

4 IN 1 PRESSED MINERAL SPF 15 PORCELAIN - titanium dioxide powder PUR MINERALS

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 : Titanium Dioxide 9 %

Purpose : Sunscreen

Discontinue use If rash or irritation develops and increases. If irritation persists, consult a health care practitioner or Contact a Poison Control Center right away.

Keep Out of Reach of Children .

Inactive Ingredients : Mica , Boron Nitride , Caprylic/Capric Triglyceride , Bismuth Oxychloride , Zinc Stearate , Magnesium Silicate , Magnesium Carbonate ,Sodium Starch Octenylsuccinate, Mannitol,

Sodium Gluconate , Citric Acid, Sodium Citrate , Waltheria Indica Leaf Extract , Dextrin , Ferulic Acid, L-Lactic Acid, Butyrospermum Parkii (Shea Butter) , Silica, Thioctic Acid,Sodium Hyarluronate, Retinol,

L-Ascorbic Acid, Ceramide 6 II , Magnolia Officinalis Bark Extract, Vitis Vinifera (Grape) Seed Extract , Tocopherol , Lecithin, Maltodextrin , Vitis Vinifera (Grape) Fruit Skin, Glycerin, Palmitoyl Tripeptide-5,

L-Glucothione, Aloe Barbadensis Leaf Extract, Hydrated Silica , Tocopheryl Acetate , Aqua, Glucosamine HCl, Pisum Sativum (Pea) Extract, Bambus Vulgaris Leaf/Stem Extract, Magnesium Carbonate ,

Iron oxide , May contain : Titanium Dioxide, Ultramarines.

For external use only. Please avoid contact inside eyes. Rinse with water to remove.

Drug Facts (continued)

Directions: Apply small amount evenly to dry skin prior to sun exposure. Children under 6 months of age consult a doctor.

Warnings: For external use only. Please avoid contact inside eyes. Rinse with water to remove. Discontinue use if skin irritation develops or increases. If irritation persists, consult a health care practitioner or contact a Poison Control Center right away. Keep out of reach of children.

Drug Facts/ Les Faits de drogue

**Medicinal Ingredient/Active Ingredient:
Ingrédient Médicinal/Ingrédient actif :**
Titanium Dioxide 17.0% w/w

Uses: Helps prevent sunburn.

Usages : Aide à prévenir les coups de soleil.

Other: In the unlikely event of an adverse reaction, please contact 1.866.PUR.0022.

Autres: Dans l'événement peu probable d'une réaction défavorable... veuillez contactez le 1.866.PUR.0022.

Les Faits de drogue

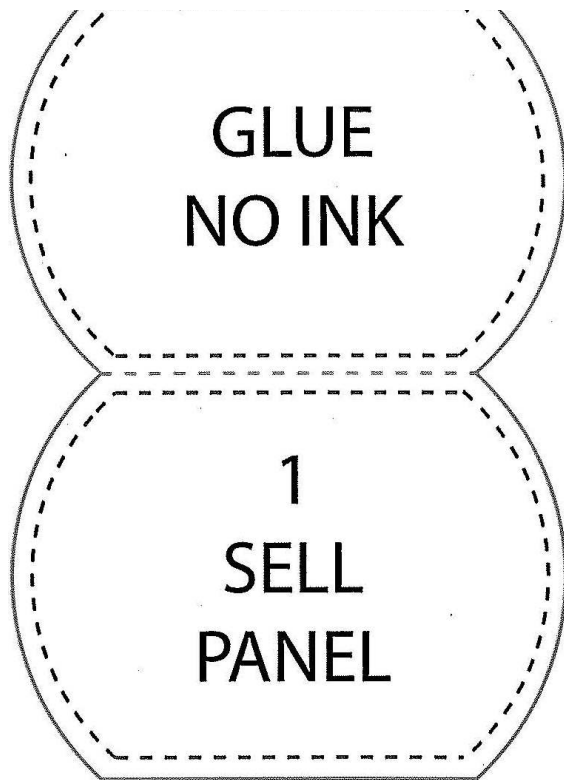
(continue)

Utilisation : Appliquer une petite quantité uniformément sur la peau sèche avant l'exposition au soleil. Les enfants de moins de 6 mois doivent consulter un médecin avant l'utilisation.

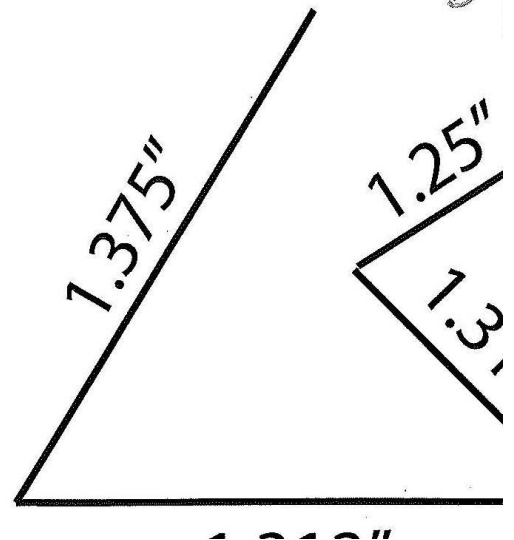
Avertissement : Pour usage externe seulement. Rincer avec de l'eau pour enlever. Éviter le contact avec les yeux. Cesser l'utilisation en cas d'irritation de la peau. Si l'irritation persiste, consulter un spécialiste de la santé ou contacter un centre anti-poison sur le champs. Garder hors de la portée des enfants.

Drug Facts (continued)/ Les Faits de drogue (continue)

**Non-Medicinal Ingredients/ Inactive
Ingredients/ Ingrédients Non-médicinaux/
ingrédient Inactifs :** Mica, Bismuth Oxychloride, Caprylic/Capric Triglyceride, Boron Nitride, Zinc Stearate, Magnesium Silicate, Sodium Starch Octenylsuccinate, Mannitol, Sodium Gluconate, Citric Acid, Sodium Citrate, Waltheria Indica Leaf Extract, Dextrin, Ferulic Acid, L-Lactic Acid, Butyrospermum Parkii (Shea Butter), Silica, Thioctic Acid, Sodium Hyaluronate, Retinol, L-Ascorbic Acid, Ceramide 6 II, Magnolia Officinalis Bark Extract, Vitis Vinifera (Grape) Seed Extract.



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TABS



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4 IN 1 PRESSED MINERAL SPF 15 PORCELAIN			
titanium dioxide powder			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67345-0780
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.72 g in 8 g

Inactive Ingredients

Ingredient Name	Strength
Mica (UNII: V8A1AW0880)	
Boron Nitride (UNII: 2U4T60A6YD)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Bismuth Oxochloride (UNII: 4ZR792I587)	
Zinc Stearate (UNII: H92E6QA4FV)	
Magnesium Silicate (UNII: 9B9691B2N9)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
Shea Butter (UNII: K49155WL9Y)	
Acetate Ion (UNII: 569DQM74SC)	
Iron (UNII: E1UOL152H7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67345-0780-0	8 g in 1 CASE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/15/2011	

Labeler - PUR MINERALS (780516402)