

**SUNSCREEN POWDER- sunscreen powder powder**  
**Guangzhou Fantasy Biotechnology 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.*

-----  
**83447-001**

**Active ingredients**

Zinc Oxide 25%

**Purpose**

Sunscreen

**Uses**

Helps prevent sunburn

**Warnings**

For external use only.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

**Do not use**

Do not use on damaged or broken skin.

**When using this product**

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

**Stop use**

Stop use and ask a doctor if rash occurs.

**Keep out of**

Keep out of reach of children.

## Directions


Apply liberally to face at least 15 minutes before sun exposure.  
Use a water resistant sunscreen if swimming or sweating.  
Reapply at least every 2 hours.  
Children under 6 months of age: Ask a doctor

## Other information

Protect this product from excessive heat and direct sun.

## Inactive ingredients

Sericite, Mica, and Silica.

 <p>F ' T S Y</p> <p>Protection Powder SPF 50 Broad Spectrum Sunscreen</p> <p>0.12 OZ / 3.5G</p>	<p><b>Drug Facts:</b> <b>Active ingredients Purpose</b> Zinc Oxide 25% .... Sunscreen</p>	<p><b>Uses:</b> Helps prevent sunburn.</p> <p><b>Warnings:</b></p> <ul style="list-style-type: none"><li>• For external use only.</li><li>• Do not use on damaged or broken skin.</li><li>• Stop use and ask a doctor if rash occurs.</li><li>• When using this product, keep out of eyes. Rinse with water to remove.</li><li>• Keep out of reach of children.</li><li>• If swallowed, get medical help or contact a Poison Control Center immediately.</li></ul>	<p><b>Directions:</b></p> <ul style="list-style-type: none"><li>• Apply liberally to face at least 15 minutes before sun exposure.</li><li>• Use a water resistant sunscreen if swimming or sweating.</li><li>• Reapply at least every 2 hours.</li><li>• Children under 6 months of age: Ask a doctor.</li></ul> <p><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 a Broad Spectrum value of 15 or higher and other sun protection measures including:</p> <ul style="list-style-type: none"><li>• Limit time in the sun, especially from 10 A.M.-2 P.M.</li><li>• Wear long-sleeved shirts, pants, hats, and sunglasses.</li></ul>	<p><b>Inactive ingredients:</b> Sericite, Mica, and Silica.</p> <p><b>Other information:</b> Protect this product from excessive heat and direct sun.</p>
---	---	--	---	---

## SUNSCREEN POWDER

sunscreen powder powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83447-001
Route of Administration	CUTANEOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>PYROPHYLLITE</b> (UNII: 1U9X05245H)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83447-001-01	3.5 g in 1 BOX; Type 0: Not a Combination Product	05/05/2023	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/05/2023	

**Labeler** - Guangzhou Fantasy Biotechnology Co.,Ltd (619047084)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Guangzhou Fantasy Biotechnology Co.,Ltd		619047084	manufacture(83447-001)

Revised: 5/2023

Guangzhou Fantasy Biotechnology Co.,Ltd