# LEADER DARK TANNING SPF 4- octinoxate and oxybenzone aerosol, spray Cardinal Health

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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# Leader Dark Tanning SPF 4 Continuous Spray Sunscreen 6 fl oz - Drug Facts Label

# **Active Ingredients**

Octinoxate 2.0%, Oxybenzone 0.5%

## Purpose

Sunscreen

#### Uses

• helps prevent sunburn

## Warnings

**Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

# **IFor external use only**

#### **FLAMMABLE**

- do not use near heat, flame or while smoking
- avoid long term storage above 104°F (40°C)

#### Do not use

on damaged or broken skin

#### When using this product

keep out of eyes. Rinse with water to remove. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120° F.

### 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

Hold can 4-6 inches away from body, spray evenly to ensure complete coverage

Do not spray into face. Spray into hand and apply to face.

Use in well ventilated, but not windy areas

Reapply:

After 80 minutes of swimming or sweating

Immediately after towel drying

At least every 2 hours

#### **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 am - 2 pm

wear long sleeve shirts, pants, hats, and sunglasses

Children under 6 months: ask a doctor

# **Inactive Ingredients**

Alcohol denat., C12-15 alkyl benzoate, aloe barbadensis leaf juice, retinyl palmitate (vitamin A), ascorbic acid (vitamin C), tocopheryl acetate (vitamin E), daucus carota sativa (carrot) root extract, acrylates/octylacrylamide copolymer, fragrance

#### **Questions or Comments?**

Call toll free 1-800-200-6313

Label



Label8.jpg

### LEADER DARK TANNING SPF 4

octinoxate, oxybenzone aerosol, spray

# Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:37205-722 Route of Administration Topical DEA Schedule

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (OCTINOXATE)	OCTINOXATE	16.6 mg in 1 mL

O XYBENZO NE (O XYBENZO NE)	OXYBENZONE	4.15 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL		
CARROT JUICE		
C12-15 ALKYL BENZO ATE		
ASCORBIC ACID		
VITAMIN A PALMITATE		
.ALPHATO COPHEROL ACETATE		
ALOE		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:37205-722-30	177 mL in 1 CAN		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/15/20 12	

# Labeler - Cardinal Health (097537435)

# **Registrant** - Fruit of the Earth (008193513)

Establishment			
Name	Address	ID/FEI	Business Operations
Fruit of the Earth		008193513	manufacture(37205-722)

Revised: 1/2013 Cardinal Health