SUFFUSION K PS MOUSSE- chlorhexidine gluconate, ketoconazole, phytosphingosine salicyloyl liquid

Aspen Veterinary Resource, LTD.

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.

Suffusion K +PS Mousse

ACTIVE INGREDIENTS: Chlorhexidine Gluconate 2%, Ketoconazole 1%, Phytosphingosine Salicyloyl 0.05%.

INACTIVE INGREDIENTS: Water, Propylene Glycol, Glycerin, Polysorbate 20, Lactic Acid, Fragrance, Methylisothiazolinone.

PROPERTIES: Suffusion K +PS Mousse is a formulation designed to manage skin infections without bathing. It is soap-free, rubbing alcohol-free and moisturizing. Suffusion K +PS Mousse also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier.

INDICATIONS: For the management of bacterial and fungal skin infections on dogs and cats.

DIRECTIONS FOR USE: Shake well before use. Brush the fur and then apply on dry hair. Apply every 3 days for 2 to 3 weeks or as directed by your veterinarian.

For localized application: Dispense 1 or 2 pumps onto your palm and then apply on the targeted area(s). Massage into the skin until fully penetrated. Do not rinse, let air dry. Once dry, brush the fur again.

For whole body application: Dispense 1 or 2 pumps onto your palm and then apply on the skin and hair. Massage into the skin until fully penetrated. Repeat as many times and necessary to cover the whole body, avoiding areas around the eyes and mouth. Do not rinse, let air dry. Once dry, brush the fur again.

Dosage:

Under 11 lbs: 1 pump per 2 lbs

11-88 lbs: 1 pump per 4 lbs

Over 88 lbs: 1 pump per 6 lbs

Dosage may be doubled for long-haired breeds.

CAUTIONS: For external use on dogs and cats only. Avoid contact with eyes. If eye contact occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Wash hands after use.

WARNINGS: Keep out of reach of children.

STORAGE CONDITIONS: Store at controlled room temperature. Do not freeze.

QUESTIONS? 1-800-999-0297

Pivetal

Distributed by: Aspen Veterinary Resources , LTD. Liberty, MO 64068 www.pivetalvet.com

PRINCIPAL DISPLAY PANEL - 6.8 OUNCE (200 mL) Bottle

NDC 460066-155-14

SUFFUSIONTM

K +PS Mousse

Chlorhexidine Gluconate 2%, Ketoconazole 1%, Phytosphingosine Salicyloyl 0.05%

Antiseptic Mousse

FOR CATS & DOGS

Phytosphingosine

Wellness

• PIVETAL •

SHAKE WELL BEFORE USE

6.8 FL. OZ. (200 mL)

NDC 46066-155-14

SUFFUSION[™]

K +PS Mousse

Chlorhexidine Gluconate 2%, Ketoconazole 1%, Phytosphingosine Salicyloyl 0.05%

Antiseptic Mousse FOR CATS & DOGS





SHAKE WELL BEFORE USE 6.8 FL. 0Z. (200 mL) Distributed by: Aspen Veterinary Resources[®], LTD. Liberty, MO 64068 www.pivetalvet.com



Rev. 07/19 P113CV

Piveral

F39210F-US 18-L1-v2

SUFFUSION K PS MOUSSE

chlorhexidine gluconate, ketoconazole, phytosphingosine salicyloyl liquid

Product Information

ACTIVE INGREDIENTS: Chlorhexidine Gluconate 2%, Ketoconazole 1%, Phytosphingosine Salicyloy 0.05%.

INACTIVE INGREDIENTS: Water, Propylene Glycol, Glycerin, Polysorbate 20, Lactic Acid, Fragrance, Methylisothiazolinone.

PROPERTIES: Suffusion K +PS Mousse is a formulation designed to manage skin infections without rinsing. It is soap-free, rubbing alcohol-free and moisturizing. Suffusion K +PS Mousse also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier.

INDICATIONS: For the management of bacterial and fungal skin infections on dogs and cats.

DIRECTIONS FOR USE: Shake well before use. Brush the fur and then apply on dry hair. Apply every 3 days for 2 to 3 weeks or as directed by your veterinarian.

For localized application: Dispense 1 or 2 pumps onto your palm and then apply on the targeted area(s). Massage into the skin until fully penetrated. Do not rinse, let air dry. Once dry, brush the fur again.

For whole body application: Dispense 1 or 2 pumps onto your paim and then apply on the skin and hair. Massage gently into the skin until fully penetrated. Repeat as many times as necessary to cover the whole body, avoiding areas around the eyes and mouth. Do not rinse, let air dry. Once dry, brush the fur again.

Dosage:

Under 11 lbs: 1 pump per 2 lbs 11–88 lbs: 1 pump per 4 lbs Over 88 lbs: 1 pump per 6 lbs Dosage may be doubled for long-haired breeds.

CAUTIONS: For external use on dogs and cats only. Avoid contact with eyes. If eye contact occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Wash hands after use.

WARNING: Keep out of reach of children.

STORAGE CONDITIONS: Store at room temperature. Do not freeze. QUESTIONS7 1-800-999-0297

CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - CHLORHEXIDINE GLUCONATE 20 mg GLUCONATE 10 mg in 1 mL KETOCONAZOLE (UNII: R9400W9271) (KETOCONAZOLE - UNII:R9400W9271) KETOCONAZOLE 10 mg in 1 mL SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNIEU891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNIEU891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNIEU891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNIEU891J4JCNH) SALICYLOYL SALICYLOYL PHYTOSPHINGOSINE 0.5 mg in 1 mL Ingredients Strength	Product Type	oduct Type OTC ANIMAL DRUG			Item Code (Source)		NDC:4606	NDC:46066-155	
Ingredient Name Basis of Strength Strength CHLORHEXIDINE GLUCONATE (UNIE: MOR84MUD8E) (CHLORHEXIDINE - UNIE:R4KOODYS2L) CHLORHEXIDINE GLUCONATE 20 mg in 1 mL KETOCONAZOLE (UNIE: R9400W927)) (KETOCONAZOLE - UNIE:R9400W927)) KETOCONAZOLE 10 mg in 1 mL SALICYLOYL PHYTOSPHINGOSINE (UNIE: U891J4JCNH) (SALICYLOYL SALICYLOYL PHYTOSPHINGOSINE (UNIE: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNIE:U891J4JCNH) SALICYLOYL SALICYLOYL PHYTOSPHINGOSINE 0.5 mg in 1 mL Inactive Ingredients Ingredient Name Strength WATER (UNIE: 059QF0KO0R) PROPYLENE GLYCOL (UNIE: 6DC9Q167V3) Strength GLYCERIN (UNIE: 059QF0KO0X) Ingredient Satat Date Strength PROPYLENE GLYCOL (UNIE: 7T1F30V5YH) METHYLISOTHIAZOLINONE (UNIE: 729D0E1QFA) Ingredient Satat Date Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1< NDC:46066-155-14 200 mL in 1 BOTTLE, PLASTIC Marketing Start Date Marketing End Date	Route of Administratio	n	TOPICAL						
Ingredient Name Basis of Strength Strength CHLORHEXIDINE GLUCONATE (UNIE: MOR84MUD8E) (CHLORHEXIDINE - CHLORHEXIDINE CHLORHEXIDINE 20 mg in 1 ml. INMERAKOODYS2L) KETOCONAZOLE (UNIE: R9400W927I) (KETOCONAZOLE - UNIE:R9400W927I) KETOCONAZOLE 10 mg in 1 ml. SALICYLOYL PHYTOSPHINGOSINE (UNIE: U89 11/4)CNH) (SALICYLOYL SALICYLOYL PHYTOSPHINGOSINE (UNIE: U89 11/4)CNH) (SALICYLOYL SALICYLOYL ONLOWN Ingredient Name Strength Market ingredients Ingredient Name Strength MATER (UNIE: 059QF0K00R) PROPYLENE GLYCOL (UNIE: 6DC9Q167V3) GLYCOL (UNIE: 6DC9Q167V3) GLYCOL (UNIE: 33X04XA5A5T) POLYSORBATE 20 (UNIE: 7T1F30V5YH) METHYLISOTHIAZOLINONE (UNIE: 229D0E1QFA) Packaging # Item Code Package Description Marketing Start Date Marketing Information									
CHLORHEXIDINE GLUCONATE (UNIE: MOR84MUD8E) (CHLORHEXIDINE - CHLORHEXIDINE - CHLORHEXIDIXE - CHL	Active Ingredient/A	ctive Moie	ty						
UNIER4K00DY52L) GLUCONATE GLUCONATE GLUCONATOLE (UNIE R9400W927I) (KETOCONAZOLE - UNIER9400W927I) (KETOCONAZOLE - UNIER9400W927I) (KETOCONAZOLE - UNIER9400W927I) (KETOCONAZOLE - UNIER9400W927I) (SALICYLOYL SALICYLOYL SALICYL SALICY		Ing	redient Name			Basis of	Strength	Strengt	
KETOCONAZOLE (UNIE: N3400 W92/1) (KETOCONAZOLE - UNIER9400 W92/1) KETOCONAZOLE in 1 ml. SALICYLOYL PHYTOSPHINGOSINE (UNIE: UB91J4JCNH) (SALICYLOYL SALICYLOYL 0.5 mg PHYTOSPHINGOSINE - UNIE: UB91J4JCNH) SALICYLOYL SALICYLOYL 0.5 mg Inactive Ingredients Ingredient Name Strength Inactive Ingredients Strength Intell Intell Information Intell Information Marketing Start Date Marketing End Date		ONATE (UNII:	MOR84MUD8E) (CHLORHE	XIDINE -				0	
PHYTOSPHINGOSINE - UNIE U89 1J 4J CNH) PHYTOSPHINGOSINE - UNIE U89 1J 4J CNH) PHYTOSPHINGOSINE - UNIE UNIE UNIE UNIE UNIE UNIE UNIE UNIE	KETOCONAZOLE (UNII:	R9400W927I) (KETOCONAZOLE - UNII:F	9400W927	7I)	KETOCONAZ	ZOLE	0	
Ingredient Name Strength W JERE GLYCOL (UNII: 6DC9Q167V3) GLYCERIN (UNII: 7DC6 A3C00X) LACTIC ACID (UNII: 33X04XA5AT) POLYSORBATE 20 (UNII: 7T1F30V5YH) METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) Prove the state of the stat								-	
Ingredient Name Strength W JERE GLYCOL (UNII: 6DC9Q167V3) GLYCERIN (UNII: 7DC6 A3C00X) LACTIC ACID (UNII: 33X04XA5AT) POLYSORBATE 20 (UNII: 7T1F30V5YH) METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) Prove the state of the stat									
wATER (UNII: 059QF0K00R) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) GLYCERIN (UNII: PDC6A3C00X) LACTIC ACID (UNII: 33X04XA5AT) POLYSORBATE 20 (UNII: 711F30V5YH) METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) Packaging # Item Code Package Description Marketing Start Date Marketing Information Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing Start Date Marketing End Date	Inactive Ingredients	5							
PyLene GLYCOL (UNII: 6DC9Q167V3) GLYCERIN (UNII: PDC6A3C00X) LACTIC ACID (UNII: 33X04XA5AT) POLYSORBATE 20 (UNII: 71F30V5YH) METHYLISOTHIAZOLINOE (UNII: 229D0E1QFA) Packaging I tem Code Package Description Marketing Start Date Marketing End Date 1 NDC:46066-155-14 200 mL in 1 BOTTLE, PLASTIC Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	Ingredient Name							Strength	
GLYCERIN (UNII: PDC6A3C00X) LACTIC ACID (UNII: 33X04XA5AT) POLYSORBATE 20 (UNII: 711F30V5YH) METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) Packaging I tem Code Package Description Marketing Start Date Marketing End Date Marketing Enformation Number or Monograph Citation Marketing Start Date Marketing End Date Marketing End Date	WATER (UNII: 059QF0KC	00R)							
IACTIC ACID (UNII: 33X04XA5AT) I I I I I I I BOTTLE, PLASTIC	PROPYLENE GLYCOL (UNII: 6DC9Q1	67V3)						
POLYSORBATE 20 (UNII: 7T1F30 V5YH) METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA) Packaging # Item Code Package Description Marketing Start Date Marketing End Date NDC:46066-155-14 200 mL in 1 BOTTLE, PLASTIC Marketing Information Marketing Start Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing Start Date Marketing End Date	GLYCERIN (UNII: PDC6A	3C0OX)							
METHYLISOTHIAZOLINONE (UNII: 229 D0E1QFA) F Karketing Code Package Description Marketing Start Date Marketing End Date NDC:46066-155-14 200 mL in 1 BOTTLE, PLASTIC Varketing Information Marketing Start Date Marketing Start Date Marketing End Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing Start Date Marketing End Date	LACTIC ACID (UNII: 33X))4XA5AT)							
Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:46066-155-14 200 mL in 1 BOTTLE, PLASTIC Image: Comparison of the start of the	POLYSORBATE 20 (UNI	I: 7T1F30V5YH	I)						
Item Code Package Description Marketing Start Date Marketing End Date NDC:46066-155-14 200 mL in 1 BOTTLE, PLASTIC Image: Constant Co	METHYLISOTHIAZOLIN	NONE (UNII: 22	29 D0 E1QFA)						
Item Code Package Description Marketing Start Date Marketing End Date NDC:46066-155-14 200 mL in 1 BOTTLE, PLASTIC Image: Constant Co									
1 NDC:46066-155-14 200 mL in 1 BOTTLE, PLASTIC Marketing Information Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	Packaging								
Marketing Information Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	# Item Code	Pac	kage Description	Marke	ting Start	Date	Marketing End Date		
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	1 NDC:46066-155-14	200 mL in 1	BOTTLE, PLASTIC						
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date									
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date									
	Marketing Infor	mation							
unapproved drug other 10/11/2019	Marketing Category	Application	n Number or Monograph	Citation	Marketin	g Start Date	Marketin	Marketing End Date	
	unapproved drug other				10/11/2019				

Labeler - Aspen Veterinary Resource, LTD. (627265361)

Registrant - Ceva Sante Animale (261126049)

Revised: 10/2019

Aspen Veterinary Resource, LTD.