

Read all of this leaflet carefully before you starts using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others.
- It may harm them, even if their symptoms are the same as yours - If you get side effects and they become serious or if you notice any side effects

not listed in this leaflet, please tell your doctor or pharmacist In this leaflet

- 1- What Conazol cream is and what it is used for
- 2- Before you use Conazol cream
- 3- How to use Conazol cream
- 4- Possible side effects
- 5- How to store Conazol cream
- 6- Further information
- 1- What Conazol cream is and what it is used for

Conazol Cream is a medicine which is used in the treatment of fungal and associated bacterial infections of the skin and nails. Skin infections may appear on the hands, feet, outer ear, trunk or groin and include athlete's foot, dhobie itch and intertrigo. Conazol Cream is also effective against infected nappy rash.

The cream contains miconazole nitrate which works by destroying both the fungus that causes the infection and some of the associated bacteria which may also be present. It also has moisturising properties to help soothe cracked, red skin. This medicine is for use in adults and children of all ages.

2- Before you use Conazol cream This medicine is suitable for most adults and children but a few people should not

use it. If you are in any doubt, talk to your doctor or pharmacist. Do not use Conazol cream if

- If you have ever had a bad reaction to any of the ingredients. If this applies to you, get advice from a doctor or pharmacist without using Conazol

Cream.

Talk to your doctor or pharmacist if you are taking-

- Oral anticoagulants (drugs used to thin the blood, such as warfarin). If you are not sure about any of the medicines you are taking, get advice from a

doctor or pharmacist. If you are pregnant or breast-feeding-- Ask your doctor or pharmacist for advice before using this medicine if you are

pregnant or breast-feeding.

Special warnings about this medicine - Do not let the cream get into your eyes.

- If you experience any irritation or sensitivity to the cream, stop using this medicine.

Some of the ingredients can cause problems

- Butylated hydroxyanisole (E320) may cause local skin reactions (e.g. contact $\label{eq:dermatitis} \mbox{dermatitis), or irritation to the eyes and mucous membranes.}$

3- How to use Conazol cream

- Each tube of cream is sealed - use the cap to pierce the seal.

- For cutaneous use only, which means it is applied directly to the affected area of

How to apply the cream

- Wash the infected area and dry it well. As many skin conditions are contagious, you should keep a towel and flannel for your own use and not share it so that you do not infect anyone else.

- Apply the cream onto the infected area and surrounding skin. - Wash your hands carefully after applying the cream to avoid spreading the

infection to other parts of the body or to other people. Similarly, clothing which comes into contact with the infected areas, such as socks, should be washed and changed frequently.

Adults and children of all ages Skin infections

- Apply to the infected skin twice a day. Continue treatment for 7 days. after all the symptoms have cleared to prevent them from coming back.

- Apply to the infected area once or twice daily. Continue treatment for 10 days.

after all the symptoms have cleared to prevent them from coming back

If symptoms persist talk to your doctor.

If anyone has swallowed this product

If anyone accidentally swallows Conazol Cream, contact a doctor or your nearest Accident and Emergency department (Casualty), taking this leaflet and pack with you. If you forget to use the medicine

If you forget to use a dose, use the next dose when needed. Do not use a double dose. 4- Possible side effects

Conazol Cream can have side-effects, like all medicines, although these don't

affect everyone and are usually mild.

If you experience any of the following, stop using the medicine and seek immediate medical help-Uncommon:

(less than 1 in 100 people are affected)

- Skin burning sensation, application site reactions, application site irritation, application site burning, application site warmth, application site itchiness, skin

inflammation, skin discoloration. Other side-effects which may occur but it is

Unknown how often:

- Intolerance, severe allergic reaction including: swelling of the face, lips, tongue or throat, skin irritation, rash, redness, and itchiness.

If you experience any side-effects not included in this leaflet or are not sure about anything, talk to your doctor or pharmacist.

5- How to store Conazol cream

- Keep out of the reach and sight of children
- Store below 30° C.
- Store in the original container.
- To be used within one month after first opening.

- Do not use Conazol cream after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month.

- Do not use Conazol cream if you notice any visible signs of deterioration.

- Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6- Further information

a- What Conazol cream contain

Each one gram contains

Miconazole Nitrate 20 mg

The other ingredients are cetostearyl alcohol, cremophor A25, light liquid paraffin, white soft paraffin, (E211), (E320), E (330), E (1520), disodium EDTA and purified Water.

b- What Conazol cream looks like and contents of the pack

Conazol cream is homogenous smooth white cream to pale yellow color, odorless. Pack size: collapsible aluminum tube containing 15 gm, 30 gm capacity.

c- Marketing Authorisation Holder and Manufacturer Manufactured by DEEF Pharmaceutical Industries

Tel: 016 332 3333

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For any information about this medicinal product, please contact the local representative of the marketing authorization holder: DEEFيف

DEEF Pharmaceutical Industries

Badaye - Qassim Saudi Arabia

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E-mail: npc.drug@sfda.gov.sa - Web: www.sfda.gov.sa/npc

To report any side effect(s)-rmacovigilance and Drug Safety Center (NPC) To report any side effectia.

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Fax. +966-11-205-7662
Calling Yigilance and Crisis Management Executive Directorate
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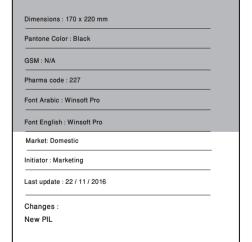
This is a medicament

Medicament is a product which affects your health, and its consumption contrary to instruction dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the Phywho sold the medicament.

wno solo the medicament. The doctor and the pharmacist are experts in medicine, its benefits and risks. Do not by yourself interrupt the period of treatment prescribed for you. Do not repeat the same prescription without consulting your doctor. Keep the medicament out of reach of children

Council of Arab Health Ministers & Union of Arab Pharmacists



| PRODUCT | PRODUCT Conazole 30 gm Domestic | | DRAWING NO. | Al0093-02 | | |
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| PREPARED BY | REVIEWED BY | | | | | APPROVED BY |
| AW Manager | Medical manager | R&D Manager | Marketing Director | Medical & RA Director | Technical director | QA Manager |
| Sign: | | | | | | |
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