TERSI- selenium sulfide aerosol, foam
Quinnova Pharmaceuticals, Inc.

TERSI

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.

DOSAGE AND ADMINISTRATION
Unless otherwise directed by a prescribing physician,TERSI should be applied to affected area twice a day.TERSI should be rubbed into the skin until it is 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 10 gram or 0.36 ounce aerosolized canister bearing the NDC Number 23710-025-01. The 10 gram canister is physician dispensed sample product.

Store at controlled room temperature 15º - 25ºC (59º - 77ºF).

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.

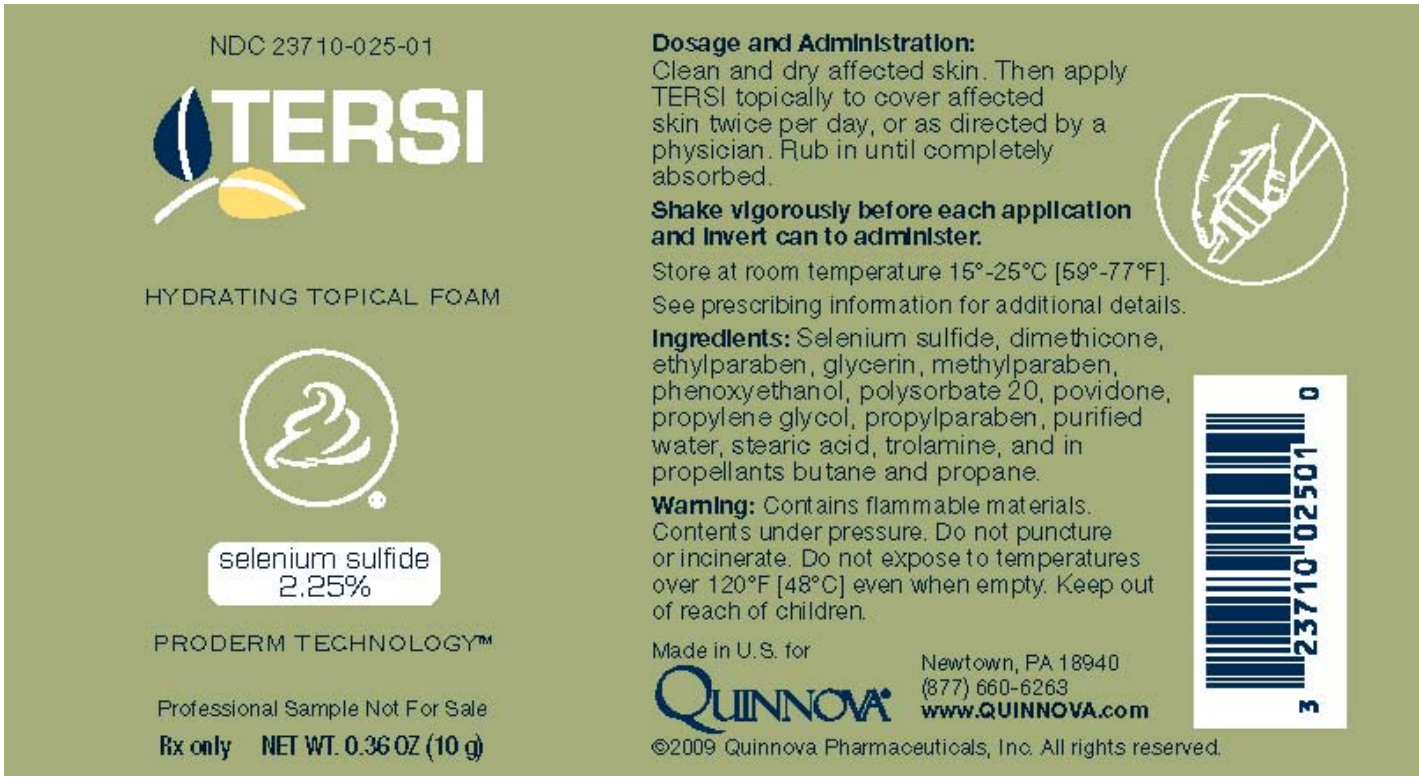
TERSI is covered by U.S. Patent 5,993,830.

TERSI is manufactured for Quinnova Pharmaceuticals, Inc., Newtown, PA 18940, (877) 6606263, www.QUINNOVA.com.

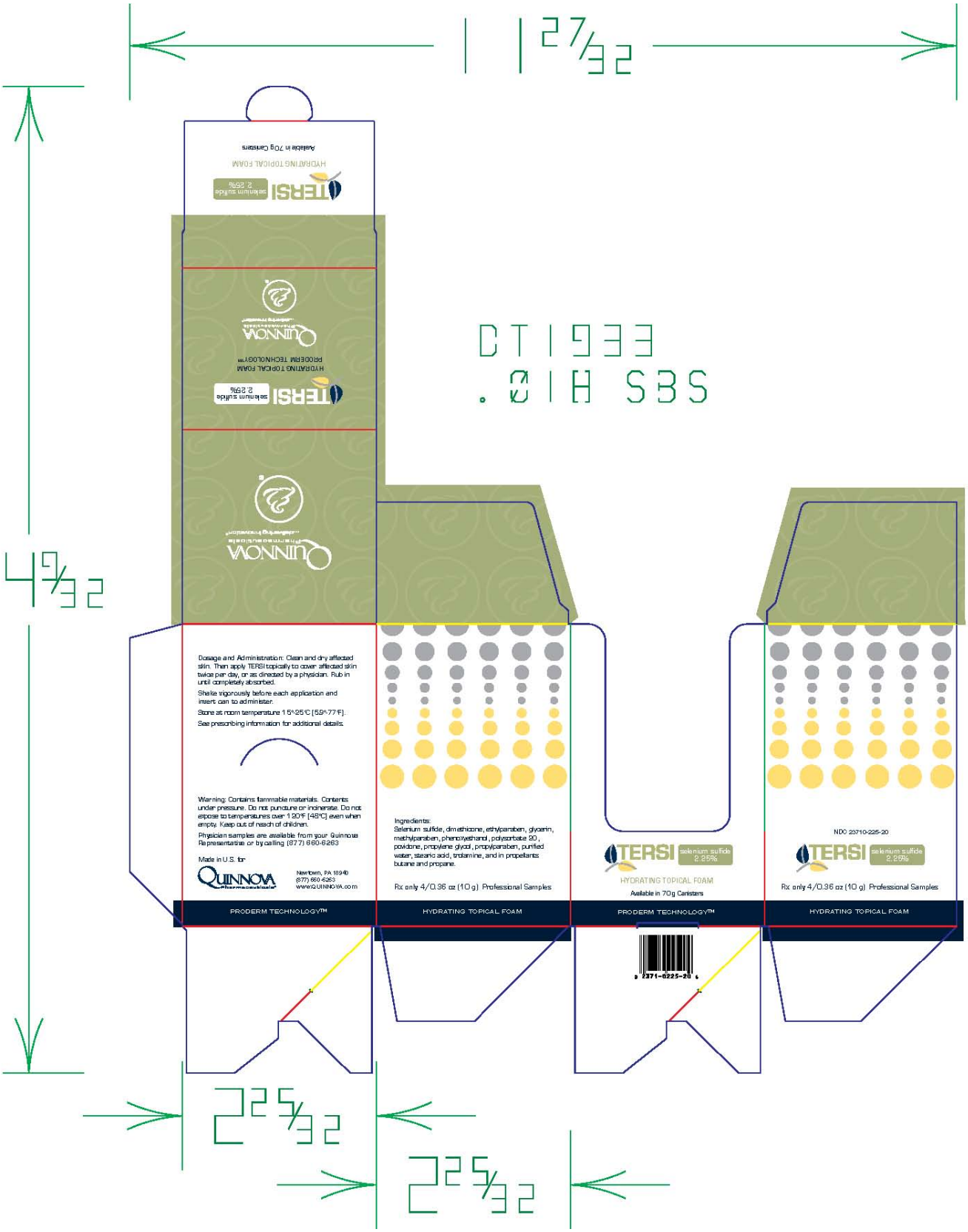
Prescribing Information as of September2007.

TRSFO025 7/08

Can Label



Folding Carton



TERSI

selenium sulfide aerosol, foam

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:23710-225

Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM - UNII:H6241UJ22B)	SELENIUM SULFIDE	1.44 g in 70 g

Inactive Ingredients	
Ingredient Name	**Strength**
POVIDONE K29/32 (UNII: 390RMW2PEQ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ETHYLPARABEN (UNII: 14255EXE39)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:23710-225-70	70 g in 1 CANISTER		
2	NDC:23710-225-01	10 g in 1 CANISTER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/01/2009	

Labeler - Quinnova Pharmaceuticals, Inc. (607183766)

Revised: 12/2009 Quinnova Pharmaceuticals, Inc.