SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Nitrofurazone Cream 0.2% 30g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For product Nitrofurazone Cream, it contains 0.06g Nitrofurazone per tube.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nitrofurazone Cream is indicated in bacterial skin infections including pyodermas,infected dermatoses and infections of cuts, wounds, burns and ulcers due to susceptible organisms. Nitrofurazone Cream is also of value in other conditions such as treatment of skin graft donor sites and otitis externa.

4.2 Posology and method of administration

Always use Nitrofurazone Cream as directed by your doctor. Check the label on the medicine for exact dosing instructions.

Nitrofurazone Cream is administered topically.Apply directly to the wound with sterile tongue-depressor or other spatula.Alternatively,melt the Cream in a beaker at a litle above body temperature and pour gently on to the wound. The Cream may also be applied on a gauzc dressing. For extensive burned areas, large strips of sterile gauze impregnated with Nitrofurazone Skin Cream by covering the Nitrofurazone Skin Cream impregnated gauze with an impermeable layer such as jaconet or gauze saturated with petroleum jelly. If bandages stick, remove them by saturating with sterile saline. with petroleum jelly. If bandages stick, remove them by saturating with sterile saline.

4.3 Contraindications

Nitrofurazone Cream is contra- indicated in patients with known sensitivity to nitrofurazone.

4.4 Special warnings and special precautions for use

It is not recommended to continue using Nitrofurazone Cream when the infection is cleared. When Nitrofurazone Skin Cream is used in the treatment of ear infection ,the patient should be warned to stop therapy if any signs of irritation or oedema of the meatus appear.

4.5 Interaction with other FPPs and other forms of interaction

Nitrofurazone Cream is contra- indicated in patients with known sensitivity to nitrofurazone.

4.6 Known symptoms of over dosage and particulars of its treatment:

See side effects.

Treatment is symptomatic and supportive.

4.7 Storage instructions: .

Nitrofurazone Cream is supplied in aluminum collapsible tubes and the Cream also in black plastic jars. It should be stored in light proof containers and contact with metals other than stainless steel or aluminum should be avoided.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification:

Wound disinfectants.

5.2 Pharmacokinetic properties

Nitrofurazone Cream is a synthetic topical antibacterial agent unrelated to the antibiotics and sulphonamides, with a broad spectrum of action.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Antibacterial; topical antiprotozoal.

5.2 Pharmacokinetic properties

Nitrofuracilin is a synthetic antibacterial agent, which can inhibit Gram-positive and Gram-negative bacteria

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Composition
Nitrofurazone
Stearyl Alcohol
Glycerin Monostearate
Stearic acid
White Petrolatum
Liquid paraffin
Ethylparaben
Primary Alcobol Ethoxylate
Sodium Lauryl Sulfate
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30 ℃. Sealed well and protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

It is sealed Aluminium tube with a cap, and kept cream inside. One Aluminium tube in one box.

6.6 Instructions for use and handling

Local external use. Apply appropriate amount of the product to the affected area and gently rub for a while 2-3 times a day.

Ask your pharmacist how to dispose of medicines no longer required.

7. MARKETING AUTHORISATION HOLDER

Jiangxi Xier Kangtai Pharmaceutical Co.,Ltd

North Zone, High New-Tech Industrial Zone, Pingxiang, China

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

07897/08777/NMR/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Oct 6, 2022

10. DATE OF REVISION OF THE TEXT

Dec.21，2019.

1. Label