SCARTRATE CREAM- dimethicone, allantoin cream
Puretek Corporation

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.

Scartrate Cream

Description:

Scartrate™ Cream contains 50 mg of Dimethicone and 22.5 mg of Alantoin per gram in a vehicle consisting of Aleurites Moluccana (Kukui) Seed Oil, Aloe Barbadensis Leaf (Aloe Vera) Juice, Aqua (Purified Water), Butylene Glycol, Carthamus Tinctorius (Safflower) Oil, Cetyl Alcohol, Dimethicone Crosspolymer, Disodium EDTA, DL-alpha Tocopheryl Acetate, GenRx® Complex (proprietary blend), Glycerin, Glyceryl Stearate, PEG-100 Stearate, Phenoxyethanol, sh-Polypeptide-121, Sodium Hydroxide, Stearic Acid, and Fragrance.

Indications and Usage:

Scartrate™ Cream is indicated for temporary protection and relief of chapped or cracked skin, it also effectively reduces the overall appearance of scars.

Dosage and Administration:

After cleansing, apply **Scartrate™ Cream** evenly to the affected area until it blends into the skin. Do not rinse off. Recommended for use in the morning (AM) and evening (PM). Reapply as needed to maintain skin protection and moisture.

Contraindications:

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

Warnings and Precautions:

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

For external use only. Avoid contact with eyes. If the condition worsens, stop use and consult a licensed healthcare practitioner.

Adverse Reactions:

No adverse reactions have been reported under normal conditions of use. If you experience any unusual reactions, discontinue use and consult your licensed healthcare practitioner.

Use in Specific Populations:

Not specifically tested for use in pregnant or nursing women, children, or the elderly. Use caution and consult a licensed healthcare practitioner if you belong to one of these populations.

How Supplied:

Scartrate™ Cream is supplied in a 3 oz (85 g) tube (NDC 59088-326-07) with CRC Cap.

Store at 20º-25ºC (68º-77ºF) [see USP Controlled Room Temperature]. Keep container tightly closed.

Use under the direction of a licensed healthcare practitioner. Call your doctor about side effects. To report side effects, call **PureTek Corporation** at **1-877-921-7873.**

Manufactured by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: **877-921-7873**

SCARTRATE CREAM

dimethicone, allantoin cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-326
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	22.5 mg in 1 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MARINE COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-326-07	85 g in 1 TUBE; Type 0: Not a Combination Product	07/18/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/18/2024	

Labeler - Puretek Corporation (785961046)

Revised: 7/2024 Puretek Corporation