

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 21-501

LABELING

MÉCANIQUE SOLAIRE
BLEU SOLAIRE 2718
GRIS P431-432
FORME DE DÉCOUPE

Complete Primary Mechanical

Logo VICHY: Call Standard 15.75 pt
L'ESSENCE: Call Standard 3.14 pt

VICHY
LABORATOIRES

Reduction: Histo 50 Roman 14.75 pt

**CAPITAL
SOLEIL 15**
SOLAIRE
PROTECTION

Minuterie: Histo 76 Bold 9 pt

Helvetica Neue 35 Black 5.5 pt

Helvetica Neue 77 Bold Cond 16 pt

Helvetica Neue 40 Light 9.75 pt

FOR FACE AND BODY

Helvetica Neue 75 Bold 8 pt

Helvetica Neue 36 Black 8 pt

Helvetica Neue 75 Bold 6.5 pt

Helvetica Neue 76 Bold 8.5 pt

WITH
MEXORYL™ SX (ECAMSULE)
A UNIQUE UVA FILTER

**BROAD SPECTRUM
UVA / UVB PROTECTION**

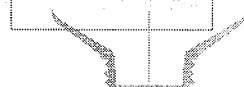
Helvetica Neue 48 Light 5.75 pt

Helvetica Neue 76 Bold 7 pt

Suitable for sensitive skin
Allergy-tested. Oil-free
Dermatologist tested
**Water/Perpiration
Resistant**

Helvetica Neue 50 Roman 15.50 pt

100g 3.4 OZ.



WITH **MEXORYL™ SX (ECAMSULE)**
**BROAD SPECTRUM
UVA/UVB PROTECTION**

UVA and UVB rays may increase the risk of skin cancer. UVA rays can diminish the skin's natural protective mechanism. The cumulative effects of exposure to UVA can cause an alteration to the skin structure leading to wrinkles, loss of firmness and the appearance of age spots. UVB rays may also contribute to premature skin aging.

CAPITAL SOLEIL 15's innovative formula combines a unique UVA filter, Mexoryl™ SX (ecamsule), with Parsol® 1789 (avobenzone) to create a new concept in sun protection. **CAPITAL SOLEIL 15** with Mexoryl™ SX protects against both long and short UVA rays, while also providing UVB protection against sunburn. The skin is protected, moisturized and healthy-looking.

Active Ingredients: Avobenzone* 3%, Ecamsule** 3%, Octocrylene 10%.

Uses: Helps prevent sunburn. Higher SPF gives more sunburn protection. Reapply SPF after 40 minutes of activity in the water or perspiring. Helps provide protection from UVA rays (short and long wavelength).

Warnings: For external use only. Do not use on broken skin or serious burns. When using this product, keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash or irritation develops and lasts. Keep out of 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 after 40 minutes of swimming or perspiring and after towel drying. Children under 6 months of age, ask a doctor.

Questions? xxxxxx-xxxx-xxxx Monday - Friday (9 a.m. to 5 p.m. EST)

*Avobenzone (Parsol 1789) is a trademark of DPH Nutritional Products.

** Ecamsule (MEXORYL) is a trademark of L'Oréal S.A.

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Store at 20-25° C (68-77° F).

Distributed by Vichy LLC,
New York, NY 10017
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www.vichy.com

ALL HEADINGS: Call Sans Bold Bold 3 pt

ALL TEXT: Call Sans Standard 6 pt

ALL SUBHEADINGS: Call Sans Bold 6 pt

Call Sans Standard 6.25 pt

Call Sans Standard 5.75 pt

Call Sans Standard 7 pt

Call Sans Light 7.75 pt

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■ BLEU SOLAIRE 2718
■ GRIS P431-432
■ FORME DE DÉCOUPE

$$2 + 5/32 \times 1 + 35/64 \times 6 + 5/32$$

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Susan Johnson
10/2/2006 03:01:16 PM

Susan Walker
10/2/2006 03:03:03 PM