated with diaper rash ● Helps protect from wetness

Warnings **For external use only**

When using this product ● Do not get into eyes

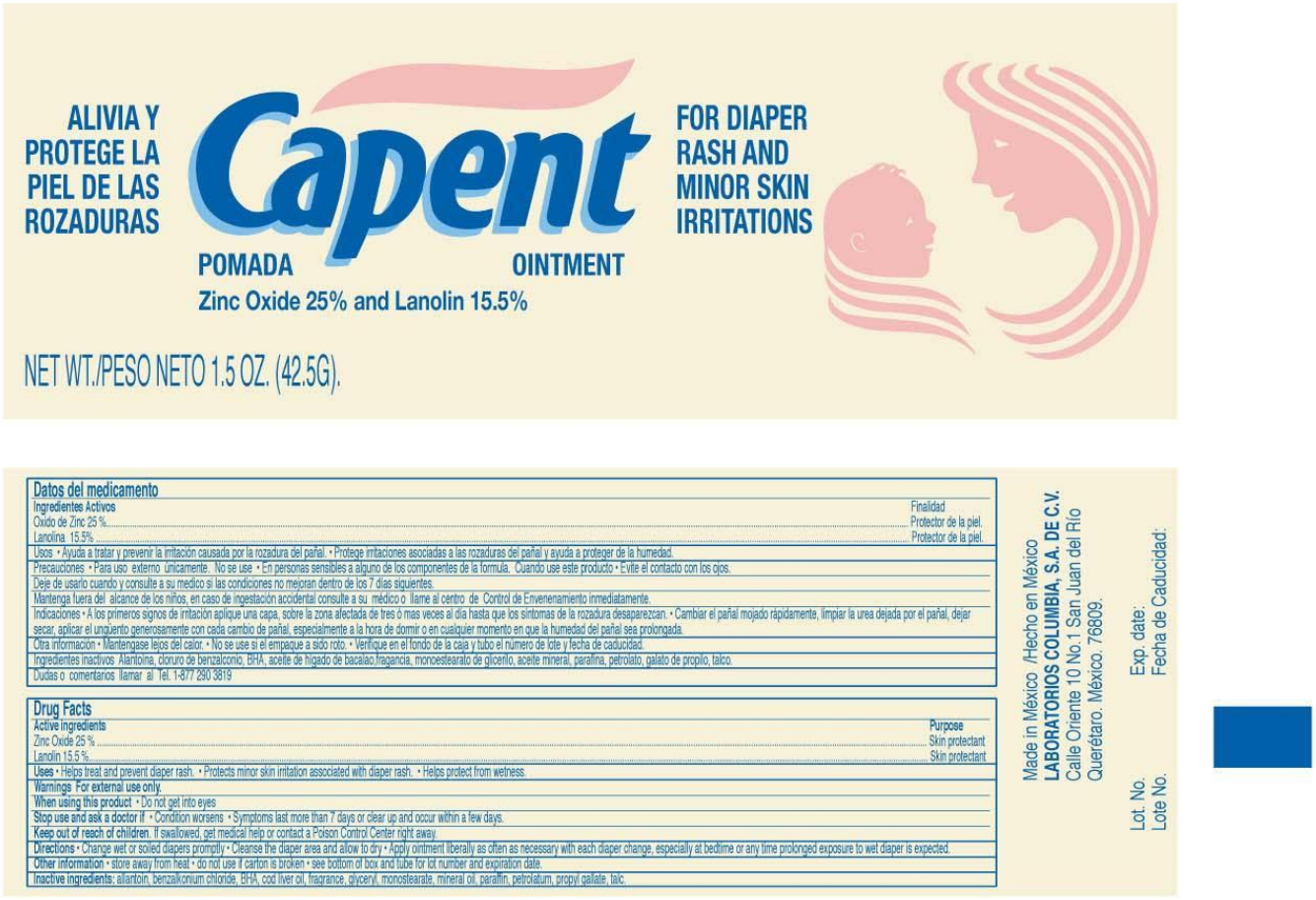
Stop use and ask a doctor if ● Condition worsens ● Symptoms last for more than 7 days or clear up and occur within a few days

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away

Directions ● Change wet or soiled diapers promptly ● Cleanse the diaper area and allow to dry ● Apply ointment liberally as often as necessary with each diaper change, especially at bedtime or any time prolonged exposure to wet diaper is expected

Other information ● store away from heat ● do not use if carton is broken ● see bottom of box and tube for lot number and expiration date

Inactive ingredients: allantoin, benzalkonium chloride, BHA, cod liver oil, fragrance, glyceryl monostearate, mineral oil, paraffin, propyl gallate, talc



CAPENT DIAPER RASH

zinc oxide lanolin ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59567-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 g in 100 g
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	15.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALLANTOIN (UNII: 344S277G0Z)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
COD LIVER OIL (UNII: BBL281NWFG)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59567-001-42	42.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/01/2013	

Labeler - Laboratorios Columbia S.A. de C.V. (812685253)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Columbia S.A. de C.V.		812685253	manufacture(59567-001)

Revised: 2/2013 Laboratorios Columbia S.A. de C.V.