

**KVG GROUP, INC. FXP CRACKED HEEL FORMULA- dimethicone spray**  
**Prime Packaging Inc.**

*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.*

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**FXP Cracked Heel Formula**

***Active Ingredients***

Dimethicone 1%

***Purpose***

Skin protectant

***Footlogix™***

**Cracked Heel Formula:** Moisturizes and protects extremely callused, cracked skin

- Natural skin functions remain unhindered
- Is absorbed immediately without any greasy residue
- Clothing can be worn immediately after application
- Free of perfumes
- Dermatologist tested

***Warnings***

**For external use only**

- Avoid spraying into the eyes

**Do not use** on deep wounds, animal bites or serious burns

***Caution:***

Contents are under pressure

- Protect from direct sunlight and do not store at temperatures above 120°F / 50°C
- After use, do not puncture or incinerate container
- Spray only in a well ventilated area
- Do not spray in the presence of an open flame, spark or while smoking

**Stop use and ask a doctor if:** Condition worsens

- symptoms last more than 7 days or clear up and re-occur within a few days

***If pregnant or breast-feeding,*** ask a health professional before use.

**Keep out of reach of children.** In case of accidental ingestion, contact a doctor or Poison Control Center immediately.

***Directions:***

Clean the affected area and dry thoroughly

- Hold can upright
- Shake can well before each use

- Use sparingly twice daily for the first two weeks and continue once daily until the problem is corrected
- When used as directed, this can contains enough mousse for approximately two months supply
- Supervise children in the use of this product

**Inactive Ingredients**

Aloe Barbadosis Leaf Juice, Butane, Cetearyl Ethylhexanoate, Disodium EDTA, Glycerin, Stearic Acid, Methylparaben, Oenothera Biennis Oil, Phenoxyethanol, Polysorbate 20, Propane, Propylene Glycol, Propylparaben, PVP, Tocopheryl Acetate, Triethanolamine, Ubiquinone, Urea, Water.

**FXP Cracked Heel Formula**



**Drug Facts**

<b>Active Ingredient</b>	<b>Purpose</b>
Dimethicone 1%	Skin protectant

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Distributed by: KVG Group Inc. P.O. Box 35A, Etobicoke, Ontario, Canada, M9C 4V2  
 Questions: 1-888-442-4403 - www.footlogix.com - Footlogix™ is a trademark of KVG Group, Inc.

Made in the U.S.A.



Safety sealed for your protection. Do not use if seal is broken or missing. LOT N° & EXP DATE: See bottom

**KVG GROUP, INC. FXP CRACKED HEEL FORMULA**

dimethicone spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0114
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10.2 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TROLAMINE (UNII: 9O3K93S3TK)	
UREA (UNII: 8W8T17847W)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
UBIDECARENONE (UNII: EJ27X76M46)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

**Product Characteristics**

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0114-3	125 mL in 1 CAN; Type 0: Not a Combination Product	05/21/2014	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/21/2014	

**Registrant** - Prime Packaging Inc. (805987059)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Prime Enterprises Inc		101946028	analysis(13630-0114) , manufacture(13630-0114)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Prime Packaging Inc.		805987059	pack(13630-0114) , label(13630-0114)

Revised: 1/2020

Prime Packaging Inc.