

ELAVE AGE DELAY DAILY LIP DEFENCE SPF20- octinoxate, zinc oxide ointment
Ovelle 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.

DRUG FACTS

ACTIVE INGREDIENTS	PURPOSE
Octinoxate 7.5%w/w	Sunscreen
Zinc Oxide 4.0%w/w	Sunscreen

USES

- helps protect against sunburn
- for lips that sunburn easily
- helps provide protection against UVA and UVB rays

WARNINGS

For external use only

Do not use on

- broken skin
- serious burns

When using this product

- keep out of the eyes. Rinse with water to remove
- not suitable for ingestion

Stop use and ask a doctor if

- rash or irritation develops and lasts

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away

DIRECTIONS

- apply to lips 15 - 20 minutes before sun exposure
- re-apply as needed, especially after prolonged sun exposure, drinking or eating

OTHER INFORMATION

- store below 25C, do not freeze
- not recommended for children under 6 months of age

INACTIVE INGREDIENTS

Ricinus Communis (Castor) Seed Oil, Hydrogenated Castor Oil, Cera Alba (Beeswax), Oryza Sativa (Rice) Bran Wax, Butyrospermum Parkii (Shea Butter), Stearyl Dimethicone, Copernicia Cerifera (Carnauba) Wax, Dipalmitoyl Hydroxyproline, Phenyl Trimethicone, Bixa Orellana Seed Oil, Mentha

Piperita (Peppermint Oil), Tocopheryl Acetate, Aloe Barbadensis Leaf Extract, Cocos Nucifera (Coconut) Oil, BHT, Triethoxycaprylylsilane

QUESTIONS OR COMMENTS

Distributor: Ashette LLC, 27-28 Thomson Ave, Long Island City NY11101

www.ashette.com

Manufacturer: Ovelle Pharmaceuticals, Coes Road, Dundalk, Co Louth, Ireland

age delay daily lip defence

SPF20

Sensitive Formula

Broad-Spectrum UVA/UVB Protection

Preservative Free

Anti-oxidant Vitamin E

Soothing Aloe Vera Leaf Extract

Triple Firming Natural Lipoamino Acid

Refreshing Peppermint Oil

FREE FROM

Parabens, Alcohol, Sulfates, SLES/SLS, Formaldehyde, Dyes, Colours, Phthalates, Lanolin, Fragrance



age delay
daily lip
defence

SPF20

broad spectrum
UVA/UVB protection



15ml 0.507fl oz e

Dermatologically Tested

DIRECTIONS FOR USE:

Using the angled tube applicator, squeeze tube and apply daily directly to lips 15-30 minutes before sun exposure. Reapply as needed, especially after prolonged sun exposure, drinking or eating.

ACTIVE INGREDIENTS:

Octinoxate: 7.5%w/w
Zinc Oxide: 4.0%w/w

NON ACTIVE INGREDIENTS:

Ricinus Communis (Castor) Seed Oil, Hydrogenated Castor Oil, Cera Alba (Beeswax), Oryza Sativa (Rice) Bran Wax, Butyrospermum Parkii (Shea Butter), Stearyl Dimethicone, Copernicia Cerifera (Carnauba) Wax, Dipalmitoyl Hydroxyproline, Phenyl Trimethicone, Bixa Orellana Seed Oil, Mentha Piperita (Peppermint) Oil, Tocopheryl Acetate, Aloe Barbadensis Leaf Extract, Cocos Nucifera (Coconut) Oil, BHT, Triethoxycaprylsilane.

WARNINGS:

Stop and ask a doctor if a rash or irritation develops or lasts. Not suitable for ingestion. Avoid contact with the eyes. If contact occurs rinse with copious amounts of water. Keep out of childrens reach. Store below 25°C. The elave ranges are not tested on animals.

FOR EXTERNAL USE ONLY



Ovelle Pharmaceuticals
Coes Road, Dundalk, Ireland.



7229 Rev000

MADE IN IRELAND



ELAVE AGE DELAY DAILY LIP DEFENCE SPF20

octinoxate, zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46006-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	1.125 mL in 15 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.6 mL in 15 mL

Inactive Ingredients

Ingredient Name	Strength
Castor Oil (UNII: D5340Y2I9G)	
Hydrogenated Castor Oil (UNII: ZF94AP8MEY)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Rice Bran (UNII: R60QEP13IC)	
Shea Butter (UNII: K49155WL9Y)	
Dimethicone (UNII: 92RU3N3Y1O)	
Carnauba Wax (UNII: R12CBM0EIZ)	
Dipalmitoyl Hydroxyproline (UNII: E6AHA53N1H)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Bixa Orellana Seed Oil (UNII: 3R3HS2KR6P)	
Peppermint Oil (UNII: AV092KU4JH)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Coconut Oil (UNII: Q9L0O73W7L)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46006-002-01	15 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/20/2011	

Labeler - Ovelle Ltd (219542784)

Registrant - Ovelle Ltd (219542784)

Establishment

Name	Address	ID/FEI	Business Operations
Ovelle Ltd		219542784	manufacture

Revised: 12/2011

Ovelle Ltd