

ESIKA MEN MULTI-ACTION 2-IN-1- pyrithione zinc liquid
Ventura Corporation (San Juan, P.R)

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.

ē sika
MEN
2 en
1
shampoo
Multi-action

Drug Facts

Active Ingredients

Pyrithione Zinc (1.1 %)

Purpose

Antidandruff

Uses

- Helps stop irritation and flaking associated with dandruff.

Warnings

- **for external use only.**
- avoid contact with eyes. If contacts occurs, rinse eyes thoroughly with water.
- if condition worsens or does not improve after regular use of this product as directed, consult a doctor (or physician).
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply shampoo to wet hair. Massage until foaming. Rinse with water to remove all hair shampoo. Repeat if necessary.
- For best results, use at least 2 times a week or as directed by a doctor (or physician).

Other information

- Ask a doctor before use if you have seborrheic dermatitis that covers a large area of the body.

Inactive ingredients

Aqua (water), sodium laureth sulfate, cocamidopropyl betaine, cocamide dea, dimethiconol, hydrolyzed soy protein, sodium chloride, hydrolyzed wheat protein, glycol distearate, acrylates/c10-30 alkyl acrylate crosspolymer, triethanolamine, guar hydroxypropyltrimonium chloride, parfum (fragrance),

coco-glucoside, hydrolyzed rice protein, tea-dodecylbenzenesulfonate, propylene glycol, CI 77891 (titanium dioxide), glyceryl oleate, glyceryl stearate, magnesium nitrate, zinc chloride, citric acid, butylene glycol, bambusa arundinacea leaf extract, CI 42090 (blue 1), panthenol, CI 19140 (yellow 5), methylchloroisoithiazolinone, magnesium chloride, ppg-26-buteth-26, methylisoithiazolinone, peg-40 hydrogenated castor oil, menthyl pca, menthol, dipropylene glycol , apigenin, CI 17200 (red 33), oleanolic acid, biotinoyl tripeptide-1.

PRINCIPAL DISPLAY PANEL - 300 ml Bottle Label

MEN

2 en

1

shampoo

Multi-action

- > maximum brilliance and softness
- > controls symptoms of dandruff
with pyrithione zinc
- > hair can be combed more easily

ēsika

300 ml e (10.1 fl.oz)



2^{en}₁

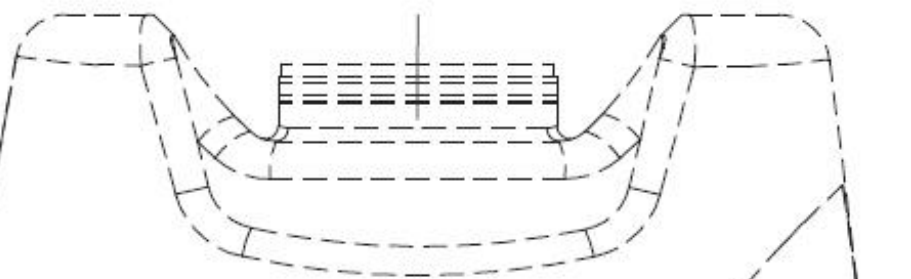
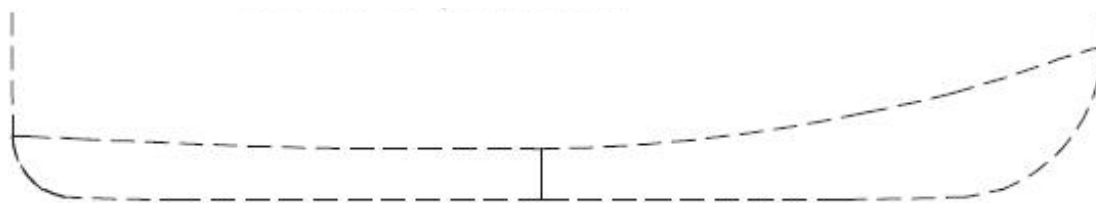
NEW

shampoo

Multi-action

- > maximum brilliance and softness
- > controls symptoms of dandruff with pyrithione zinc
- > hair can be combed more easily

ēsika
300 ml e (10.1 fl.oz)



With Total Tech System, that incorporates bamboo-leaf extract and rice-hydrolyzed proteins to protect hair from external agents and to give hair more softness. Besides, it has Zinc-Pyrithionate (effective anti-dandruff agent for controlling scale-formations); Procapil complex that strengthens hair and conditioning silicones that help to give hair a healthy appearance besides facilitating its combing.

Drug Facts

| Active Ingredients | Purpose |
|---------------------------|----------------|
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protein, glycol distearate, acrylates/c10-30 alkyl acrylate crosspolymer, triethanolamine, guar hydroxypropyltrimonium chloride, parfum (fragrance), coco-glucoside, hydrolyzed rice protein, tea-dodecylbenzenesulfonate, propylene glycol, CI 77891 (titanium dioxide), glyceryl oleate, glyceryl stearate, magnesium nitrate, zinc chloride, citric acid, butylene glycol, bambusa arundinacea leaf extract, CI 42090 (blue 1), panthenol, CI 19140 (yellow 5), methylchloroisothiazolinone, magnesium chloride, ppg-26-buteth-26, methylisothiazolinone, peg-40 hydrogenated castor oil, menthyl pca, menthol, dipropylene glycol, apigenin, CI 17200 (red 33), oleanolic acid, biotinoyl tripeptide-1.

PUERTO RICO: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Colombia.

ESIKA MEN MULTI-ACTION 2-IN-1

pyrithione zinc liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13537-342 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| Pyrithione Zinc (UNII: R953O2RHZ5) (Pyrithione Zinc - UNII:R953O2RHZ5) | Pyrithione Zinc | 0.011 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0KO0R) | |
| sodium laureth sulfate (UNII: BPV390UAP0) | |
| cocamidopropyl betaine (UNII: 5OCF3O11KX) | |
| coco diethanolamide (UNII: 92005F972D) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| glycol distearate (UNII: 13W7MDN21W) | |
| trolamine (UNII: 9O3K93S3TK) | |
| coco glucoside (UNII: ICS790225B) | |
| tea-dodecylbenzenesulfonate (UNII: 8HM7ZD48HN) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| glyceryl monooleate (UNII: 4PC054V79P) | |
| glyceryl monostearate (UNII: 230OU9XXE4) | |
| magnesium nitrate (UNII: 77CBG3UN78) | |
| zinc chloride (UNII: 86Q357L16B) | |
| citric acid monohydrate (UNII: 2968PHW8QP) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| bambusa arundinacea leaf (UNII: HW86D1FGSS) | |

| |
|---|
| fd&c blue no. 1 (UNII: H3R47K3TBD) |
| panthenol (UNII: WV9CM0O67Z) |
| fd&c yellow no. 5 (UNII: I753WB2F1M) |
| methylchloroisothiazolinone (UNII: DEL7T5QRPN) |
| magnesium chloride (UNII: 02F3473H9O) |
| methylisothiazolinone (UNII: 229D0E1QFA) |
| polyoxyl 40 hydrogenated castor oil (UNII: 7YC686GQ8F) |
| menthol (UNII: L7T10EIP3A) |
| dipropylene glycol (UNII: E107L85C40) |
| d&c red no. 33 (UNII: 9DBA0SBB0L) |
| oleanoic acid (UNII: 6SMK8R7TGJ) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:13537-342-01 | 300 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part358H | 05/17/2011 | |

Labeler - Ventura Corporation (San Juan, P.R) (602751344)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---------------------|
| Bel Star S.A. (Colombia) | | 880160197 | MANUFACTURE |

Revised: 5/2011

Ventura Corporation (San Juan, P.R)