

BUTTIEZZZ INTENSE- 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

Zinc Oxide 10%

Purpose

Skin Protectant

Uses

Helps treat and prevent diaper rash

Protect chafed skin due to diaper rash and helps seal out wetness

Warning

For external use only

Avoid contact with eyes

Stop use and contact a Doctor if

Condition worsens

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

Not to be applied over deep or 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

Change wet or soiled diapers promptly

Shake well before use. Make sure the tin is clean and dry before use. Use a sweeping movement to spray on the cream in a thin and uniform layer on the buttocks

Buttiezzz Intense is more effective when you apply a single thin layer. Use a spraying distance approximately 2 to 3 inches. It is not necessary to rub the cream. Apply Buttiezzz Intense liberally as often as necessary or at every diaper change

Other Information

Store at room temperature below 77° F

Inactive Ingredients

Water(aqua)

Coco-Caprilate/Caprates

Glycerin

Alkyl-Alcohols

Alkyl Glucoside

Propylene Glycol

Cocoglycerides

Caprylyl glycol

Capryl Hydroxamic acid

Chamomilla Recutita(Matricaria)Flower Extract

Calendula Officinalis Flower Extract

Silica

Oleic Acid

Principle Display Panel.50ml Bottle Spray carton

INTENSE
Buttiezzz

*baby
bottom
cream
spray*

With extra Zinc Oxide

Buttiezzz Intense

Buttiezzz Intense is a hygienic pump spray-on cream that helps to relieve, soothe and protect against skin discomfort related to diaper rash. The intensely caring cream absorbs directly into the skin so the Zinc Oxide will effectively block baby's bottom against the diaper content with a protective layer. Buttiezzz Intense cream can be sprayed directly onto the skin and therefore the often sensitive and irritated skin does not need to be touched. The added Calendula and Chamomile protect, soothe, calm and promote the natural recovery of the skin. The use of the pump spray also helps to prevent (re)contamination.

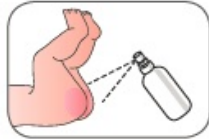
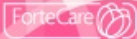
Manufactured by:
ForTunique B.V., Lindenlaan 31C,
6584 AC Molenhoek (LB),
The Netherlands
www.fortunique.com

Distributed by: Nutritional Products
International, Boca Raton, FL

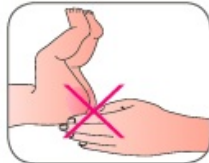
Questions? Call 561-544-0719.

Made in The Netherlands

Butiezzz Intense 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).

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

INTENSE
Buttiezzz

*baby
bottom
cream
spray*

*Soothes diaper rash
and red, sensitive
baby bottoms*

With extra Zinc Oxide
Skin protectant

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

Drug Facts	
Active Ingredient	Purpose
Zinc Oxide 10%	Skin Protectant
Uses	
<ul style="list-style-type: none"> Helps treat and prevent diaper rash. Protects chafed skin due to diaper rash and helps seal out wetness 	
Warnings	
<ul style="list-style-type: none"> For external use only. Avoid contact with eyes. <p>Stop use and contact a doctor if:</p> <ul style="list-style-type: none"> Condition worsens Symptoms last more than 7 days or clear up or occur within a few days. Not to be applied over deep or puncture wounds, infection or lacerations. <p>Keep out of reach of children.</p> <ul style="list-style-type: none"> If swallowed, get medical help or contact a Poison Control Center right away. 	
Directions	
<p>Change wet or soiled diapers promptly. Shake well before use. Make sure the skin is clean and dry before use. Use a sweeping movement to spray on the cream in a thin and uniform layer on the buttocks. Buttiezzz Intense is more effective when you apply a single thin layer. Use a spraying distance of approximately 2 to 3 inches. It is not necessary to rub the cream. Apply Buttiezzz Intense liberally as often as necessary or at every diaper change.</p>	
Other Information	
Store at room temperature below 77°F.	
Inactive Ingredients	
Water (Aqua), Coco-Caprylate/Caprate, Glycerin, Alkyl-alcohols, Alkyl glucoside, Propylene glycol, Cocoglycerides, Caprylyl glycol, Caprylhydroxamic acid, Chamomilla recutita (matricaria) flower extract, Calendula officinalis flower extract, Silica, Oleic Acid.	

03036130v2



Batch no:

Exp. date:

BUTTIEZZZ INTENSE

zinc oxide spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70359-4102

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
COCO-GLYCERIDES (UNII: ISE9I7DNUG)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
OLEIC ACID (UNII: 2UM9U37CP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHAMOMILE (UNII: FGL3685T2X)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
GLYCERIN (UNII: PDC6A3C0OX)	
C14-22 ALCOHOLS (UNII: B1K89384RJ)	
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70359-4102-1	1 in 1 CARTON	01/20/2016	
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	01/20/2016	

Labeler - Fortunique B.V. (407788616)

Registrant - Fortunique B.V. (407788616)

Establishment

Name	Address	ID/FEI	Business Operations
Fortunique B.V.		407788616	manufacture(70359-4102)

