Rx Only
Selenium Sulfide
2.25% Shampoo

DESCRIPTION: A liquid antiseborrheic, antifungal preparation for topical application. Each mL of Selenium Sulfide 2.25% Shampoo contains 22.5 mg selenium sulfide, ammonium lauryl sulfate, caprylic/capric triglyceride, citric acid, cocamidopropyl betaine, chromium oxide green, FD&C yellow 8, distearyl phthalic acid amide, diazolidinyl urea, edetate disodium, fragrance, hydroxypropyl methylcellulose, magnesium aluminum silicate, methylparaben, panthenol, PPG-2 hydroxyethyl coco/isostearamide, propylene glycol, propylparaben, purified water, FD&C Red 40, sodium citrate, tocopherol acetate, titanium dioxide, urea, and zinc pyrithione.

CLINICAL PHARMACOLOGY: Selenium sulfide appears to have a cytostatic effect on cells of the epidermis and follicular epithelium, reducing corneocyte production.

PHARMACOKINETICS: The mechanism of action of topically applied selenium sulfide is not yet known.

INDICATIONS & USAGE: A liquid antiseborrheic, antifungal preparation for the treatment of seborrheic dermatitis of the scalp, dandruff and tinea versicolor. Urea hydrates and is useful for conditions such as dry scalp.

CONTRAINDICATIONS: Contraindicated in persons with known or suspected hypersensitivity to any of the listed ingredients.

WARNINGS: For external use only. Not for ophthalmic use. DO NOT USE ON BROKEN SKIN OR INFLAMED AREAS. If allergic reaction occurs, discontinue use. Avoid contact with eyes, genital areas and skin folds, as irritation and burning may result. If accidental contact occurs, rinse thoroughly with water. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

PRECAUTIONS: This medication is to be used as directed by a physician. Not to be used when inflammation or exudation is present as increased absorption may occur.

CARCINOGENESIS: Dermal application of 25% and 50% solutions of 2.5% selenium sulfide lotion on mice over an 88-week period indicated no carcinogenic effects.

USE IN PREGNANCY:
CATEGORY C
Animal reproduction studies have not been conducted with this medication. It is also not known whether this product can cause fetal harm when applied to the body surfaces of a pregnant woman or can affect reproduction capacity. Under ordinary circumstances, selenium sulfide 2.25% shampoo should not be used by pregnant women.

NURSING MOTHERS: It is not known whether or not this drug is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when this product is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: In decreasing order of severity: skin irritation; occasional reports of
increase in normal hair loss; discoloration of hair (can be avoided or minimized by thorough rinsing of hair after treatment). As with other shampoos, oiliness or dryness of hair and scalp may occur.

**OVERDOSAGE:** There are no documented reports of serious toxicity in humans resulting from acute ingestion of selenium sulfide 2.25% shampoo. However, acute toxicity studies in animals suggest that ingestion of large amounts could result in potential human toxicity. Evacuation of the stomach contents should be considered in cases of acute oral ingestion.

**DOSAGE AND ADMINISTRATION:**

**SHAKE WELL BEFORE USING** For *seborrheic dermatitis* and *dandruff*: Generally 2 applications each week for 2 weeks will control symptoms. Subsequently, shampoo may be used less frequently – weekly, every 2 weeks, every 3 to 4 weeks or as directed by a physician. Should not be applied more frequently than necessary to maintain control.

For *tinea versicolor*: Wet skin and apply to affected areas. Massage gently into skin working to a full lather. Allow product to remain on skin for 10 minutes, then rinse thoroughly. Repeat procedure once a day for seven days or as directed by a physician.

**HOW SUPPLIED:** Selenium Sulfide 2.25% Shampoo is supplied in 6 fluid oz. (180 mL) bottles, NDC 42192-152-06. Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized. Protect from freezing.

All prescription substitutions and / or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please NOTE: This is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or otherequivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the active ingredients, inactive ingredients (excipients) and other chemical information provided herein.

Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
Rev 0417-01

**Principal Display Panel -180 mL Bottle**

**NDC 42192-152-06**

Rx Only

Selenium Sulfide 2.25% Shampoo

6 fluid oz. (180 mL)

FOR TOPICAL USE ONLY

NOT FOR OPTHALMIC USE
Selenium Sulfide 2.25% Shampoo

6 fluid oz. (180 mL)

FOR TOPICAL USE ONLY
NOT FOR OPHTHALMIC USE

Ingredients: Each mL of Selenium Sulfide 2.25% Shampoo contains 22.5 mg selenium sulfide, ammonium lauryl sulfate, caprylic/capric triglyceride, citric acid, cocamidopropyl betaine, chromium oxide green, FD&C yellow 8, dstearyl phthalic acid amide, diazolidinyl urea, edetate disodium, fragrance, hydroxypropyl methylcellulose, magnesium aluminium silicate, methylparaben, panthenol, PPG-2 hydroxyethyl cocoyl/isostearamide, propylene glycol, propylparaben, purified water, FD&C Red 40, sodium citrate, tocopherol acetate, titanium dioxide, urea, and zinc pyrithione.

Dosage and Administration:
SHAKE WELL BEFORE USING

For seborrheic dermatitis and dandruff: Generally 2 applications each week for 2 weeks will control symptoms. Subsequently, shampoo may be used less frequently—weekly, every 2 weeks, every 3 to 4 weeks or as directed by a physician. Should not be applied more frequently than necessary to maintain control.

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See insert for full Prescribing Information.

Warnings: For external use only. Not for ophthalmic use. DO NOT USE ON BROKEN SKIN OR INFLOATED AREAS. If allergic reaction occurs, discontinue use. Avoid contact with eyes, genital areas and skin folds, as irritation and burning may result. If accidental contact occurs, rinse thoroughly with water.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Storage: Store at 20° C to 25° C (68° F to 77° F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Protect from freezing.

Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
Rev 1417-221
### Selenium Sulfide Shampoo

**Product Information**

- **Product Type**: HUMAN PRESCRIPTION DRUG
- **Item Code (Source)**: NDC:42192-152
- **Route of Administration**: TOPICAL

### Active Ingredient/Active Moiety

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<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tr>
<td>Selenium Sulfide (UNII: Z69D9E381Q) (Selenium Sulfide - UNII:Z69D9E381Q)</td>
<td>Selenium Sulfide</td>
<td>22.5 mg in 1 mL</td>
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### Inactive Ingredients

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<tr>
<th>Ingredient Name</th>
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<tr>
<td>Ammonium Lauryl Sulfate (UNII: Q7AO2R1M0B)</td>
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</tr>
<tr>
<td>Caprylic/Capric/Lauric Triglyceride (UNII: EJ1H6M2JG9)</td>
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<tr>
<td>Citric Acid Monohydrate (UNII: 2968PHW8QP)</td>
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<tr>
<td>Cocamidopropyl Betaine (UNII: 5OCF3O11KX)</td>
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**Warnings**: For external use only. Not for ophthalmic use. **Do not use on broken skin or inflamed areas.** If allergic reaction occurs, discontinue use. Avoid contact with eyes, genital areas and skin folds, as irritation and burning may result. If accidental contact occurs, rinse thoroughly with water. **Keep this and all medications out of the reach of children.**

**Precautions**: This medication is to be used as directed by a physician. Not to be used when inflammation or exudation is present as increased absorption may occur.

**Carcinogenesis**: Dermal application of 25% and 50% solutions of 2.5% selenium sulfide lotion on mice over an 88-week period indicated no carcinogenic effects.

**Use in Pregnancy**: Category C Animal reproduction studies have not been conducted with this medication. It is also not known whether this product can cause fetal harm when applied to the body surfaces of a pregnant woman or can affect reproduction capacity. Under ordinary circumstances, selenium sulfide 2.25% shampoo should not be used by pregnant women.

**Nursing Mothers**: It is not known whether or not this drug is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when this product is administered to a nursing woman.
CHROMIC OXIDE (UNII: X5Z09SU859)
FD&C YELLOW NO. 6 (UNII: H77VE93A8)
DISTEARYL PHthalAMIC ACID (UNII: 5552GSZ9LJ)
DIAZoledINYL UREA (UNII: H5RIZ3MPW4)
EDETATE DISODIUM (UNII: 7FLD91C86K)
HYPRO MELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
METHYL PARABEN (UNII: A28C7H9T)
PANTHENOL (UNII: WV9CM0O67Z)
PPG-2 HYDROXYETHYL ISO Stapamamide (UNII: 083X27325R)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PROPYLE PARABEN (UNII: Z81X25C10H)
WATER (UNII: 059QF0KO0R)
FD&C RED NO. 40 (UNII: WZB9127XOA)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
A.LPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
UREA (UNII: 8W8T17847W)
PYRITHIONE ZINC (UNII: R953O2RHZ5)

Packaging
#  Item Code  Package Description  Marketing Start Date  Marketing End Date
1  NDC:42192-152-06  1 in 1 CARTON  07/12/2017
1  180 mL 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

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment
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<td>manufacture(42192-152)</td>
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Revised: 9/2018