

ZARASYL COMPANION- barrier cream cream
Dara Craiceann Limited

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

For external use only.
For animal use only.

Store in cool dry conditions.

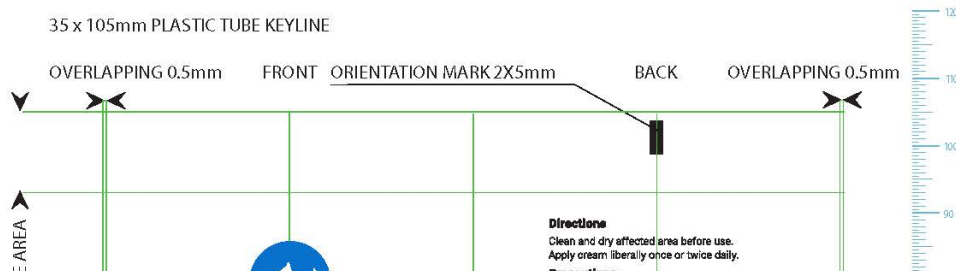
Keep out of reach of children.

Not for use in animals intended for food.
Do not use on deep or puncture wounds

Discontinue use and consult your veterinarian if swelling, redness, irritation or excessive drainage develops at the site of application or if healing is delayed

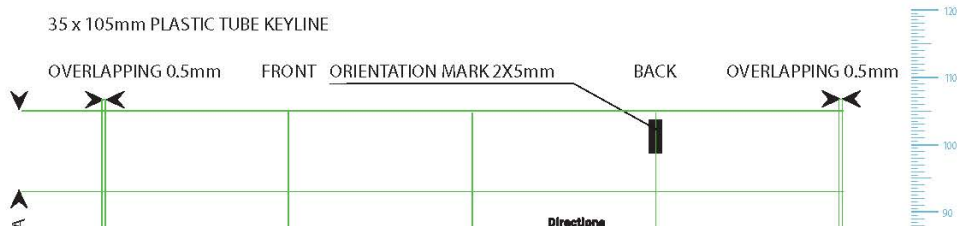
Clean and dry affected area before use. Apply cream liberally once or twice daily.

BlueColor is Pantone : 285 C
Dark Text is Color is Pantone : 433C





BlueColor is Pantone : 285 C
 Dark Text is Color is Pantone : 433C



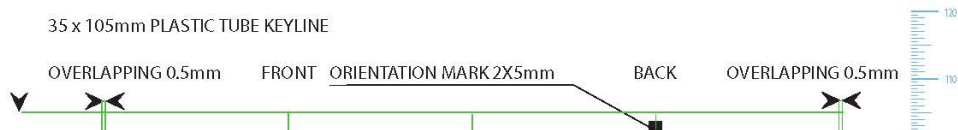


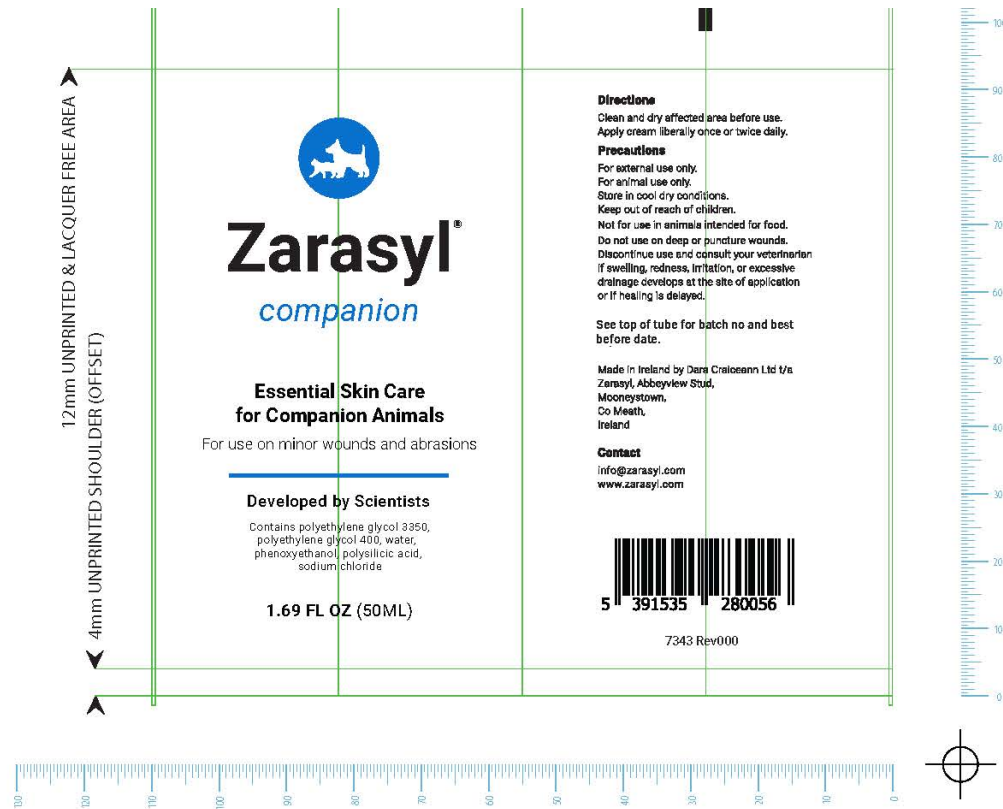
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ZARASYL COMPANION

barrier cream cream

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86107-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDRATED SILICA (UNII: Y607T4G8P9) (ORTHOSILICIC ACID - UNII:623B93YABH)	ORTHOSILICIC ACID	0.074 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	

Product Characteristics

Color	white (white/off white cream)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86107-002-01	50 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/27/2022	

Labeler - Dara Craiceann Limited (985720091)

Establishment

Name	Address	ID/FEI	Business Operations
Dara Craiceann Limited		985720091	label

Establishment

Name	Address	ID/FEI	Business Operations
Ovelle Ltd.		219542784	manufacture, api manufacture

Revised: 7/2022

Dara Craiceann Limited