SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

Brand name: Finasil

Product name: Terbinafine Hydrochloride Spray

Strength: Terbinafine Hydrochloride 10mg.

Pharmaceutical: Spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration, The active substance should be declared by its recommended INN. Accompanied by itssalt or hydrate form if relevant

Terbinafine Hydrochloride

Quantitative Declaration, The quantity of the active substance must be expressed per dosage unit.

Each gram contains Terbinafine Hydrochloride 10mg

3. PHARMACEUTICAL FORM

Clear liquid, colorless to light yellow spray

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Terbinafine Hydrochloride Spray for the treatment of tinea manus, tinea pedis, tinea corporis, tinea cruris and Tinea versicolor

4.2 Posology/Dosage and method of administration

For external use, limited to adult patients.

Clean and dry skin before use. Spray generously on and around the affected skin.

Interphalangeal athlete's foot, tinea corporis, jock itch, once a day, 1 week of treatment; Pityriasis versicolor, 2 times a day, course of treatment for 1 week

4.3 Contraindication

Terbinafine Hydrochloride Spray is contraindicated in patients with known hypersensitivity to any of its ingredients. Lactating women are banned..Disabled for children.

4.4 Special warnings and precautions for use

1. For external use only.

2. Avoid spraying into the face and eyes, as alcohol can cause irritation. In case of contact with eyes and other mucous membranes (such as mouth, nose, etc.), immediately rinse thoroughly with plenty of running cold water, and consult a doctor if necessary.

3. Pregnant women and women who may become pregnant or are trying to get pregnant should be used with caution. Consult a doctor or pharmacist before using this product. This product is not recommended for pregnant women unless necessary.

4. If there is a burning sensation, redness and swelling in the medication site, the drug should be stopped, and the local drug should be washed, and consult a doctor if necessary.

5. This product does not need to be bandaged after application. When treating infections in the folds of the skin, the treated area can be covered with gauze, especially at night. If gauze is to be used, use new, clean gauze every time.

6. Do not use on skin breaks.

7. Those who are allergic to this product are banned, and those who are allergic should use it with caution.

8. It is forbidden to use this product when the properties change.

9. Keep this product out of reach of children.

10. Do not allow the infant to come into contact with the treated skin, including the breast, of others.

11. If you inhale this product accidentally and have any symptoms or persistent symptoms, please consult a doctor immediately.

12. If you are using other drugs, please consult a doctor or pharmacist before using this product.

13. When using this product, do not use other drugs in the treatment area.

14. If symptoms do not improve after two weeks of medication, consult a physician or pharmacist.

15. Keep the affected area clean and avoid rubbing, washing towels and laundry frequently can help treatment.

16. Avoid scratching the affected area, as this may lead to further damage, delay healing or spread the infection.

17. Wash your hands after touching the affected area and do not share towels or clothing with others to avoid the spread of infection.

18. This product contains propylene glycol, which may cause skin irritation.

19. This product has no effect on the ability to drive and use machinery.

4.5 Interaction with other drug products and other forms of interaction

Drug interactions may occur if used concomitantly with other drugs, please consult a physician or pharmacist for details

4.6 Fertility, pregnancy and lactation

Terbinafine topical has been assigned to pregnancy category B by the FDA. Animal studies using high oral and subcutaneous doses have not revealed evidence of teratogenicity. There are no controlled data in human pregnancy. Terbinafine should only be used during pregnancy when the need has been clearly established.

Terbinafine is excreted into human milk in small amounts. Following a 500 mg oral dose of terbinafine to two subjects, 0.65 mg and 0.15 mg were excreted into breast milk, representing 0.13% and 0.03%, respectively.

Excretion of terbinafine into breast milk following topical exposure is expected to be minimal. The manufacturer recommends that due to the potential for adverse reactions in nursing infants, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. Nursing mothers should avoid applying terbinafine topical to the breast.

4.7 Effects on ability to drive and use machines

Terbinafine Hydrochloride Spray has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Similar to all drugs, this product can cause adverse reactions, but not everyone can occur. Most people benefit from the use of this product.

Common adverse reactions (less than 1 in 10 people may be affected): skin desquamation, itching.

Occasional adverse reactions (less than 1 in 100 people may be affected): skin lesions, crusting, skin discomfort, skin color change, redness, burning sensation, pain, pain at the site of administration, irritation at the site of administration.

Rare adverse reactions (less than 1 per 1000 people may be affected): dry skin, eczema, contact dermatitis, worsening of symptoms; If accidentally touched with the eyes, it may have a stimulating effect on the eyes.

If you experience any of the following symptoms that may indicate an allergic reaction, stop taking the drug and seek medical help immediately:

difficulty breathing or swallowing;

swelling of the face, lips, tongue or throat;

The skin is severely itchy and accompanied by a red rash or raised erythema nodosum.

If you experience any adverse reactions, tell your doctor or pharmacist. Includes any possible adverse reactions not listed in this specification

4.9 Overdose

Terbinafine Hydrochloride Spray is for external use only. If accidental ingestion of the cream occurs, appropriate method of gastric lavage can be used.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Terbinafine is an allylamine that has a broad spectrum of antifungal activity. At low concentrations Terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi.

Terbinafine interferes specifically with fungal sterol biosynthesis at an early step. This leads to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane.

The enzyme squalene epoxidase is not linked to the cytochrome P-450 system. Terbinafine does not influence the metabolism of hormones or other drugs depending on cytochrome P-450 system.

Terbinafine provides long-lasting protection. More than 90% of patients with interdigital tinea pedis (athlete's foot) treated with Terbinafine 1 % cream for one week show no mycological evidence of relapse or re-infection

by three months after start of treatment. No such data on tinea cruris are available.

5.2 Pharmacokinetic properties

Less than 5% of the dose is absorbed after topical application; systemic exposure is therefore very slight.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl glycol, Alcohol, Ethoxylated C16-18 alcohols, Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C in dry place away from sunlight.

Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Inner-package: High density polyethylene bottles for external use in liquid medicine

Pack Size: 15ml/bottle, 1bottle/box

Packaging Specifications (primary packaging, secondary packaging)

Packed in bottle in box with 15ml and printed with batch number and manufacturing date.

Packed into carton with paper boxed inside.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE F PRODUCT REGISTRATION

Applicant: AKSO PHARMACEUTICAL NIGERIA LIMITED..

Adress: No. 320, Odusami Street, off Wempco Road, Ogba , Lagos Nigeria

E-mail: 506798052@qq.com

Contact person : Brian Fu

Tel: 09118269061

8. DRUG PRODUCT MANUFACTURER

Manufacturer name: FRONT PHARMACEUTICAL PLC

Physical address: No.369 Baocheng Road, Xuancheng Economic and Technical Development Zone, Anhui, China

Tel: 86-0563-2625199

Fax: 86-0563-2625199

E-mail: export@frontpharm.com

9. NAFDAC REGISTRATION NUMBER(S)