

POXIEZZZ- menthol, zinc oxide spray
Fortunique B.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.

Drug Facts

Active Ingredients

Menthol 1%

Zinc Oxide 4%

Purpose

Topical Analgesic

Skin Protectant

Uses

For the temporary relief of pain and itching associated with minor skin irritations

Protects chafed skin

Warning

For external use only

When using this product

Avoid contact with eyes

Stop use and contact a Doctor if

Condition worsens .

Symptoms last more than 7 days or clear up and occur within a few days.

Not to be applied over deep a puncture wounds, infection or lacerations

Keep out of reach of children

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

Directions

Not suitable for children under 2 years of age. Adults and children 2 years of age and older: Apply to affected area no more than 2 to 3 times daily. Shake well before use. Make sure the skin is clean and dry before spraying. Use a sweeping movement to spray-on the cream in a thin and uniform layer directly onto the affected skin. Use a spraying distance of approximately 2 to 3 inches. It is not necessary to rub the cream. When the skin is very sensitive, it is advised not to touch the skin too frequently.

Other information

Store at room temperature bellow 77° F

Inactive Ingredients

Water (aqua)

Coco-Caprylate/Caprata

Glycerin

Cetearyl Alcohol

Cetearyl Glucoside

Alky-Alcohols

Alkyl Glucoside

Cocoglycerides

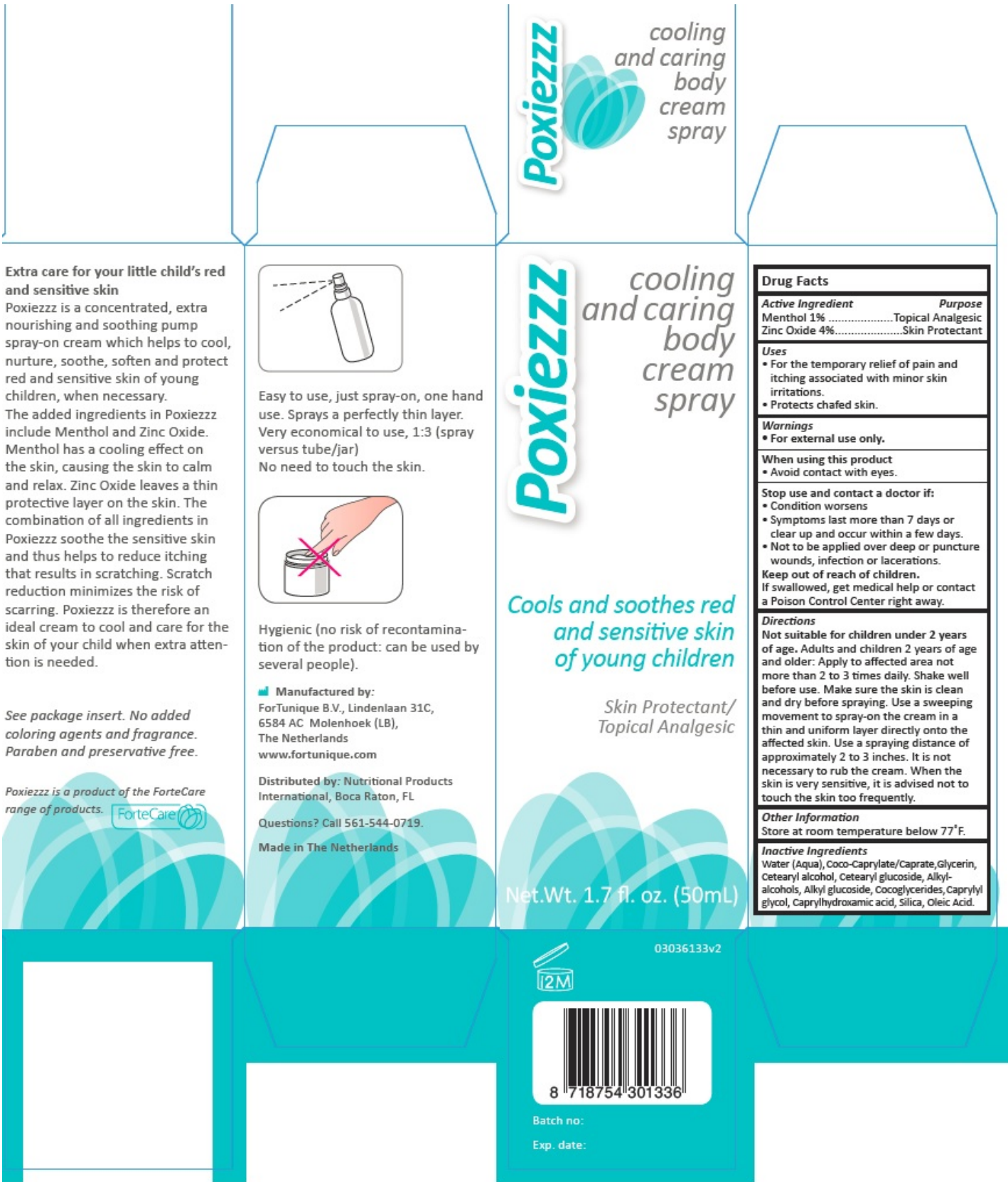
Caprylylglycol

Caprylhydroxamic Acid

Silica

Oleic Acid

Principle Display Panel.Bottle Spray 50 ml



Extra care for your little child's red and sensitive skin

Poxiezz is a concentrated, extra nourishing and soothing pump spray-on cream which helps to cool, nurture, soothe, soften and protect red and sensitive skin of young children, when necessary.

The added ingredients in Poxiezz include Menthol and Zinc Oxide. Menthol has a cooling effect on the skin, causing the skin to calm and relax. Zinc Oxide leaves a thin protective layer on the skin. The combination of all ingredients in Poxiezz soothe the sensitive skin and thus helps to reduce itching that results in scratching. Scratch reduction minimizes the risk of scarring. Poxiezz is therefore an ideal cream to cool and care for the skin of your child when extra attention is needed.

See package insert. No added coloring agents and fragrance. Paraben and preservative free.

Poxiezz is a product of the ForteCare range of products.



Easy to use, just spray-on, one hand use. Sprays a perfectly thin layer. Very economical to use, 1:3 (spray versus tube/jar) No need to touch the skin.



Hygienic (no risk of recontamination of the product: can be used by several people).

Manufactured by:
ForTunique B.V., Lindenlaan 31C,
6584 AC Molenhoek (LB),
The Netherlands
www.fortunique.com

Distributed by: Nutritional Products
International, Boca Raton, FL

Questions? Call 561-544-0719.

Made in The Netherlands

Poxiezz cooling and caring body cream spray

Poxiezz cooling and caring body cream spray

Cools and soothes red and sensitive skin of young children

Skin Protectant/
Topical Analgesic

Net.Wt. 1.7 fl. oz. (50mL)

Drug Facts	
Active Ingredient	Purpose
Menthol 1%	Topical Analgesic
Zinc Oxide 4%	Skin Protectant
Uses	
<ul style="list-style-type: none"> For the temporary relief of pain and itching associated with minor skin irritations. Protects chafed skin. 	
Warnings	
<ul style="list-style-type: none"> For external use only. 	
When using this product	
<ul style="list-style-type: none"> Avoid contact with eyes. 	
Stop use and contact a doctor if:	
<ul style="list-style-type: none"> Condition worsens Symptoms last more than 7 days or clear up and occur within a few days. Not to be applied over deep or puncture wounds, infection or lacerations. 	
<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<p>Not suitable for children under 2 years of age. Adults and children 2 years of age and older: Apply to affected area not more than 2 to 3 times daily. Shake well before use. Make sure the skin is clean and dry before spraying. Use a sweeping movement to spray-on the cream in a thin and uniform layer directly onto the affected skin. Use a spraying distance of approximately 2 to 3 inches. It is not necessary to rub the cream. When the skin is very sensitive, it is advised not to touch the skin too frequently.</p>	
Other Information	
Store at room temperature below 77°F.	
Inactive Ingredients	
Water (Aqua), Coco-Caprylate/Caprate, Glycerin, Cetearyl alcohol, Cetearyl glucoside, Alkyl-alcohols, Alkyl glucoside, Cocoglycerides, Caprylyl glycol, Caprylylhydroxamic acid, Silica, Oleic Acid.	

03036133v2



Batch no:

Exp. date:

POXIEZZZ

menthol, zinc oxide spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70 359-4106

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CO CO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
CO CO-GLYCERIDES (UNII: ISE9I7DNUG)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
OLEIC ACID (UNII: 2UMI9U37CP)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
C14-22 ALCOHOLS (UNII: B1K89384RJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70359-4106-1	1 in 1 CARTON	01/21/2016	
1		50 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/21/2016	

Labeler - Fortunique B.V. (407788616)

Registrant - Fortunique B.V. (407788616)

Establishment

Name	Address	ID/FEI	Business Operations
Fortunique B.V.		407788616	manufacture(70359-4106)

