

**FACE GUARD 15- titanium dioxide cream**  
**Janssen Cosmetics GmbH**

*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.*

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**Titanium Dioxide**

**Active Ingredients**

Active Ingredients: Titanium Dioxide 4.2% Purpose: Sunscreen

**Inactive Ingredients**

Aqua [water], C12-15 alkyl benzoate, dicaprylyl carbonate, butylenes glycol, methylene BIS-benzotriazolyl tetramethylbutylphenol, BIS-ethylhexyloxyphenol methoxyphenyl triazine, cetearyl alcohol, steareth-21, dimethicone, ectoin, trimethylsiloxysilicate, tetra [trimethylsiloxy] silane, glyceryl stearate, ascorbyl palmitate, tocopherol, propylene glycol, xanthan gum, polyhydroxystearic acid, aluminum stearate, alumina, decyl glucoside, lecithin, disodium EDTA, citric acid, ethylhexylglycerin, phenoxyethanol, methylparaben, ethylparaben, propylparaben, butylparaben, isobutylparaben

**Ask Doctor Section**

Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor

**Warnings**

For external use only. Not to be swallowed. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water

Keep out of reach of children

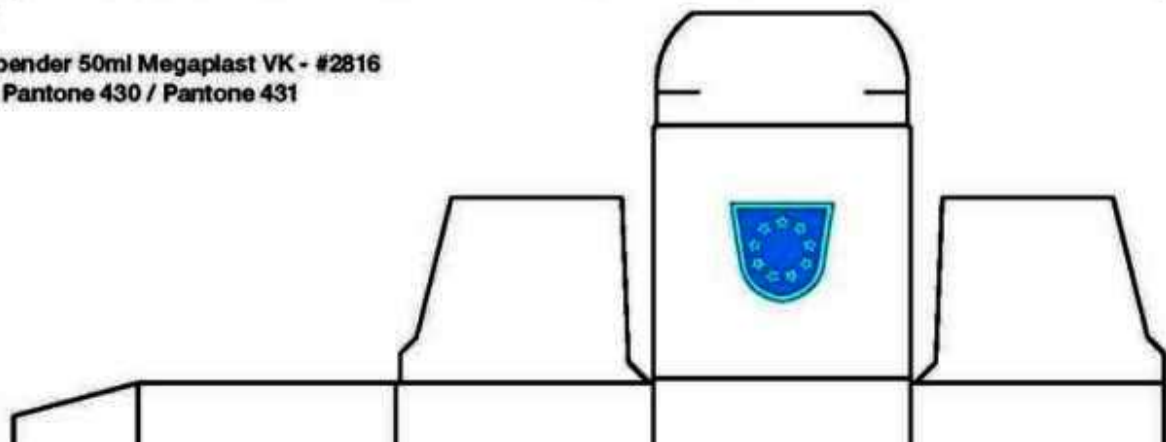
**Directions**

Simply apply onto the face, neck and neckline after cleansing in the morning and then apply the usual day cream on top

Children under six months of age: consult a doctor

**Front Panel of Box**

schachtel Spender 50ml Megaplast VK - #2816  
ck: 2-farbig; Pantone 430 / Pantone 431



538 mm



**Active Ingredients:** titanium dioxide 4,2 %

**Ingredients:** Aqua [water], CI2-15 alkyl benzoate, dicaprylyl carbonate, butylene glycol, methylene BIS-benzotriazolyl tetramethylbutylphenidol, BIS-ethylhexyloxyphenyl methoxyphenyl triazine, octyl-ethyl alcohol, steareth-21, dimethicone, ectoin, trimethylsilyloxy silane, glyceryl stearate, ascorbyl palmitate, tocopherol, propylene glycol, xanthan gum, polyhydroxystearic acid, aluminum stearate, alumina, decylglucoside, leothin, disodium EDTA, citric acid, ethylhexylglycerin, phenyl-ethanol, methylparaben, ethylparaben, propylparaben, butylparaben, isobutylparaben

**Warning:** For external use only. Not to be swallowed. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor. **Keep out of reach of children.**



**JANSSEN COSMETICS**

52005 Aachen • Germany  
www.janssen-cosmetics.com  
Made in Germany • Ref.: 2816

**UV protection concentrate, SPF 15, with photostable UVA and UVB filters.**

Ideal for all skin types and for combining with all day care products. With cell protection factor ectoin.

**Directions:** Simply apply onto the face, neck and neckline after cleansing in the morning and then apply the usual day cream on top. Children under six months of age: consult a doctor.

**Lichtschutzkonzentrat, SPF 15 mit photostabilen UVA- und UVB-Filtern.** Für jeden Hauttyp und mit jeder Tagespflege kombinierbar. Mit Zellschutzfaktor Ectoin. Auftragen und gewünschte Tagescreme darüber geben.

**Concentré protection UV, SPF 15 avec protection UVA et UVB photo stable.** Idéale pour chaque type de peau et à combiner avec chaque crème de jour. Contient un facteur de protection cellulaire à l'ectoine.

A appliquer sous votre crème de jour habituelle.

**Protezione UV SPF15 (concentrato) con filtri fotostabili UVA e UVB.** Ideale protezione aggiuntiva per tutti i tipi di pelle. Con fattore di protezione ectoina.

Applicare sul viso e quindi stendere la crema da giorno sopra.

ALL SKIN NEEDS  
OPTIONS TOUTE PEAU

**Concentrado con protección UV, FPS 15 con filtros UVA y UVB fotoestables.** Ideal para todo tipo de pieles y para combinar con cada crema de día. Con factor de protección celular ectoina. Distribuir y aplicar la crema de día correspondiente.

**Линей концентратная основа под дневной крем (SPF 15) со светостабилизированными UVA- и UVB-фильтрами.** Идеально подходит для всех типов кожи, сочетается со всеми средствами дневного ухода. Содержит защитный компонент эктоин.

**Emulsie met UV bescherming, SPF 15 met UV-bestendige UVA- en UVB-filters.** Ideale voor alle huidtypen en met alle dag-cremes te combineren. Bevat ectoine voor actieve celbescherming. Onder de gebruikelijke dag-creme aanbrengen.

**紫外线防护精华, SPF15不感光UVA、UVB防晒功能。** 适合所有类型的皮肤, 与日间护肤产品搭配使用。在面霜之前使用, 将会获益多倍。

Face Guard  
SPF 15  
Soin  
Protecteur

NET. 1.7 FL. OZ. 50ml e



## FACE GUARD 15

titanium dioxide cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:24653-8 16

Route of Administration

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.2 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BISOTRIZOLE (UNII: 8NT850T0YS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
STEARETH-21 (UNII: 53J3F32P58)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ECTOINE (UNII: 7GXZ3858RY)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
GLYCERETH-17 STEARATE (UNII: 02R46S8KUH)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
ALUMINUM OXIDE (UNII: LM26O6933)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
EDETIC ACID (UNII: 9G34HU7RV0)	
PROPYLENE (UNII: AUG1H506LY)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
BUTYL PARABEN (UNII: 3QP1U3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
ISOBUTYL PARABEN (UNII: 0QJ25X58G)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-816-02	1 in 1 BOX		
1	NDC:24653-816-01	50 mL in 1 BOTTLE, PUMP		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/02/2012	

**Labeler** - Janssen Cosmetics GmbH (499187946)

**Registrant** - Janssen Cosmetics GmbH (499187946)

**Establishment**

Name	Address	ID/FEI	Business Operations
Janssen Cosmetics GmbH		499187946	manufacture(24653-816)

Revised: 8/2012

Janssen Cosmetics GmbH