

DIAL ANTIBACTERIAL- triclocarban soap
VVF Illinois Services LLC

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.

Dial Gold

Active ingredient

Triclocarban 0.30%

Purpose

Antibacterial

Keep out of reach of children.

If swallowed, get medical
help or contact Poison Control right away.

Use

For washing to decrease bacteria on the skin

Warnings

For external use only

When using this product

- Avoid contact with eyes. In case of eye contact, flush with water

Stop using and ask doctor if irritation and redness develops

Directions

wet bar with water - lather vigorously -
and wash skin - rinse and dry thoroughly

Inactive ingredients

soap (sodium cocoate*, sodium
palm kernelate*, sodium palmate*, sodium tallowate*), water, talc
coconut acid*, palm acid*, tallow acid*, palm kernel acid*, PEG-6 methyl
ether, fragrance, glycerin, sorbitol, sodium chloride, pentasodium
pentate¹, tetra sodium etidronate¹, yellow 5, yellow 8, red 4

*contains one or more of these ingredients

¹contains one or more of these ingredients

triclocarban soap

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:518 15-300 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------|-------------------|-----------------|
| TRICLO CARBAN (UNII: BGG1Y1ED0 Y) (TRICLOCARBAN - UNII:BGG1Y1ED0 Y) | TRICLOCARBAN | .339 g in 113 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------------|----------|
| SODIUM CO COATE (UNII: R1TQH25F4I) | |
| SODIUM PALM KERNELATE (UNII: 6H91L1NXTW) | |
| SODIUM PALMATE (UNII: S0A6004K3Z) | |
| SODIUM TALLO WATE, BEEF (UNII: 07RIK6QMEW) | |
| WATER (UNII: 059QF0K00R) | |
| TALC (UNII: 7SEV7J4R1U) | |
| COCONUT ACID (UNII: 40U37V505D) | |
| PALM ACID (UNII: B6G0Y5Z616) | |
| TALLO W ACID, BEEF (UNII: 5U9XZ261ER) | |
| PALM KERNEL ACID (UNII: 79P21R4317) | |
| PEG-6 METHYL ETHER (UNII: WXH089JZ5E) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SORBITOL (UNII: 506T60A25R) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| PENTASODIUM PENTETATE (UNII: 961TOZ5L7T) | |
| ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| D&C YELLOW NO. 8 (UNII: 93X55PE38X) | |
| FD&C RED NO. 4 (UNII: X3W0AM1JLX) | |

Product Characteristics

| | | | |
|-----------------|-----------|---------------------|------|
| Color | yellow | Score | |
| Shape | RECTANGLE | Size | |
| Flavor | | Imprint Code | Dial |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|---------------------|----------------------|--------------------|
| 1 | NDC:518 15-300-01 | 3 in 1 CELLO PACK | | |
| 1 | NDC:518 15-300-00 | 113 g in 1 PACKAGE | | |
| 2 | NDC:518 15-300-02 | 8 in 1 PACKAGE | | |
| 2 | NDC:518 15-300-00 | 113 g in 1 PACKAGE | | |

| | | | | |
|---|-------------------|--------------------|--|--|
| 3 | NDC:518 15-300-03 | 10 in 1 CELLO PACK | | |
| 3 | NDC:518 15-300-00 | 113 g in 1 PACKAGE | | |
| 4 | NDC:518 15-300-04 | 20 in 1 PACKAGE | | |
| 4 | NDC:518 15-300-00 | 113 g in 1 PACKAGE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part333E | 12/0 1/20 12 | |

Labeler - VVF Illinois Services LLC (024177178)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|-------------------------|
| VVF Illinois Services LLC | | 024177178 | manufacture(518 15-300) |

Revised: 5/2013

VVF Illinois Services LLC