

**GLYTONE HYDRA LIPID UV MINERAL SUNSCREEN SPF 40 PLUS- zinc oxide, titanium dioxide lotion**  
**Pierre Fabre USA Inc.**

-----  
**Glytone Hydra Lipid UV Mineral Sunscreen SPF 40 PLUS**

***Drug Facts***

***Purpose***

Sunscreen

***Active ingredients***

Titanium Dioxide 2%

Zinc Oxide 1%

***Uses***

- Helps prevent 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 eyes with water to remove.**

**Stop use and ask a doctor if rash occurs**

**Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.**

***Directions***

- Apply liberally 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 of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.

- wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

**Other information**

- Protect this product from excessive heat and direct sun.

**Inactive ingredients**

Water, Butyloctyl Salicylate, Octyldodecyl Neopentanoate, Ethylhexyl Isononanoate, Polyester-7, Glycerin, Neopentyl Glycol, Diheptanoate, Cetyl Alcohol, Glyceryl Stearate, Squalane, Phenoxyethanol, PEG-75 Stearate, Bisabolol, Hydrolyzed Sodium Hyaluronate, Pyrus Malus (Apple) Fruit Extract, C12-15 Alkyl Benzoate, Lysolecithin, Sclerotium Gum, Dimethiconol/Octylsilsesquioxane/Silicate Crosspolymer, Allantoin, Ceteth-20, Steareth-20, Caprylyl Glycol, Triceteareth-4 Phosphate. Pullulan. Xanthan Gum, Sodium Hyaluronate, Dimethiconol/Propylsilsesquioxane/Silicate Crosspolymer Disodium EDTA, Ethylhexylglycerin, Hexylene Glycol, Dicrateria Rotunda Oil, Ruttnera Lamellosa Oil, Lecithin, Silica, Camellia Sinensis Leaf Extract, Avena Sativa (Oat) Kernel Extract, Sodium Ascorbate, Potassium Sorbate, Tocopherol.

**Questions or comments?**

visit [www.glytone.com](http://www.glytone.com) or call toll-free 800-GLYTONE (459-8663)

**Indications**

Apply generously 15 minutes before sun exposure  
etc

**Keep out of reach of children.**

If swallowed, call a Poison Control Center right away.

**Do not use**

On broken skin

**Principal Display Panel - 50 mL Carton**

GLYTONE

Hyda Lipid UV

Mineral Sunscreen

Broad spectrum SPF 40+

Sun Protection

Hyaluronic Acid  
 Squalane  
 Titanium Dioxide  
 Zinc Oxide  
 FRAGRANCE-FREE  
 50 mL / 1.7 FL. OZ.

Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Titanium Dioxide 2% _____ Sunscreen Zinc Oxide 1% _____ Sunscreen	
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• Helps prevent sunburn.</li> <li>• If used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and early skin aging caused by the sun.</li> </ul>	
<b>Warnings</b>	
<b>For external use only.</b>	
<b>Do not use</b> on damaged or broken skin.	
<b>When using this product</b> keep out of eyes. Rinse with water to remove.	
<b>Stop use and ask a doctor</b> if rash occurs.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Apply liberally 15 minutes before sun exposure</li> <li>• Reapply at least every 2 hours</li> <li>• Use a water resistant sunscreen if swimming or sweating</li> <li>• <b>Sun Protection Measures.</b> Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures including:               <ul style="list-style-type: none"> <li>• limiting time in the sun, especially from 10 a.m.-2 p.m.</li> <li>• wearing long-sleeved shirts, pants, hats and sunglasses</li> <li>• Children under 6 months of age: ask a doctor.</li> </ul> </li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• Protect the product in this container from excessive heat and direct sunlight.</li> </ul>	

Drug Facts (Continued)
<b>Inactive Ingredients</b>
WATER, BUTYLOCTYL SALICYLATE, OCTYLDODECYL NEOPENTANOATE, ETHYLHEXYL ISONONANOATE, POLYESTER-7, GLYCERIN, NEOPENTYL GLYCOL DIHEPTANOATE, CETYL ALCOHOL, GLYCERYL STEARATE, SQUALANE, ALLANTOIN, AVENA SATIVA (OAT) KERNEL EXTRACT, BISABOLOL, C12-15 ALKYL BENZOATE, CAMELLIA SINENSIS LEAF EXTRACT, CAPRYLYL GLYCOL, CETETH-20, DICRATERIA ROTUNDA OIL, DIMETHICONOL/OCTYLSILSESQUOXANE/SILICATE CROSSPOLYMER, DIMETHICONOL/PROPYLSILSESQUOXANE/SILICATE CROSSPOLYMER, DISODIUM EDTA, ETHYLHEXYLGLYCERIN, HEXYLENE GLYCOL, HYDROLYZED SODIUM HYALURONATE, LECITHIN, LYSOLECITHIN, PEG-75 STEARATE, PHENOXYETHANOL, POTASSIUM SORBATE, PULLULAN, PYRUS MALUS (APPLE) FRUIT EXTRACT, RUTINERA LAMELLOSA OIL, SCLEROTLUM GUM, SILICA, SODIUM ASCORBATE, SODIUM HYALURONATE, STEARETH-20, TOCOPHEROL, TRICETEARETH-4 PHOSPHATE, TRIAURETH-4 PHOSPHATE, XANTHAN GUM.
<b>Questions?</b>
1-800-GLYTONE (459-8663). You may also report adverse events to this number.

GLYTONE

**Hydra Lipid UV Mineral Sunscreen Broad Spectrum SPF 40+** features mineral UVA/UVB filters and an **Active Stress Defense™ Technology** to protect and defend skin from oxidative stress by boosting antioxidant protection by up to 200%<sup>(1)</sup> and reducing pollution-induced free radicals.

Formulated with **Hyaluronic Acid** and plant-derived **Squalane** to boost skin's moisture content and reduce appearance of fine lines and wrinkles, this lightweight mineral sunscreen leaves skin feeling smooth and moisturized. Ideal for daily use on all skin types.

100% mineral UV filter sunscreen, Paraben-free, Fragrance-free, Cruelty-free.

**Hydra Lípido UV Protección Solar Mineral de Amplio Espectro 40+** presenta filtros minerales UVA/UVB y una **Tecnología Activa de Defensa al Estrés™** para proteger y defender la piel del estrés oxidativo incrementando la protección antioxidante hasta el 200%<sup>(1)</sup> y reduciendo radicales libres inducidos por la contaminación.

Formulada con **Ácido Hialurónico** y **Escualano** de origen vegetal para aumentar el contenido de humedad de la piel y reducir la apariencia de las líneas finas y arrugas, este protector solar mineral de textura ligera deja la piel alisada e hidratada. Ideal para el uso diario de todo tipo de piel.

Hydra Lipid UV  
 Mineral Sunscreen  
 Broad Spectrum SPF 40+

**SUN PROTECTION**

Hyaluronic Acid  
 Squalane  
 Titanium Dioxide  
 Zinc Oxide

FRAGRANCE-FREE

50 mL / 1.7 FL. OZ.

Protector solar con filtros UV 100% minerales, sin parabenos, sin fragancia, libre de crueldad.

*Ácido Hialurónico  
 Escualano  
 Dióxido de Titanio  
 Óxido de Zinc*

(1) In-vitro measure of antioxidant activity after being exposed to 2MED of UV.

  
**Pierre Fabre**  
 Dermo-Cosmétique

Distributed by:  
**Pierre Fabre USA Inc.**  
 Parsippany, NJ 07054  
 800-GLYTONE (459-8663)  
 84351L www.glytone.com

zinc oxide, titanium dioxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64760-720
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 mg in 50 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1 mg in 50 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PEG-75 STEARATE</b> (UNII: OT38R0N74H)	
<b>.BETA.-BISABOLOL</b> (UNII: LP618AV2EA)	
<b>APPLE FRUIT OIL</b> (UNII: 9NT987I3A8)	
<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	
<b>CAMELLIA SINENSIS FLOWER</b> (UNII: 9I2BJY2J17)	
<b>OAT KERNEL OIL</b> (UNII: 3UVP41R77R)	
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>ALPHA-TOCOPHEROL, L-</b> (UNII: 82190DH9F2)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ETHYLHEXYL ISONONANOATE</b> (UNII: I6KB4GE3K4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>DICRATERIA ROTUNDA OIL</b> (UNII: Z0DWU9R4GM)	
<b>SODIUM ACETYLATED HYALURONATE</b> (UNII: VN66R7GL93)	
<b>DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW)</b> (UNII: 9KB5R958PB)	
<b>DITETRACYCLINE TETRASODIUM EDETATE</b> (UNII: WX0A0IT7K5)	
<b>TRILAURETH-4 PHOSPHATE</b> (UNII: M96W2OLL2V)	
<b>POLYESTER-7</b> (UNII: 0841698D2F)	
<b>C12-15 ALKYL ETHYLHEXANOATE</b> (UNII: GQJ580CH83)	
<b>LOCUST BEAN GUM</b> (UNII: V4716MY704)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>RUTTNERA LAMELLOSA OIL</b> (UNII: 5XZ38R4SUT)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-720-01	1 in 1 CARTON	07/02/2020	03/31/2026
1		50 mL 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 Drug	M020	07/02/2020	03/31/2026

**Labeler** - Pierre Fabre USA Inc. (117196928)**Registrant** - Pierre Fabre USA Inc. (117196928)

Revised: 4/2024

Pierre Fabre USA Inc.