

PYRATINE XR CREME WITH SUNSCREEN BROAD SPECTRUM SPF30- zinc oxide cream
Allure Labs 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.

Drug Facts

Active Ingredient: Zinc oxide - 18.6%

Purpose: Sunscreen

Uses:

- Help prevent sunburn. Higher SPF gives more sunburn protection. Provide high protection against sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings: For external use only. Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

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:

- For sunscreen use. Apply generously 15 minutes before sun exposure. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating.
- Sun protection measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other protection measures including: limit time in the sun, especially from 10 am - 2 pm. Wear long-sleeved shirts, pants, hats, and sunglasses. Children under 6 months of age: Ask a doctor.

protect this product from excessive heat and direct sun.

Call toll free 1-888-467-9728

Store at controlled room temperature 59 F - 89 F (15 C - 30 C).

Inactive Ingredients: Water (Aqua), Cyclopentasiloxane, Butylene glycol, glycerin, Propylene Glycol, Caprylic/Capric triglyceride, Glycerin Stearate, PEG-100 Stearate, Polyglyceryl-3 Polymethylsiloxeethyl Dimethicon, Cyclohexasiloxane, Sorbitan Stearate, Dimethicone, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene glycol, Imperata Cylindrica Root Extract, PEG-8, Carbomer, triethoxysilylethyl Polydimethylsiloxeethyl Hexyl Dimethicone, Cetyl Alcohol, Lecithin, Tocopherol, Ascorbyl Palmitate, Ascorbic Acid, Citric Acid, Xanthan gum, Furfuryl Tetrahydropyraniladine, tocopherol Linoleate/Oleate, Teprenone, Phoenix Dactylifera (Date) Fruit Extract, Sodium Lactate, Disodium EDTA, Dipotassium Glycyrrhizate, Arabidopsis Thaliana Extract, Plankton Extract and Micrococcus Lysate.

Developed, Distributed and Marketed by:

Pyratine LLC

2950 Main Street

Morro Bay, CA 93442

1-888-467-9728

<p>Drug Facts</p>	<p>Drug Facts (continued)</p>	<p>CRÈME with Sunscreen</p>	<p>Pyratine^{XR}</p>
<p>Active Ingredients Zinc Oxide 18.6% Purpose Sunscreen</p>	<p>Other information • protect this product from excessive heat and direct sun</p>	<p>BROAD SPECTRUM SPF 30</p>	<p>A physical sunscreen containing Zinc Oxide which absorbs quickly without leaving a white residue on the skin. Broad spectrum coverage protects the skin from harmful UVA and UVB rays while antioxidants provide the skin with further protection. The soothing and healing benefits of Zinc Oxide makes this sunscreen an excellent choice for sensitive skin types and for use during a professional treatment series.</p>
<p>Uses • helps prevent sunburn (higher SPF gives more sunburn protection) • provides high protection against sunburn • if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun</p>	<p>Inactive Ingredients Water (Aqua), Cyclopentasiloxane, Butylene Glycol, Glycerin, Propylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Cyclohexasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Sorbitan Stearate, Dimethicone, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Imperata Cylindrica Root Extract, PEG-8, Carbomer, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Cetyl Alcohol, Lecithin, Tocopherol, Ascorbyl Palmitate, Ascorbic Acid, Citric Acid, Xanthan Gum, Furfuryl Tetrahydropryaniladenine, Tocopheryl Linoleate/Oleate, Taprenone, Caprylo/Capric Triglyceride, Phoenix Dactylopera (Date) Fruit Extract, Sodium Lactate, Disodium EDTA, Dipotassium Glycyrrhizate, Arabidopsis Thaliana Extract, Plankton Extract, and Micrococcus Lysate</p>	<p>Pyratine^{XR}</p>	<p>PRODUCT FEATURES:</p> <ul style="list-style-type: none"> • Broad Spectrum UVA and UVB protection • Soothes and heals the skin • Reduces redness • Powerful antioxidant, scavenges free radicals • Physical sunscreen • Absorbs quickly without leaving a white residue • Application is smooth and silky on the skin • Safe for post-professional treatment and children
<p>Warnings • For external use only • Do not use on damaged or broken skin • When using this product keep out of eyes. Rinse with water to remove. • 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.</p>	<p>Questions or comments? Call toll free 1-888-467-9728</p>	<p>2 OZ (56.7 GM) ☺</p>	
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zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4145
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	186 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CARBOMER 1342 (UNII: 809Y72KV36)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYESTER-7 (UNII: 0841698D2F)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
.ALPHA.-TOCOPHEROL LINOLEATE, D- (UNII: G0N132Q0ED)	
TEPRENONE (UNII: S8S8451A4O)	
DATE (UNII: H3O7QI5HY7)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	

EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
ARABIDOPSIS THALIANA (UNII: AI3L60HQ81)	
MICROCOCCUS LUTEUS (UNII: LV6L29Z6AX)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4145-2	1 in 1 CARTON	12/07/2017	
1	NDC:62742-4145-1	56.7 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/07/2017	

Labeler - Allure Labs Inc (926831603)

Registrant - Allure Labs Inc (926831603)

Establishment			
Name	Address	ID/FEI	Business Operations
Allure Labs Inc		926831603	manufacture(62742-4145)