

Rx Only

**Selseb**<sup>®</sup>

*(selenium sulfide 2.25%)*

SHAMPOO

**DESCRIPTION:** A liquid antiseborrheic, antifungal preparation for topical application.

Each gram of **Selseb**<sup>®</sup> Shampoo contains 22.5 mg selenium sulfide, urea, zinc pyrithione, purified water, edetate disodium, propylene glycol, diazolidinyl urea, methylparaben, propylparaben, hypromellose, ammonium lauryl sulfate, titanium dioxide, caprylic/capric triglyceride, D&C yellow #8, FD&C red #40, chromium oxide greens, citric acid, sodium citrate, cocamidopropyl betaine, lauramide DEA, magnesium aluminum silicate and fragrance.

**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 AND 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.

**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 **Selseb**<sup>®</sup>. It is also not known whether **Selseb**<sup>®</sup> can cause fetal harm when applied to the body surfaces of a pregnant woman or can affect reproduction capacity. Under ordinary circumstances, **Selseb**<sup>®</sup> 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 **Selseb**<sup>®</sup> 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 **Selseb**<sup>®</sup>. 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:** *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:* Apply to affected areas and lather with a small amount of water. 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:** **Selseb**<sup>®</sup> (selenium sulfide 2.25%) **Shampoo** is supplied in 180 mL bottles, NDC 10337-500-10.

Store at controlled room temperature 15° - 30° C (59° - 86° F). Protect from freezing.

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

Mfd. for: **DERMarts**<sup>®</sup> DIVISION



**DOAK DERMATOLOGICS**

A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.



383 Route 46 West • Fairfield, New Jersey 07004-2402 USA  
1-800-405-DOAK • www.doakderm.com

Patent Pending

Manufactured by:  
Groupe PARIMA, Inc., Montreal, QC H4S 1X6 CANADA

IL202-R2  
Rev. 11/05