

SUMMARY OF PRODUCT CHARACTERSTICS

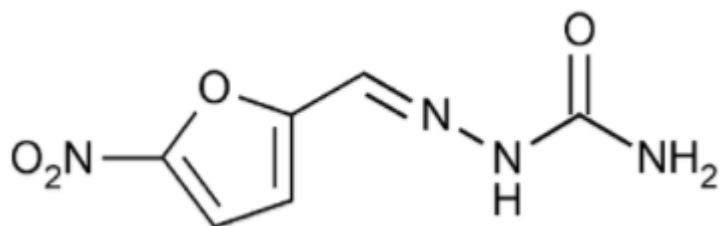
1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Name of product: Nitrofurazone Ointment

Strength: 0.2%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient: Nitrofurazone



C₆H₆N₄O₄ 198.14

Hydrazinecarboxamide, 2-[(5-nitro-2-furanyl)methylene]-.
5-Nitro-2-furaldehyde semicarbazone [59-87-0].

3. PHARMACEUTICAL FORM

Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nitrofurazone Ointment is indicated in bacterial skin infections including pyodermas, infected dermatoses and infections of cuts, wounds, burns and unclear due to susceptible organisms. Nitrofurazone ointment 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

Nitrofurazone ointment is administered topically. Apply directly to the wound with sterile tongue-depressor or other spatula. Alternatively, melt the ointment or cream in a beaker at a little above body temperature and pour gently on to the wound.

The ointment or cream may also be applied on a gauze dressing. For extensive burned areas, large strips of sterile gauze impregnated with Nitrofurazone ointment by covering the Nitrofurazone ointment 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. Dressing may be left undisturbed on burns, cuts and wounds for 7-19 days.

4.3 Contraindications

This product is contraindicated in patients with known sensitivity to nitrofurazone.

4.4 Special warnings and special precautions for use

Nitrofurazone ointment should be used with caution in patients with known or suspected renal impairment, the polyethylene glycols present in the base can be absorbed through large areas and denuded skin and may cause progressive renal impairment and metabolic acidosis.

4.5 Interaction with other FPPs and other forms of interaction

If combined with other drugs, drug interactions may occur. For details, please consult your physician or pharmacist..

4.6 Pregnancy and lactation

Pregnancy and lactation: not clear.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Side effects

Sensitization and generalized allergic skin reactions may be produced. Intolerance to nitrofurazone, necessitating withdrawal, has been encountered. Cross sensitization to other nitrofurans derivatives may occur.

4.9 Overdose

See Side effects.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Nitrofurazone is a synthetic antibacterial drug that inhibits both Gram-positive and Gram-negative bacteria.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin
Paraffin
White Soft Paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at a temperature below 30°C, preferable between 15°C and 30 °C.

6.5 Nature and contents of container

It is collected in an Aluminum tube, one tube per box.

6.6 Instructions for use and handling

Apply to the eyelids, generally 3 times a day.

7. MARKETING AUTHORISATION HOLDER

SHANGHAI GENERAL PHARMACEUTICAL CO., LTD.

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

06123/07989/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 07-07-2021

10. DATE OF REVISION OF THE TEXT

20/12/2022

8. Packing of product: Nitrofurazone 0.2% Ointment, tube of 50gm

LABEL

上版本: 20190713 修改次: 001 单位: mm			
客户名称:	浙江圣华 (638)	备注:	批号改为 201007 10/2020 10/2023
产品名称:	呋喃西林 50g		

1:1图 **规格:** 27X155 **光标:** 3X9 **留尾:** 38.5

155.00 mm

84.00 mm

38.50 mm管尾到字体

颜色按旧版

生产打板均以本稿为准
 请校对并确定本稿为最
 终稿后签字确认, 谢谢!

日期: 2020/08/26

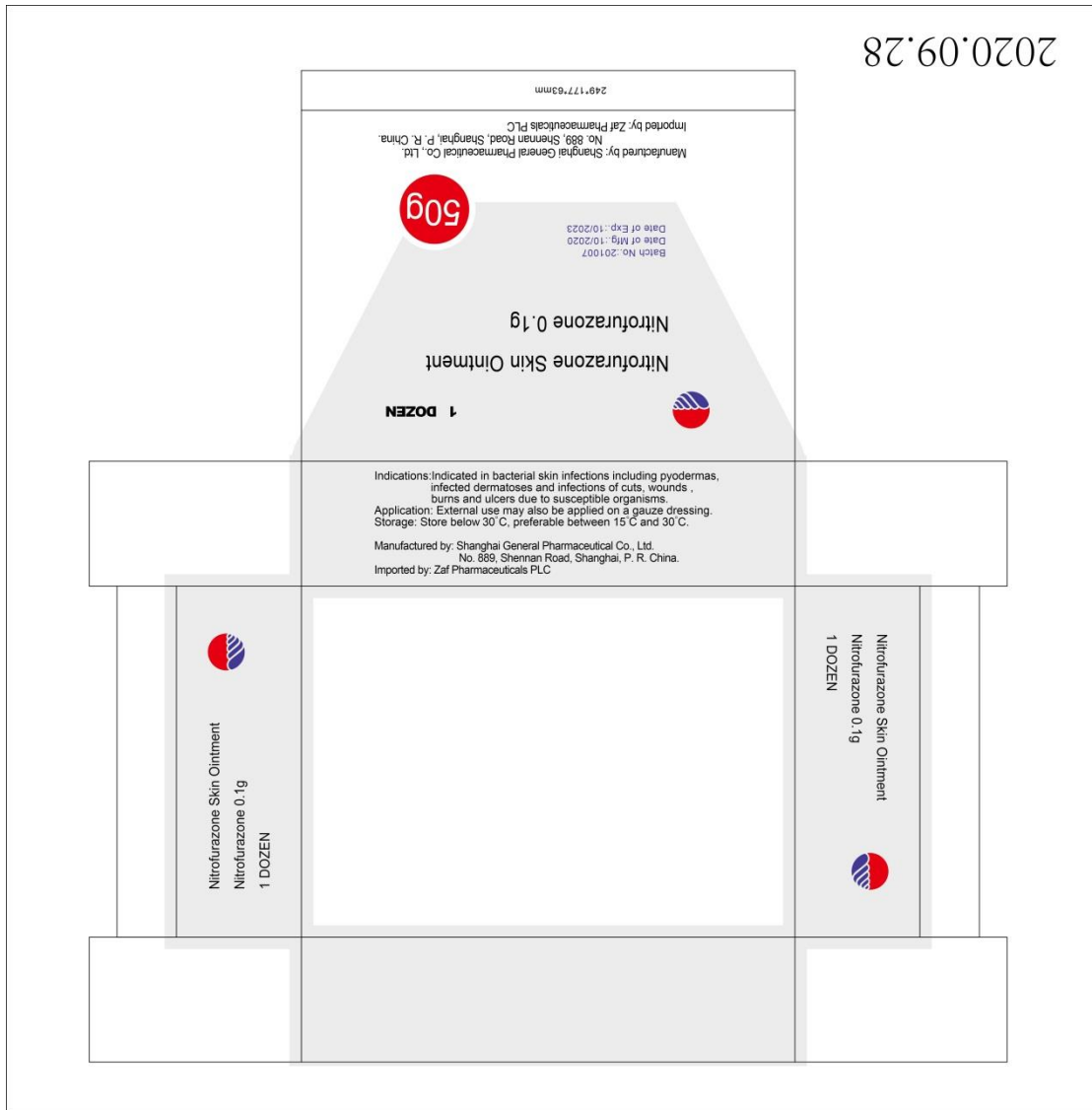
SMALL BOX

175X40X30MM




2020.09.28

MIDDLE BOX



CARTON

52X37.3X34.5CM

<p>Nitrofurazone Skin Ointment 0.2%, 50g 12tubesx20boxes</p> <p><small>Manufactured by: Shanghai General Pharmaceutical Co.,Ltd. No.889 Sherman Road,Shanghai, P. R. China Imported by: Zaf Pharmaceuticals P.L.C. Addis Ababa,Ethiopia</small></p>	<p> Batch No.: 201007 Mfg. Date: 10/2020 Exp Date: 10/2023 N.W.: 16 KGS G.W.: 20.5 KGS Meas.: 52X37.3X34.5 CM HANDLE WITH CARE!</p>	<p>Nitrofurazone Skin Ointment 0.2%, 50g 12tubesx20boxes</p> <p><small>Manufactured by: Shanghai General Pharmaceutical Co.,Ltd. No.889 Sherman Road,Shanghai, P. R. China Imported by: Zaf Pharmaceuticals P.L.C. Addis Ababa,Ethiopia</small></p>	<p>Store below 30°C,preferable between 15°C and 30°C. Protect from freezing.</p>
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