SCHEDULING STATUS

S1

SUTHAREX CREAM, 2 g per 100 g, Cream

Miconazole nitrate

Read all of this leaflet carefully because it contains important information for you.

SUTHAREX CREAM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SUTHAREX CREAM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SUTHAREX CREAM with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What SUTHAREX CREAM is and what it is used for

2. What you need to know before you use SUTHAREX CREAM

3. How to use SUTHAREX CREAM

4. Possible side effects

5. How to store SUTHAREX CREAM

6. Contents of the pack and other information

1. What SUTHAREX CREAM is and what it is used for

SUTHAREX CREAM is a topical anti-fungal preparation used for the treatment of skin infections caused by fungi including yeasts, and some bacteria.

These infections may appear on the:

- Trunk
- Hands or feet

- Scalp or outer ear
- Groin
- Buttocks
- Mouth

SUTHAREX CREAM can be used for the treatment of Athlete's foot and nappy rash.

2. What you need to know before you use SUTHAREX CREAM

Do not use SUTHAREX CREAM:

- if you are allergic (hypersensitive) to miconazole nitrate, any other similar antifungals, or any other ingredient used in SUTHAREX CREAM.

Warnings and precautions

Take special care with SUTHAREX CREAM:

- If your condition worsens or does not improve; or if a rash or new symptom present, discontinue the use of SUTHAREX CREAM (see section 4).
- SUTHAREX CREAM is for or external use only.
- Especially when applied to infants, avoid contact with eyes. If you accidently get SUTHAREX CREAM in their eyes, immediately rinse them thoroughly with clean water.
- Do not close the application site or use towelling nappies after SUTHAREX CREAM is applied. These conditions favour the growth of yeast and the release of its irritating substances.

Children and adolescents

No data are available.

Other medicines and SUTHAREX CREAM

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

It is unlikely that SUTHAREX CREAM may interact with any medicines or substances; this is because it is applied locally.

Please discuss the use of the following medicines or substances in combination with SUTHAREX CREAM with your doctor or pharmacist:

- Anticoagulants medicines (medicines that prevent clotting of blood) such as warfarin. Your doctor may check whether these medicines are working properly.
- Medicine taken orally for diabetes.
- Phenytoin (a medicines used for epilepsy).

SUTHAREX CREAM with food and drink

Not applicable.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not use SUTHAREX CREAM if you are pregnant or breastfeeding your baby.

Driving and using machines:

If used as directed, SUTHAREX CREAM should not influence your ability to drive and use machines.

3. How to take SUTHAREX CREAM

Do not share medicines prescribed for you with any other person:

Always use SUTHAREX CREAM exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

SUTHAREX CREAM is to be applied topically.

Directions for use:

1. Each tube of SUTHAREX CREAM is sealed. You will need to use the cap to pierce the seal.
2. Apply a sufficient amount of SUTHAREX CREAM to cover the affected area and rub in gently.
3. SUTHAREX CREAM should be applied twice a day (morning and evening).

4. Use SUTHAREX CREAM for 2 – 5 weeks or until after all signs of relief are seen.
5. Continue treatment with for an additional 10 – 14 days after the affected area has healed and no signs of infection are present. This will prevent the infection from returning.

Continue to apply SUTHAREX CREAM for the full period of treatment.

Do not close the application site or use towelling nappies after SUTHAREX CREAM is applied (see "**Take special care with SUTHAREX CREAM**").

Personal hygiene:

- Unless the affected skin is on your hands, wash your hands with soap and water after using the cream.
- Washing your hands after using the cream will prevent the spreading of the infection to other parts of your body or to other people.
- Do not allow other people to use the same towel or hand cloth. This will prevent them from getting your infection.
- Clothing that is in contact with the infected skin should be washed and changed often. SUTHAREX CREAM is non-greasy and should not stain clothes.

FOR EXTERNAL USE ONLY. DO NOT SWALLOW.

Do not put SUTHAREX CREAM into or near the eyes - it is for use on the skin only.

If you are unsure how to use SUTHAREX CREAM, consult your doctor, pharmacist or other healthcare professional for advice.

If you use more SUTHAREX CREAM than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Overdosage may occur if SUTHAREX CREAM is used for prolonged periods and with extensive application. Skin irritation may occur with an overdosage, which usually disappears after you discontinue the use of SUTHAREX CREAM.

If you forget to use SUTHAREX CREAM

Always use SUTHAREX CREAM as prescribed. If you miss a dose, apply as soon as you remember. Do not apply more of SUTHAREX CREAM to make up for a

forgotten dose. If you do not remember a missed dose until the next dose is due, skip the missed dose and continue with the regular dosing schedule.

If you stop using SUTHAREX CREAM

You should continue using SUTHAREX CREAM for at least 10 to 14 days to prevent your skin condition (infection) from returning.

4. Possible side effects

SUTHAREX CREAM can have side effects.

Not all side effects reported for SUTHAREX CREAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SUTHAREX CREAM, please consult your health care provider for advice.

The side-effects experienced with SUTHAREX CREAM may be limited to the area of application, because it is applied topically.

The following side-effects may be experienced with the use of SUTHAREX CREAM:

- Allergic reaction. Signs of an allergic reaction include a rash, difficulty swallowing or breathing, and swelling of your lips, face, throat or tongue.
- Burning sensation
- Contact dermatitis (skin inflammation caused by application of SUTHAREX CREAM)
- Itching
- Redness of the skin
- Rash
- Skin inflammation
- Skin irritation
- Swelling of skin
- Blistering
- Hives

Discontinue the use of SUTHAREX CREAM if these effects occur.

The side-effects are not frequent.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA"s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SUTHAREX CREAM.

5. How to store SUTHAREX CREAM

Store all medicines out of reach of children.

Store at or below 25 ºC in a well closed container and protected from light and freezing.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SUTHAREX CREAM contains

The active substance is miconazole nitrate.

Preservatives:

Imidurea:	0,2 % *m/m*
Methyl paraben:	0,15 % *m/m*
Sodium propyl paraben:	0,15 % *m/m*

Antioxidant:

Butylated Hydroxytoluene:	0,02 % *m/m*

The other ingredients are cetearyl octanoate, glycerine, glyceryl stearate, mineral oil (light), incromega E5015 [ethyl ester of eicosapentaenoic acid (EPA) (50 %) and docosahexaenoic acid (DHA) (15 %)], PEG 100 stearate, polyoxyl 40 hydrogenated castor oil, polawax GP 200, purified water and vitamin F ethyl ester.

What SUTHAREX CREAM looks like and contents of the pack

A smooth white to off-white cream. No lumps or flocculation.

SUTHAREX CREAM is packed in a white Aluminium Barrier Laminated Tubes (ABL) tubes with a white cap containing 25 g, 30 g, 40 g or 50 g cream, in a carton outer box.

Holder of Certificate of Registration and Manufacturer

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