

**TERSI Hydrating Topical Foam***(selenium sulfide in a water and lipid based foam, 2.25%)***Rx Only****DESCRIPTION**

TERSI, which is applied topically, is an antiseborrheic, antifungal preparation for the treatment of seborrheic dermatitis and tinea versicolor of the skin. Each gram of TERSI contains selenium sulfide 2.25% as the active ingredient, and the following inactive ingredients: dimethicone, ethylparaben, glycerin, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, trolamine, and in propellants butane and propane.

**CHEMICAL STRUCTURE**

Selenium sulfide has the following chemical structure:

**CLINICAL PHARMACOLOGY**

Topically applied selenium sulfide appears to have a cytostatic effect on cells of the epidermis, reducing corneocyte production.

**PHARMACOKINETICS**

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

**INDICATIONS AND USAGE**

For the treatment of seborrheic dermatitis and tinea versicolor of the skin.

**CONTRAINDICATIONS**

Known hypersensitivity to any of the listed ingredients.

**WARNINGS**

TERSI is for external use only. It is not for ophthalmic, oral, anal or intravaginal use. Contact with eyes, lips, broken or inflamed skin, and all mucous membranes should be avoided. TERSI should not be used by persons who have a known hypersensitivity to selenium sulfide or any of the other listed ingredients.

**PRECAUTIONS**

TERSI should be used only as directed by a physician and should not be used to treat any condition other than that for which it is prescribed. TERSI should not be used on any skin area where inflammation or exudation is present as increased absorption may occur. If redness or irritation occurs, discontinue use and consult with prescribing physician.

*Pregnancy (Category C)*—Animal reproduction studies have not been performed with topically applied selenium sulfide and it is not known whether TERSI can cause fetal harm when administered to a pregnant woman. Nevertheless, TERSI should be used by a pregnant woman only if necessary.

*Nursing Mothers*—It is not known whether topically applied selenium sulfide is excreted in human milk. Due to the fact that many drugs are excreted in human milk, caution should be exercised by physicians when administering TERSI to nursing mothers.

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

Transient stinging, burning, itching or irritation is possible.

**DOSE AND ADMINISTRATION**

Clean and dry affected skin. Then apply TERSI topically to cover affected skin twice per day, or as directed by a physician. Rub in until completely absorbed.

**TERSI should be shaken vigorously before each application and inverted to administer.**

**HOW SUPPLIED**

TERSI is supplied in a 70 gram or 2.5 ounce aerosolized canister bearing the NDC Number 23710-225-70 and a 22 gram or 0.79 ounce aerosolized canister bearing the NDC Number 23710-225-20. The 22 gram canister is physician-dispensed sample product.

Store at controlled room temperature 15° - 25°C (59° - 77°F).

Contains flammable materials. Contents under pressure. Do not puncture or incinerate. Do not expose to temperatures over 120°F [48°C] even when empty. Keep out of reach of children.

TERSI is covered by U.S. Patent 5,993,830.

TERSI is manufactured for Quinova Pharmaceuticals, Inc., Newtown, PA 18940, (877) 660-6263

[www.QUINNOVA.com](http://www.QUINNOVA.com).

Prescribing Information as of September 2007.

