## HAIRQ - pyrithione zinc solution Cresson

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.

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#### **Drug Facts**

active ingredient: zinc pyrithion

inactive ingredient: water,copper tripeptide, sodium chloride, sodium metasilicate, sodium thiosulfate, sodium carbonate, sodium citrate, citric acid, tetrasodium EDTA

hair growth, hair loss prevention and scalp protectant

keep out of reach of the children

- apply only for scalp

- apply 2 or 3 times a day with 5~6ml
- massage with your finger over 2 min and let them dry

- keep out of eyes, ears and mouth

- if contact occurs, rinse away with plenty of cold water
- for external use only

| HAIR Q   |   | HAIRQ<br>HAIR LOSS<br>PREVENTION & HAIR<br>GROWTH AND<br>SCALP PROTECTANT   |  |
|--|---|---|--|
| HAIR COST PREVENTION<br>& HAIR GROWER<br>AND SCALP<br>PROTECTANT |   | USES : Hair growth,<br>hair loss prevention<br>and scalp protectant<br>Direction :<br>- Apply only scalp<br>- Apply 2 or 3 times<br>a day and each one<br>5m/~ 6m),<br>- Massage with your<br>finger over 2 min and   | Active Ingradients<br>(per 1ml) :<br>Zinc Pyrithion-0,1%,<br>1   |
| CRESSON<br>(용량) 200ml  | www.cresson.kr<br>Cresson Co., L11<br>Made in Korea | Iet them dry,<br>ATTENTION :<br>For external use only,<br>Do not use swallow,<br>Keep out of eyes,<br>ears, and mouth, If<br>contact occurs, rinse<br>with plenty of cold<br>water right away and<br>in a critical situation,<br>contac doctor,<br>keep out of reach of<br>the children<br>CRESSON CO,LTD. :<br>4F Hoyoung blads,<br>Jiyangro 86,<br>Yangchun ku, Seoul | IN GRADIENTS :<br>Copper Tripeptide<br>Aqua<br>Sodium Chloride<br>Sodium Metasilicate<br>Sodium Thiosulfate,<br>Sodium Carbonate,<br>Sodium Citrate,<br>Citric Acid,<br>Tetrasodium EDTA |
| 200 <b>ml/6, 76fl, OZ</b>  |   | Korea   |  |
|  |   | LOT.NO :<br>EXP.DATE :  |  |

**HAIRQ** pyrithione zinc solution

| Inactive Ingredients       Ingredient Name       Strength         WATER (UNII: 059QF0K00R)       Strength         SODIUM CHLORIDE (UNII: 451W47IQ8X)       Strength         SODIUM THIO SULFATE (UNII: 451032V43M)       Strength         SODIUM CARBONATE (UNII: 459326 1C7T)       Strength         SODIUM CITRATE (UNII: 1Q73Q2JULR)       Strength         CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)       Strength         EDETATE SODIUM (UNII: MP1J8420LU)       Strength  | Product Information   | 011                 |                            |                              |           |                 |               |                 |                  |
|--|---|---------------------|----------------------------|------------------------------|-----------|-----------------|---------------|-----------------|------------------|
| Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength PYRITHIONE ZINC (UNII: R95302RHZ5) (PYRITHIONE ZINC - UNII:R95302RHZ5) SODIUM CLORIDE (UNII: 451947IQ8X) SODIUM CLORIDE (UNII: 451947IQ8X) SODIUM CLORIDE (UNII: 451947IQ8X) SODIUM CLRARE (UNII: 451947IQ8X) SODIUM CLRARE (UNII: 451947IQ8X) SODIUM CLRARE (UNII: 4519420LU) SODIUM CLRARE (UNII: 12968PHW8QP) EDETATE SODIUM (UNII: MPIJ8420LU) PACkaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:49658-3001-1 200 mL in 1 BOTTLE, WITH APPLICATOR Marketing Information Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date   | Product T ype   |                     | HUMAN OTC DRUG             | Ite m C                      | ode (Sou  | rce)            | NDC:4         | DC:49658-3001   |                  |
| Ingredient Name       Basis of Strength       Strength         PYRITHIONE ZINC (UNIE R95302RHZ5) (PYRITHIONE ZINC - UNIER95302RHZ5)       PYRITHIONE ZINC       0.1 mL in 100 ml         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Ingredient Name       Strength         Ingredient Name       Strength       Strength         Ingredient Name       Strength       Strength         Ingredient Name       Strength       Strength         Ingredient Name       Strength       Strength         SoDIUM CHLORIDE (UNIE 451947IQ8 X)       SoDIUM CHLORIDE (UNIE 4519326 IC7T)       SoDIUM CARBONATE (UNIE 1073Q2JULR)         CTTRIC ACID MONOHYDRATE (UNIE 10968PHW8QP)       SoDIUM CITRATE (UNIE 1073Q2JULR)       Strength         Packaging       Item Code       Package Description       Marketing Start Date       Marketing End Date         *       Item Code       Package Description       Marketing Start Date       Marketing End Date         *       Marketing Information       Marketing Start Date       Marketing End Date  | Route of Administrati   | on                  | TOPICAL                    |                              |           |                 |               |                 |                  |
| Ingredient Name       Basis of Strength       Strength         PYRITHIONE ZINC (UNIE R95302RHZ5) (PYRITHIONE ZINC - UNIER95302RHZ5)       PYRITHIONE ZINC       0.1 mL in 100 ml         Inactive Ingredients       Ingredient Name       Strength         Inactive Ingredients       Ingredient Name       Strength         Ingredient Name       Strength       Strength         Matter (UNIE: 059QF0KOOR)       Strength       Strength         StopIUM CHLORIDE (UNIE: 451W47IQ8 X)       Strength       Strength         StopIUM CHLORIDE (UNIE: 451W47IQ8 X)       Strength       Strength         StopIUM CARBONATE (UNIE: 1073Q2JULR)       Strength       Strength         StopIUM CHI CACID MONOHYDRATE (UNIE: 2968PHW8QP)       Strength       Strength         StopIUM CHI CACID MONOHYDRATE (UNIE: 2968PHW8QP)       Strength       Strength         StopIUM StopIII (Strength)       Strength       Strength       Strength         Packaging       Strength       Strength       Strength <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>   |   |                     |                            |                              |           |                 |               |                 |                  |
| PYRITHIONE ZINC (UNII: R95302RHZ5) (PYRITHIONE ZINC - UNIER95302RHZ5) PYRITHIONE ZINC 0.1 mL in 100 ml<br>Inactive Ingredients<br>Ingredient Name Strength<br>WATER (UNII: 059QF0K00R)<br>SODIUM CHLORIDE (UNII: 451W47IQ8X)<br>SODIUM CHLORIDE (UNII: 451W47IQ8X)<br>SODIUM CHLORIDE (UNII: 45193261C7T)<br>SODIUM CARBONATE (UNII: 14593261C7T)<br>SODIUM CARBONATE (UNII: 14593261C7T)<br>SODIUM CITRATE (UNII: 1973Q2JULR)<br>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)<br>EDETATE SODIUM (UNII: MP1J8420LU)<br>Packaging<br>Y Item Code Package Description Marketing Start Date Marketing End Date<br>Marketing Information<br>Marketing Start Date Marketing End Date  | Active Ingredient/  | Active Moi          | ety                        |                              |           |                 |               |                 |                  |
| Ingredients         Ingredient Name       Strength         WATER (UNIE: 059QF0K00R)       Strength         SODIUM CHLO RIDE (UNIE: 451W47IQ8X)       SODIUM CHLO RIDE (UNIE: 451W47IQ8X)         SODIUM CHLO RIDE (UNIE: 451W47IQ8X)       SODIUM CHLO RIDE (UNIE: 451W47IQ8X)         SODIUM CHLO RIDE (UNIE: 451W47IQ8X)         SODIUM CARBONATE (UNIE: 1073Q2JULR)         CITRIC ACID MONOHYDRATE (UNIE: 2968PHW8QP)         EDETATE SODIUM (UNIE: MP1J8420LU)         Packaging         # Item Code       Package Description       Marketing Start Date       Marketing Information         Marketing Information       Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing Category   |   | Ingr                | edient Name                |                              |           | Basis of Stre   | ngth          | Strength        |                  |
| Ingredient Name       Strength         Marketing Category       Application Number or Monograph Citation       Strength         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing Start Date <td col<="" td=""><td>PYRITHIONE ZINC (UN</td><td>II: R953O2RHZ</td><td>5) (PYRITHIONE ZINC - UNII:R</td><td>.95302RH</td><td>Z5)</td><td>PYRITHIONE ZI</td><td>NC</td><td>0.1 mL in 100 mI</td></td>  | <td>PYRITHIONE ZINC (UN</td> <td>II: R953O2RHZ</td> <td>5) (PYRITHIONE ZINC - UNII:R</td> <td>.95302RH</td> <td>Z5)</td> <td>PYRITHIONE ZI</td> <td>NC</td> <td>0.1 mL in 100 mI</td> | PYRITHIONE ZINC (UN | II: R953O2RHZ              | 5) (PYRITHIONE ZINC - UNII:R | .95302RH  | Z5)             | PYRITHIONE ZI | NC              | 0.1 mL in 100 mI |
| Ingredient Name       Strength         Marketing Category       Application Number or Monograph Citation       Strength         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing Start Date <td col<="" th=""><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th></td>  | <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>   |                     |                            |                              |           |                 |               |                 |                  |
| wATER (UNE: 059QF0KOOR)   SO DIUM CHL O RIDE (UNI: 451W47IQ8 X)   SO DIUM THIO SULFATE (UNI: 4593261C7T)   SO DIUM CHTRATE (UNI: 4593261C7T)   SO DIUM CHTRATE (UNI: 1073Q2JULR)   CITRIC ACID MONOHYDRATE (UNI: 2968PHW8QP)   EDETATE SO DIUM (UNI: MP1J8420LU)   Packaging   #   Item Code   Package Description   Marketing Start Date   Marketing Information Number or Monograph Citation   Marketing Start Date   Marketing Category   Application Number or Monograph Citation  | Inactive Ingredien  | ts                  |                            |                              |           |                 |               |                 |                  |
| SO DIUM CHLO RIDE (UNII: 451W47IQ8 X)<br>SO DIUM THIO SULFATE (UNII: HX1032V43M)<br>SO DIUM CARBONATE (UNII: 45P3261C7T)<br>SO DIUM CARBONATE (UNII: 45P3261C7T)<br>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)<br>EDETATE SO DIUM (UNII: MP1J8420LU)<br>FOR TATE SO DIUM (UNII: MP1J8420LU | Ingredient Name   |                     |                            |                              |           |                 |               | Strength        |                  |
| SO DIUM THIO SULFATE (UNII: HX1032V43M)<br>SO DIUM CARBONATE (UNII: 45P3261C7T)<br>SO DIUM CITRATE (UNII: 1073Q2JULR)<br>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)<br>EDETATE SO DIUM (UNII: MP1J8420LU)<br>Packaging<br>Marketing Start Date<br>Marketing End Date<br>Marketing End Date<br>Marketing End Date<br>Marketing Start Date<br>Marketing End Date<br>Marketing Start Date<br>Marketing End Date   | WATER (UNII: 059QF0KO0R)  |                     |                            |                              |           |                 |               |                 |                  |
| SO DIUM CARBONATE (UNII: 45P3261C7T)<br>SO DIUM CITRATE (UNII: 1Q73Q2JULR)<br>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)<br>EDETATE SO DIUM (UNII: MP1J8420LU)<br>EDETATE SO DIUM (UNII: MP1J8420LU)<br>FUNC ACID MONOHYDRATE (UNII: 2968PHW8QP)<br>EDETATE SO DIUM (UNII: MP1J8420LU)<br>Marketing Start Date Marketing End Date<br>Marketing End Date<br>Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date   | SODIUM CHLORIDE (UNII: 451W47IQ8X)  |                     |                            |                              |           |                 |               |                 |                  |
| SOULIM CITRATE (UNII: 1Q73Q2JULR)<br>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)<br>EDETATE SODIUM (UNII: MP1J8420LU)<br>Packaging<br>Varketing Start Date<br>NDC:49658-3001-1 200 mL in 1 BOTTLE, WITH APPLICATOR<br>Marketing Start Date<br>Varketing Information<br>Marketing Start Date<br>Marketing Start Date<br>Marketing End Date<br>Marketing Category<br>Application Number or Monograph Citation<br>Marketing Start Date<br>Marketing Start Date<br>Marketing End Date   |   |                     |                            |                              |           |                 |               |                 |                  |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)   EDETATE SODIUM (UNII: MP1J8420LU)     Packaging   I tem Code   Package Description   Marketing Start Date   Marketing End Date   Marketing End Date   Marketing End Date  |   |                     |                            |                              |           |                 |               |                 |                  |
| Between the solution (UNII: MP1J8420LU)     Packaging   I tem Code   Package Description   Marketing Start Date   Marketing End Date     NDC:49658-3001-1   200 mL in 1 BOTTLE, WITH APPLICATOR     Marketing Information     Warketing Category     Application Number or Monograph Citation     Marketing Start Date     Marketing Start Date  |   |                     |                            |                              |           |                 |               |                 |                  |
| Packaging         Item Code       Package Description       Marketing Start Date       Marketing End Date         NDC:49658-3001-1       200 mL in 1 BOTTLE, WITH APPLICATOR       Image: Colspan="4">Image: Colspan="4" Image: Colspan="4   |   |                     |                            |                              |           |                 |               |                 |                  |
| Item Code       Package Description       Marketing Start Date       Marketing End Date         NDC:49658-3001-1       200 mL in 1 BOTTLE, WITH APPLICATOR   | EDETATE SO DIUM (UN   | II: MP1J8420LU      | J)                         |                              |           |                 |               |                 |                  |
| Item Code       Package Description       Marketing Start Date       Marketing End Date         NDC:49658-3001-1       200 mL in 1 BOTTLE, WITH APPLICATOR   |   |                     |                            |                              |           |                 |               |                 |                  |
| 1       NDC:49658-3001-1       200 mL in 1 BOTTLE, WITH APPLICATOR         Marketing Information         Marketing Category         Application Number or Monograph Citation       Marketing Start Date       Marketing End Date   | Packaging   |                     |                            |                              |           |                 |               |                 |                  |
| Marketing Information<br>Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Dat  | # Item Code   | Р                   | ackage Description         | Μ                            | larketing | Start Date      | Marl          | keting End Date |                  |
| Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Dat   | <b>1</b> NDC:49658-3001-1   | 200 mL in 1 E       | BOTTLE, WITH APPLICATOR    |                              |           |                 |               |                 |                  |
| Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Dat   |   |                     |                            |                              |           |                 |               |                 |                  |
| Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Dat   |   |                     |                            |                              |           |                 |               |                 |                  |
|  | Marketing Info  | rmation             |                            |                              |           |                 |               |                 |                  |
| inapproved drug other 05/23/2012   |   | Applicatio          | on Number or Monograph (   | Citation                     | Marke     | ting Start Date | Ma            | rketing End Dat |                  |
|  | Marketing Category  | rippinculi          | in round er or monographie |                              |           |                 |               |                 |                  |

### Labeler - Cresson (557816861)

#### Registrant - Cresson (557816861)

# Name Address ID/FEI Business Operations Cresson 557816861 manufacture

Revised: 5/2012

Cresson