

UV MILD SUN BLOCK- octinoxate cream
Coson Co., Ltd.

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.

ACTIVE INGREDIENT

Active Ingredients: ETHYLHEXYL METHOXYCINNAMATE 7.5%

INACTIVE INGREDIENT

Inactive Ingredients:

WATER, GLYCERIN, BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE, DICAPRYLYL CARBONATE, ISOAMYL p-METHOXYCINNAMATE, GLYCERYL STEARATE, PEG-100 STEARATE, CETEARYL ALCOHOL, POLYSORBATE 60, CYCLOMETHICONE, TITANIUM DIOXIDE, SILICA, ALUMINA, STEARIC ACID, POLYACRYLAMIDE, C13-14 ISOPARAFFIN, LAURETH-7, SORBITAN SESQUIOLEATE, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, TOCOPHERYL ACETATE, BETA GLUCAN, PORTULACA OLERACEA EXTRACT, ARNICA MONTANA FLOWER EXTRACT, ARTEMISIA ABSINTHIUM EXTRACT, ACHILLEA MILLEFOLIUM EXTRACT, GENTIANA LUTEA ROOT EXTRACT, RUBUS IDAEUS (RASPBERRY) FRUIT EXTRACT, DISODIUM EDTA, PHENOXYETHANOL, METHYL PARABEN, PROPYL PARABEN, FRAGRANCE

PURPOSE

Purpose: UVA/UVB Protection

WARNINGS

Warnings:

1. If following symptoms occur, stop use and consult a doctor: red spots, swelling, itching, irritation, or symptoms on applied skin under direct sunlight.
2. Do not use on scarred skin, or if you have dermatitis or eczema
3. Keep the cap close on its product.
4. Keep away from direct sunlight or heat.
5. This product blocks UVA rays and ultraviolet protection effectiveness have been measured by the Food and Drug Administration methods and standards.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children:

Keep out of reach of babies and children

INDICATIONS AND USAGE

Indication and Usage:

At your final skin care step, apply it to your whole face with the proper amount after all your basic skin care.

If you feel more perfect UV protect effect, apply it more whenever needed.

DOSAGE AND ADMINISTRATION

Dosage and Administration:

Release an appropriate amount and evenly spread over face and body with gentle patting.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



UV MILD SUN BLOCK

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62171-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62171-020-01	50 mL in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2014	

Labeler - Coson Co., Ltd. (689835593)

Registrant - Coson Co., Ltd. (689835593)

Establishment

Name	Address	ID/FEI	Business Operations
Coson Co., Ltd.		689835593	manufacture(62171-020)

Revised: 4/2014

Coson Co., Ltd.