

**DIVINE DANDRENE 2%- zinc pyrithione shampoo**  
**DS Healthcare Group, Inc.**

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***Active ingredient***

Zinc Pyrithione 2%

***Purpose***

Anti-dandruff

***Uses***

Relieves and helps prevent recurrence of scalp itch, irritation, redness, flaking and scaling associated with dandruff

***Warnings***

**For external use only.**

**When using this Product:** Avoid contact with eyes, If contact occurs, rinse eyes thoroughly with water

**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 Poison Control Center right away

***Directions***

Apply shampoo to wet hair and scalp with gentle massage, leave in for 2-3 minutes, rinse

For best results use atleast 2 times per week or as directed by a doctor

For maximum benefits use 4-5 times a week along with Dandrene anti-dandruff conditioner

***Inactive ingredients***

Water, Disodium Laureth Sulfosuccinate, Triethanolamine, Glycolic Acid, Cocamide MEA, Sodium Lauroyl Sarcosinate, Sodium Lauryl Suloacetate, Glycol Distearate, PEG-150 Distearate, Magnesium Aluminum Silicate, Sodium Citrate, Hexamidine Diisethionate, Hydrolyzed Lupine Protein, Caprylyl Glycol, Phenoxyethanol, Butylene Glycol, Punica Granatum Extract, Rosmarinus Officinalis Leaf Extract, Shikimic Acid, Tioxolone, Blue 1

## Product label

### **Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Pyrrithione zinc 2% w/w .....	Anti-dandruff

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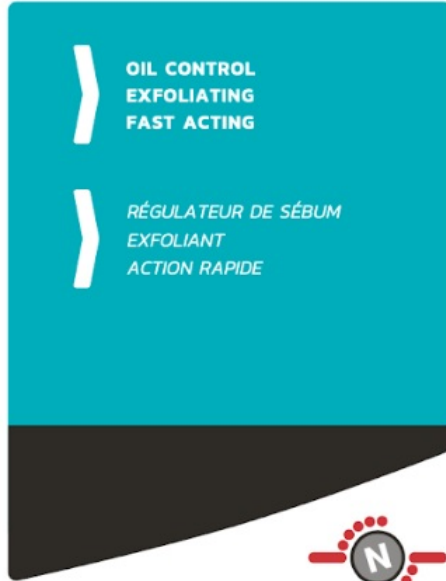
#### **Inactive ingredients**

WATER, DISODIUM LAURETH SULFOSUCCINATE, TRIETHANOLAMINE, GLYCOLIC ACID, COCAMIDE MEA, SODIUM LAUROYL SARCOSINATE, SODIUM LAURYL SULFOACETATE, GLYCOL DISTEARATE, PEG-150 DISTEARATE, MAGNESIUM ALUMINUM SILICATE, SODIUM CITRATE, HEXAMIDINE DIISETHIONATE, HYDROLYZED LUPINE PROTEIN, CAPRYLYL GLYCOL, PHENOXYETHANOL, BUTYLENE GLYCOL, POMEGRANATE PEEL (PUNICA GRANUTUM) EXTRACT, ROSEMARY (ROSMARINUS OFFICINALIS) LEAF EXTRACT, SHIKIMIC ACID, TIOXOLONE, FRAGRANCE, BLUE 1.



## ANTI-DANDRUFF SHAMPOO / SHAMPOOING ANTIPELLICULAIRE

DANDRENE®



OIL CONTROL  
EXFOLIATING  
FAST ACTING

RÉGULATEUR DE SÉBUM  
EXFOLIANT  
ACTION RAPIDE

205 mL / 7 FL OZ e



**ENGLISH**  
**INDICATIONS:** Relieves and helps prevent recurrence of scalp itch, irritation, redness, flaking and scaling associated with dandruff.  
**DIRECTIONS:** Apply shampoo to scalp with a gentle massage, leave in for 2-3 minutes, rinse. For maximum benefit use 4-5 times a week along with Dandrene® Anti-Dandruff Conditioner or as directed by a doctor.  
**PRECAUTIONS:** For external use only. When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. Stop use and ask a doctor if condition worsens or does not improve after regular use of this product. Keep out of reach of children. Consult a health care practitioner prior to use in children under 2 years of age.

**FRANÇAIS**  
**INDICATIONS:** Soulage et aide à prévenir la récurrence des démangeaisons, irritations et rougeurs du cuir chevelu liées aux pellicules.  
**MODE D'EMPLOI:** Appliquer le shampooing sur cheveux mouillés en massant le cuir chevelu, laisser reposer pendant 2-3 minutes puis rincer. Pour un résultat optimal utiliser 4-5 fois par semaine avec l'après-shampooing Dandrene® Antipelliculaire ou comme dirigé par un médecin.  
**PRÉCAUTIONS:** Pour usage externe seulement. En utilisant ce produit éviter le contact avec les yeux. En cas de contact, rincer les yeux à l'eau. Arrêtez l'utilisation et demandez à un médecin si la condition se détériore ou ne s'améliore pas après l'utilisation régulière de ce produit selon les directives. Tenir hors de portée des enfants. Veuillez consulter un médecin avant l'utilisation sur un enfant de moins de 2 ans.

**ESPAÑOL**  
**INDICACIONES:** Champú exfoliante que ayuda a aliviar y a prevenir la caspa recurrente y adherida al cuero cabelludo.  
**MODO DE EMPLEO:** Aplicar el champú sobre el cabello mojado y el cuero cabelludo con un suave masaje, dejar actuar durante 2-3 minutos, enjuague. Para el máximo beneficio utilizar 4-5 veces a la semana, junto con Dandrene® Anticaspa Acondicionador o según las indicaciones de un médico.  
**PRECAUCIONES:** Sólo para uso externo. Cuando use este producto, evite el contacto con los ojos. Si se produce el contacto, enjuague los ojos con abundante agua. Pare el uso y consulte al médico si la condición empeora o no mejora después del uso regular de este producto según las indicaciones. Mantener fuera del alcance de los niños. Consulte a un médico antes de su uso en niños menores de 2 años de edad.

**PORTUGUÊS**  
**INDICAÇÕES:** Alivia e ajuda a prevenir a recorrência de coceira no couro cabeludo, irritação, vermelhidão e descamação associados com a caspa.  
**INSTRUÇÕES:** Aplique shampoo para cabelo molhado e couro cabeludo com uma massagem suave, deixe-a por 2-3 minutos, enxaguar. Para o benefício máximo usar 4-5 vezes por semana, juntamente com Dandrene® Anti-Caspa Conditioner ou conforme indicado por um médico.  
**PRECAUÇÕES:** Para uso externo somente. Ao usar este produto evitar o contacto com os olhos. Se ocorrer contato, lavar os olhos abundantemente com água. Pare o uso e pergunte a um médico se condição piora ou não melhora depois do uso regular deste produto como indicado. Mantenha fora do alcance de crianças. Consulte um médico antes de usar em crianças menores de 2 anos de idade.

**INGREDIENTS:** For full ingredient disclosure, see accompanying box. / Pour la liste complète des ingrédients, voir le carton accompagnant.

Produced for / Producido para **DS Healthcare Group, Inc.**  
1395 Brickell Ave Suite 800, Miami, FL 33131.  
Made in / Hecho en: **United States of America, Estados Unidos de Norteamérica.**  
Imported by / Importado por: **Divine Skin Laboratories S.A. de C.V.**  
Callejales 1747, Col. Haciendas de Coyacán, C.P. 04970, CDMX.  
Importado por: **DS HEALTHCARE IBERIA S.L.**  
Mantaner, 322, 1ª 1ª - 08021 Barcelona (España)  
[www.dslaboratories.com](http://www.dslaboratories.com) | #DSLABS | [contact@dslaboratories.com](mailto:contact@dslaboratories.com)



BT0132



## DIVINE DANDRENE 2%

zinc pyrithione shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69188-200
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PYRITHIONE ZINC</b> (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	2 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DISODIUM LAURETH SULFOSUCCINATE</b> (UNII: D6DH1DTN7E)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>GLYCOLIC ACID</b> (UNII: 0WT12SX38S)	
<b>COCO MONOETHANOLAMIDE</b> (UNII: C80684146D)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>SODIUM LAURYL SULFOACETATE</b> (UNII: D0Y70F2B9J)	
<b>GLYCOL DISTEARATE</b> (UNII: 13W7MDN21W)	
<b>PEG-150 DISTEARATE</b> (UNII: 6F36Q0I0AC)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>HEXAMIDINE DISETHIONATE</b> (UNII: 023XA5Z50L)	
<b>SURINAMINE</b> (UNII: AIQ58N56TM)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PUNICA GRANATUM FLOWER</b> (UNII: D9B634V4GP)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>SHIKIMIC ACID</b> (UNII: 29MS2W2NU)	
<b>TIOXOLONE</b> (UNII: S0FAJ1R9CD)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69188-200-07	205 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	06/01/2021	

**Labeler** - DS Healthcare Group, Inc. (015504134)

## Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc		086365223	manufacture(69188-200)