

## TERSI FOAM

(selenium sulfide in a water and lipid based foam, 2.25%)

### Rx Only

### DESCRIPTION

TERSI FOAM, 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 FOAM contains selenium sulfide 2.25% as the active ingredient, and the following inactive ingredients: dimethicone, glycerine, phenonip, polysorbate 20, polyvinylpyrrolidone, propylene glycol, purified water, stearic acid, triethanolamine and in propellants butane, isobutene 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 comeocyte 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 FOAM 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 FOAM should not be used by persons who have a known hypersensitivity to selenium sulfide or any of the other listed ingredients.

### PRECAUTIONS

TERSI FOAM 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 FOAM 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 FOAM can cause fetal harm when administered to a pregnant woman. Nevertheless, TERSI FOAM 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 FOAM 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.

### DOSAGE AND ADMINISTRATION

Unless otherwise directed by a prescribing physician, TERSI FOAM should be applied to affected area twice a day. TERSI FOAM should be rubbed into the skin until it is completely absorbed.

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



### HOW SUPPLIED

TERSI FOAM is supplied in a 0.79 oz or 22 gram aerosolized canister bearing the NDC Number 23710-225-20.

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

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

TERSI FOAM is manufactured for Quinnova Pharmaceuticals, Inc., Newtown, PA 18940, (877) 660-6263, [www.QUINNOVA.com](http://www.QUINNOVA.com).

Prescribing Information as of September 2007.



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### HOW SUPPLIED

TERSI FOAM is supplied in a 70 gram aerosolized canister bearing the NDC Number 23710-225-70.

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

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

TERSI FOAM is manufactured for Quinnova Pharmaceuticals, Inc., Newtown, PA 18940, (877) 660-6263, [www.QUINNOVA.com](http://www.QUINNOVA.com).

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