#### MEDICASP ANTI-DANDRUFF- coal tar shampoo Genomma Lab USA Inc.

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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#### Medicasp Shampoo<sup>®</sup> Anti-dandruff

**Drug Facts** 

### Active ingredient

Solubilized Coal Tar Extract 2.5% (Coal Tar, 0.5%

### Purpose

Anti-dandruff

### Use

controls the symptoms of

- ♦ dandruff
- seborrheic dermatitis
- psoriasis

# Warnings

### For external use only

Ask a doctor before use if you have a condition which covers a large part of the body

# When using this product

- do not get into the eyes. If contact occurs, rinse eyes thoroughly with water
- use caution exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application.
- do not use for prolonged periods without consulting a doctor
- do not use with other forms of psoriasis therapy such as ultra violet radiation or prescription drugs unless directed to do so by a doctor.

**Stop use and ask a doctor if** condition worsens or does not improve after regular use of this product as directed.

# Keep out of reach of children.

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

# Directions

- wet hair thoroughly
- apply the shampoo into the scalp and massage

- lather and leave on hair and scalp for several minutes
- rinse and repeat
- for best results use at least twice a week or as directed by a doctor

#### Other information

- store away from direct sunlight
- in rare instances, discoloration of gray, blonde, bleached or tinted hair may occur

#### **Inactive ingredients**

water, sodium laureth sulfate, cocamide MEA, cocamidopropyl betaine, laureth-4, fragrance, polysorbate 20, citric acid, sodium chloride, tetrasodium EDTA, DMDM hydantoin, caramel, red 40

#### Questions or comments?

187799 GENOM (43666)

*Distributed by:* Genomma Lab USA, Inc., Houston, TX 77027

#### **PRINCIPAL DISPLAY PANEL - 177 ml Bottle Carton**

ORIGINAL STRENGTH SHAMPOO

SHAMPOO Medicasp<sup>®</sup>

COAL TAR 0.5%

Controls the symptoms of: PSORIASIS | DANDRUFF SEBORRHEIC DERMATITIS

COAL TAR DANDRUFF SHAMPOO

6FL OZ (177 ml)





#### Drug Facts

Active ingredient Purpose Solubilized Coal Tar Extract 2,5% (Coal Tar, 0.5%) \_\_\_\_ Anti-dandruff

Use controls the symptoms of dandruff seborrheic dermatitis

psoriasis

#### Warnings

For external use only Ask a doctor before use if you have a condition which

covers a large part of the body When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water, use caution in exposing skin to sunlight after applying this product, it may increase your tendency to sunburn for up to 24

hours after application. do not use for prolonged periods without consulting a doctor

do not use with other forms of psoriasis therapy such as ultra violet radiation or prescription drugs unless directed to do so by a doctor. Stop use and ask a doctor if condition worsens or does not

improve after regular use of this product as directed. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center

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**Questions or comments?** 1 877 99 GENOM (43666)



#### Información del Medicamento

Ingrediente Activo 

Uso

controla los síntomas de caspa

dermatitis seborreica psoriasis

#### Advertencias

Únicamente para uso externo Consulte a su médico antes de utilizarlo si usted tiene una condición que cubra una gran parte del cuerpo.

Cuando utilice este producto no aplicar en los ojos. Si ocurre el contacto, enjuagar perfectamente los ojos con agua.

tenga precaución al exponer la piel a la luz solar después de aplicar este producto. Puede incrementar su tendencia a quemaduras solares hasta por 24 horas después de su aplicación. no lo utilice por periodos prolongados sin consultar con

su médico. no lo utilice con otras formas de terapla para la psoriasis tales como radiación ultravioleta o medicamentos de prescripción a menos que así lo indique su médico.

Suspenda su uso y consulte a su médico si la condición empeora o no se observa mejoría después del uso regular de este producto de acuerdo a las indicaciones,

Manténgase fuera del alcance de los niños En caso de ingerir, obtenga asistencia médica o contacte a un Centro de Control de Envenenamiento de

manera inmediata.

Lea el panel anexo 🕨



# ALQUITRÁN DE HULLA 0,5% COAL TAR 0,5%

Contro a los sintomas de: **PSORIASIS I CASPA** DERMATITIS SEBORREICA Controls the symptoms of: **PSORIASIS | DANDRUFF** SEBORRHEIC DERMATITIS

ANTICASPA DE ALQUITRÁN DE HULLA COAL TAR DANDRUFF SHAMPOO Caja con frasco con 6FL 0Z (177 ml)



#### Información del Medicamento (cont.)

Indicaciones

humedezca perfectamente el cabello el cabello aplique el champú sobre el cuero cabelludo dando masaje produzca espuma y déjela sobre el cabello y el cuero cabelludo por varios minutos

enjuague y repita

para mejores resultados utilicose al menos dos veces a la semana o de acuerdo a las indicaciones del médico. Información adicional

amacenar alejado de la luz solar directa.

en casos raros, puede presentarse la decoloración del cabello gris, rubio, aclarado o teñido,

Ingredientes inactivos agua, lauret sulfato de socio, MEA cocamida, cocamidopropil betaína, lauret-4, fragrancia, polisorbato-20, acido cítrico, cloruro de sodio, EDTA EDTA etrasódico, hidantoina DMDM, carameto, rojo 40

¿Preguntas o comentarios? 1 877 99 GENOM (43666)



le in / Hecho en: Ca

Distributed by / Distribuido por: Genomma Lab USA, Inc., Houston, TX 77027



2FMS1MUCEWW11 07-064F

#### **MEDICASP ANTI-DANDRUFF** coal tar shampoo **Product Information** HUMAN OTC DRUG NDC:50066-054 **Product Type** Item Code (Source) **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Basis of Strength Ingredient Name** Strength Coal Tar (UNII: R533ESO2EC) (Coal Tar - UNII:R533ESO2EC) Coal Tar 5 mg in 1 mL **Inactive Ingredients Ingredient Name** Strength Water (UNII: 059QF0KO0R) Sodium Laureth-3 Sulfate (UNII: BPV390UAP0) COCO Monoethanolamide (UNII: C80684146D) Cocamidopropyl Betaine (UNII: 50CF3011KX) Laureth-4 (UNII: 6HQ855798J) Polysorbate 20 (UNII: 7T1F30V5YH) Citric Acid Monohydrate (UNII: 2968PHW8QP) Sodium Chloride (UNII: 451W47IQ8X) Edetate Sodium (UNII: MP1J8420LU) DMDM Hydantoin (UNII: BYR0546TOW) Caramel (UNII: T9D99G2B1R) FD&C Red No. 40 (UNII: WZB9127XOA) **Product Characteristics** Color BROWN Score Shape Size Flavor Imprint Code Contains Packaging **Marketing Start Marketing End Item Code Package Description** # Date Date 1 NDC:50066-054-1 in 1 CARTON 09/16/2013 01 177 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination 1 Product **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	09/16/2013	

# Labeler - Genomma Lab USA Inc. (832323534)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Garcoa, Inc.		036464697	MANUFACTURE(50066-054)	

Revised: 12/2018

Genomma Lab USA Inc.