

**FORTE MAGNETIC S3 OIL CONTROL ANTI-DANDRUFF- piroctone
olamine lotion/shampoo
FORMOSA BIOMEDICAL TECHNOLOGY CORPORATION**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Active ingredient: Piroctone Olamine 0.4g/500g

Uses: Helps prevent recurrence of flaking and itching associated with dandruff

When using this product:

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

If accidentally ingested, please seek medical treatment.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions:

For best results use at least twice a week or as directed by a doctor.

Wet your hair, and gently massage the scalp and roots with an appropriate amount of shampoo, based on your hair quantity. Rinse with clean water

Other information:

Store at 5-30C;

Keep out of direct sunlight;

This product contains plant-derived ingredients. Their odor and color may change with temperature and humidity; these changes are normal;

This product has no magnetic properties, but the ingredients are based on the interaction of opposite charges attracting.

Inactive ingredients:

Water (Aqua), Sodium lauroyl Methyl Isethionate, Disodium Laureth Sulfosuccinate, Sodium C14-16 Olefin Sulfonate, Potassium Cocoyl Glycinate, Polysorbate 20, Propylene Glycol, Potassium Cocoate, Cocamidopropyl Betaine, Fragrance, Trisodium Ethylenediamine Disuccinate, Betaine, Cetareth-60 Myristyl Glycol, Cetrimonium Chloride, Hydroxyacetophenone, Isopropyl Alcohol, Phenoxyethanol, Sodium Lauraminopropionate, Polyquaternium-10, Sodium Chloride, Hexylene Glycol, Caprylhydroxamic Acid, Capryloyl Glycine, Butylene Glycol, Polyquaternium-55, Xylitylglucoside, Glycerin, Sodium Acetate, Enantia Chlorantha Bark Extract, Caprylyl Glycol, Creatine, Glycolic Acid, Polyglyceryl-10 Laurate, Polyquaternium-7, Oleanolic Acid, Sodium Citrate, Sodium Benzoate, Citric Acid, Isostearic Acid

Questions?

Dist. By Formosa Biomedical Technology Corporation
formmosabio@fpg.com.tw

| Drug Facts | |
|--|----------------|
| Active ingredient (in each dosage unit) | Purpose |
| Piroctone Olamine 0.08 g/100g | Anti-dandruff |
| Uses | |
| <ul style="list-style-type: none"> ■Helps prevent recurrence of flaking and itching associated with dandruff. | |
| Warnings | |
| For external use only. | |
| When using this product | |
| <ul style="list-style-type: none"> ■Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. ■If accidentally ingested, please seek medical treatment. | |
| Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. | |
| Directions | |
| <ul style="list-style-type: none"> ■For best results use at least twice a week or as directed by a doctor. ■Wet your hair, and gently massage the scalp and roots with an appropriate amount of shampoo, based on your hair quantity. Rinse with clean water. | |
| Other information | |
| <ul style="list-style-type: none"> ■Store at 5-30°C ■Keep out of direct sunlight ■This product contains plant-derived ingredients. Their odor and color may change with temperature and humidity; these changes are normal. ■This product has no magnetic properties, but the ingredients are based on the interaction of opposite charges attracting. ■After opening the product, please use within six months for best quality. | |
| Inactive ingredients | |
| Water (Aqua), Sodium lauroyl Methyl Isethionate, Disodium Laureth Sulfosuccinate, Sodium C14-16 Olefin Sulfonate, Potassium Cocoyl Glycinate, Polysorbate 20, Propylene Glycol, Potassium Cocoate, Cocamidopropyl Betaine, Fragrance, Trisodium Ethylenediamine Disuccinate, Betaine, Cetareth-60 Myristyl Glycol, Cetrimonium Chloride, Hydroxyacetophenone, Isopropyl Alcohol, Phenoxyethanol, Sodium Lauraminopropionate, Polyquaternium-10, Sodium Chloride, Hexylene Glycol, Caprylhydroxamic Acid, Capryloyl Glycine, Chlorhexidine Didecylate, Butylene Glycol, Polyquaternium-55, Xylitylglucoside, Glycerin, Sodium Acetate, Enantia Chlorantha Bark Extract, Caprylyl Glycol, Creatine, Glycolic Acid, Polyglyceryl-10 Diisostearate, Polyglyceryl-10 Laurate, Polyquaternium-7, Oleanolic Acid, Sodium Citrate, Sodium Benzoate, Citric Acid, Isostearic Acid | |
| Questions? Dist. By Formosa Biomedical Technology Corporation <i>formosabio@fpg.com.tw</i> | |

piroctone olamine lotion/shampoo

Product Information

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|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:84655-101 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| PIROCTONE OLAMINE (UNII: A4V5C6R9FB) (PIROCTONE - UNII:R49EFA73Q7) | PIROCTONE OLAMINE | 0.4 g in 500 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E) | |
| ANNICKIA CHLORANTHA BARK (UNII: H70115MP4A) | |
| POTASSIUM COCOYL GLYCINATE (UNII: WZ70FUF22U) | |
| POTASSIUM COCOATE (UNII: F8U72V8ZXP) | |
| TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| POLYGLYCERYL-10 LAURATE (UNII: MPJ2Q8W8G) | |
| SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U) | |
| ISOSTEARIC ACID (UNII: X33R8U0062) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| CREATINE (UNII: MU72812GK0) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS) | |
| SODIUM LAUROYL METHYL ISETHIONATE (UNII: II6VCD3S6R) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| POLYQUATERNIUM-55 (UNII: NG3KW6CD2J) | |
| OLEANOLIC ACID (UNII: 6SMK8R7TGJ) | |
| SODIUM ACETATE (UNII: 4550K0SC9B) | |
| CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ) | |
| CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| WATER (UNII: 059QF0KO0R) | |
| BETAINE (UNII: 3SCV180C9W) | |
| POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y) | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| GLYCOLIC ACID (UNII: 0WT12SX38S) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| FRAGRANCE 13576 (UNII: 5EM498GW35) | |
| XYLITYLGLUCOSIDE (UNII: 00IEZ166FB) | |

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| GLYCERIN (UNII: PDC6A3C0OX) | |
| CETEARETH-60 MYRISTYL GLYCOL (UNII: 4O832ZOY6W) | |
| HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) | |
| SODIUM LAURAMINOPROPIONATE (UNII: X5NJA9HXPU) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:84655-101-02 | 1 in 1 BOX | 08/13/2024 | |
| 1 | NDC:84655-101-01 | 500 g in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other | | 08/13/2024 | |

Labeler - FORMOSA BIOMEDICAL TECHNOLOGY CORPORATION (658521104)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| FORMOSA BIOMEDICAL TECHNOLOGY CORPORATION | | 658521104 | manufacture(84655-101) |

Revised: 8/2024

FORMOSA BIOMEDICAL TECHNOLOGY CORPORATION