COVER FX SPF 30 BOOSTER DROPS BROAD SPECTRUM SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene oil Cover FX Skin Care 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.

COVER FX SPF 30 BOOSTER DROPS BROAD SPECTRUM SUNSCREEN

Active Ingredients

Active Ingredients:

Avobenzone 3.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 10.0%

Purpose: Sunscreen

Use

Helps prevent sunburn

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 occurs.

Keep out of the reach of children. If 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.

Children under 6 months of age, ask a doctor.

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 sun protection measures including:

- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses.

Other information

Protect the product in this container from excessive heat and direct sun

Store at 15 - 30 °C

Report serious adverse event to: 575 Fifth Ave 14th Floor, New York, NY10017

Inactive ingredients

Neopentyl Glycol Diheptanoate, Caprylic/Capric Triglyceride, Dimethicone, Butyloctyl Salicylate, Acrylates/Polytrimethylsiloxymethacrylate Copolymer, Acrylates/Dimethicone Copolymer, Cocos Nucifera (Coconut) Fruit Extract, Tocopheryl Acetate, Argania Spinosa Kernel Oil, Bisabolol, Salicornia Herbacea Extract.

Questions?

Call 866-424-3332 M-F 9:00am – 5:00pm EST

Company information

DIST BY COVER FX SKIN CARE INC.
TORONTO, ONTARIO CANADA M3J 2W8
MADE IN USA
WWW.COVERFX.COM

Product Packaging

COVER FX SPF 30 BOOSTER DROPS BROAD SPECTRUM SUNSCREEN 30 mL/1.0 FL OZ

Drug Facts/Information sur le médicament

Active Ingredients (w/w)/
Ingrédients actifs (p/p):
Avobenzone 3.0%, Homosalate 10.0%,
Octisalate 5.0%, Octocrylene 10.0%
Purpose/Utilité
Sunscreen/Ecran solaire

Use/Usage • Helps prevent sunburn/Aider à prévenir les coups de soleil

Warnings/Mise en garde For external use only. Pour usage externe seulement.

Do not use on damaged or broken skin / Ne pas utiliser sur une peau endommagée ou éraflée.

When using this product keep out of eyes. Rinse with water to remove. / Lors de l'utilisation de ce produit, évitez tout contact avec les yeux. Enlevez en rinçant à l'eau. Stop use and ask a doctor if rash occurs / En cas d'éruption cutanée, cessez l'utilisation et

consultez un médecin
Keep out of reach of children.
If swallowed, get medical help or
contact a poison control center right
away / Gardez hors de portée
des enfants. En cas d'ingestion,
consultez un médecin immédiatement
ou contactez un centre antiposison.

Directions/Mode d'emploi

 Apply liberally 15 minutes before sun exposure / Appliquez généreusement 15 minutes avant l'exposition au soleil • Reapply at least every 2 hours/ Réappliquez au moins toutes les 2 heures • Use a water resistant sunscreen if swimming or sweating / Portez un écran solaire aquarésistant si vous suez et lors de la baignade • Children under 6 months of age, ask a doctor / enfants âgés de moins de 6 mois : consultez un médecin

Sun Protection Measures/ Mesures de Protection Solaire

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 >

Drug Facts/Information sur le médicament

(continued/suite)

Broad Spectrum SPF value 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-sleeved shirts, pants, hats, and sunglasses / Mesures de protection contre le soleil. L'exposition au soleil augmente le risque de cancer de la peau et de vieillissement cutané prématuré. Afin de diminuer ce risque, appliquez régulièrement un écran solaire avec FPS à large spectre d'indice 15 ou plus, et suivez certaines mesures de protection contre le soleil telles que:
- limiter l'exposition au soleil, particulièrement entre 10h et 14h
- porter vêtements à manches longues, pantalons, chapeau et lunettes de soleil

Other information/ Autres renseignements

- Protect the product in this container from excessive heat and direct sun / Protégez le produit de la chaleur excessive et de l'ensoleillement direct au moyen de ce contenant
- Store at 15-30°C / Conserver entre 15 et 30°C
- Report serious adverse event to: 575 Frifth Ave 14th Floor, New York, NY 10017 / Signalez tout effet indésirable grave au: 575 Fifth Ave 14th Floor, New York, NY 10017

Inactive Ingredients/ Ingrédients inactifs :

Neopentyl Glycol Diheptanoate, Caprylic/Capric Triglyceride, Dimethicone, Butylochyl Salicylate, Acrylates/Polytrimethylsiloxymethacrylate Copolymer, Acrylates/Dimethicone Copolymer, Cocos Nucifera (Coconut) Fruit Extract, Tocopheryl Acetate, Argania Spinosa Kernel Oil, Bisabolol Salicomia Herbacea Extract

Questions?

Call / Composez le 866-424-3332 M-F 9:00am - 5:00pm EST

COVER FX

SPF 30 BOOSTER DROPS
BROAD SPECTRUM SUNSCREEN
FPS 30 GOUTTES
COUP DE POUCE
ÉCRAN SOLAIRE LARGE SPECTRE

30 mL/1.0 FL OZ @

PROTECT YOUR SKIN FROM UV RAYS WITH BROAD SPECTRUM SUNSCREEN SPF 30 BOOSTER DROPS. INFUSED WITH HYDRATING COCONUT FRUIT EXTRACT AND ANTIOXIDANTS, THESE CLEAR, WEIGHTLESS DROPS HELP DEFEND AGAINST SUN DAMAGE AND POLLUTION AND CAN BE ADDED TO YOUR FAVORITE LIQUID BEAUTY PRODUCTS FOR A BOOST OF SUN PROTECTION OR USED ALONE. NOTE: SPF VALUE MAY DECLINE IF USED MIXED WITH OTHER PRODUCTS.

PROTÉGEZ VOTRE PEAU DES RAYONS UV GRÂCE AUX GOUTTES COUP DE POUCE ÉCRAN SOLAIRE À LARGE SPECTRE AVEC FPS 30. INFUSÉES D'UN EXTRAIT HYDRATANT DE NOIX DE COCO ET D'ANTIOXYDANTS, CES GOUTTES LÉGÉRES ET TRANSPARENTES QUI AIDENT À PROTÉGER DES DOMMAGES CAUSÉS PAR LE SOLEIL ET LA POLLUTION, PEUVENT ÉTRE UTILISÉES SEULES OU AJOUTÉES À VOS PRODUITS DE BEAUTÉ LIQUIDES FAVORIS. À NOTER : LA VALEUR DU FPS POURRAIT DÉCROÎTRE LORS DE LA COMBINAISON À D'AUTRES PRODUITS.

CLINICALLY TESTED. VEGAN. FREE OF: PARABENS, GLUTEN, MINERAL OIL, FRAGRANCE, TALC, SULFATES, PHTHALATES.

PRODUIT TESTÉ EN CLINIQUE. VÉGANE. SANS : HUILE MINÉRALE, PARABÈNES, GLUTEN, PARFUM, TALC, SULFATES NI PHTALATES.

DIST. BY/PAR: COVER FX SKIN CARE INC. TORONTO, ONTARIO CANADA M3J 2W8 MADE IN USA/FAIT AUX É.-U. WWW.COVERFX.COM



COVER FX SPF 30 BOOSTER DROPS BROAD SPECTRUM SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene oil

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68327-074

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
SALICORNIA EUROPAEA (UNII: 6 ADL50 JAKW)			
ARGAN OIL (UNII: 4V59G5UW9X)			
LEVOMENOL (UNII: 24WE03BX2T)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
NEOPENTYL GLYCOL DIHEPTANO ATE (UNII: 5LKW3C543X)			
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)			
COCONUT (UNII: 3RT3536 DHY)			

1	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68327-074- 01	1 in 1 BOX	03/01/2019		
1		30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	0 3/0 1/20 19		

Labeler - Cover FX Skin Care Inc. (202908021)

Revised: 1/2019 Cover FX Skin Care Inc.