

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

**Xeraspor T Cream
(Clotrimazole 10 mg)**

Read all of this leaflet carefully before you start using XERASPOR T CREAM

- Keep this leaflet. You may need to read it again.
- Do not share XERASPOR T CREAM with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in the leaflet

1. What XERASPOR T CREAM is and what it is used for.
2. What you need to know before you use XERASPOR T CREAM.
3. How to use XERASPOR T CREAM.
4. Possible side effects
5. How to store XERASPOR T CREAM.
6. Contents of the pack and other information.

1.What XERASPOR T CREAM is and what it is used for

The active substance in XERASPOR T CREAM is clotrimazole. Antifungals for topical use – imidazole and triazole derivatives.

XERASPOR T CREAM is used treat fungal infections of the skin caused by moulds, yeasts and fungi and also for skin diseases with secondary infections of these fungi.

These fungal infections may include among others:

1. Fungal infections of the skin and skin folds, (e.g. fungal infections of the groin, Dhobie itch or jock itch and barber's itch.)
2. Ringworm.
3. Fungal infections in-between toes or fingers e.g. athlete's foot.
4. Candida vulvitis (vulval thrush).
5. Candida balanitis, (thrush of the glans penis).
6. Pityriasis (Tinea) versicolor.
7. Erythrasma.
8. Paronychias, associated with nail mycoses, (fungal infections of the tissues adjacent to the nail of a finger or toe).

2. What you need to know before you use XERASPOR T CREAM

Do not use XERASPOR T CREAM

If you are allergic to clotrimazole or any of the other ingredients in XERASPOR T CREAM (listed in section 6).

Warnings and precautions

Take special care with XERASPOR T CREAM

- Direct contact with XERASPOR T CREAM may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.
- Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis)
- Not intended for ophthalmic use.

Other medicines and XERASPOR T CREAM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Pregnancy, breastfeeding and fertility

- If you are pregnant or breastfeeding your baby, 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.
- Safety and efficacy of XERASPOR T CREAM has not been established in pregnancy.
- XERASPOR T CREAM during pregnancy but only under the supervision of a medical practitioner or midwife.
- Breastfeeding should be discontinued during treatment with XERASPOR T CREAM

Driving and using machines

XERASPOR T CREAM has no or negligible influence on the ability to drive or use machinery.

3. How to use XERASPOR T CREAM

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

XERASPOR T CREAM should be applied thinly to the affected areas 2-3 times a day and rubbed in. A small amount of cream is usually sufficient for an area about the size of a palm.

Successful treatment demands that XERASPOR T CREAM be applied correctly and over a sufficiently long period of time. The normal period of treatment is 3-4 weeks.

Topical treatment of fungal infections should be continued for approximately 2 weeks after the disappearance of all symptoms despite a rapid, subjective improvement, in order to prevent relapse.

For the treatment of athlete's foot and other fungal infections in skin folds it is important to dry the area

carefully.

If you use more XERASPOR T CREAM than you should

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

In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

If you forget to use XERASPOR T CREAM

Apply the cream as soon as possible and then continue the rest of your treatment as usual.

4. Possible side effects

XERASPOR T CREAM can have side effects.

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

If any of the following happens, using XERASPOR T CREAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rash
- Swallowing or breathing problems.
- Swelling of your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.

These are all very serious side effects. If you have them, you may have had a serious reaction to XERASPOR T CREAM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of skin.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Local reactions including skin irritation and burning may occur.
- Contact allergic dermatitis has been reported.
- In cases of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur.

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

Applicant: FDC SA (Pty) Ltd
Product Name: Xeraspor T Cream
(Clotrimazole 10 mg)
Dosage form and strength: Cream, 10 mg

Approved Date: 21 August 2023

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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 XERASPOR T CREAM.

5. How to store XERASPOR T CREAM

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What XERASPOR T CREAM contains

The Active substance is Clotrimazole.

Each 1 g of cream contains: 10 mg Clotrimazole

The other ingredients are

Propylene glycol

Purified water

Biopure 100

Nipastat

Liquid paraffin

Cremophor A25

Cremophor A6

Cetostearyl alcohol

What XERASPOR T CREAM looks like and contents of the pack

A soft white cream.

Aluminium printed tube containing 20 g of cream.

HOLDER OF CERTIFICATE OF REGISTRATION

FDC SA (PTY) LTD

Unit J3, The Willows Office Park,

Farm Road, The Willows, Pretoria East,

Pretoria, 0081, South Africa.

This leaflet was last revised in

21 AUGUST 2023

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Product Name: Xeraspor T Cream
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Dosage form and strength: Cream, 10 mg

Approved Date: 21 August 2023

Registration number

20/20.2.2/0390

Access to the corresponding Professional Information

Please find the submitted Professional information

MOCKUP CLEAN PIL

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	FDC Limited	LEAFLET	Minipharma Code No.:
Size	122 (L) x 440 (H) mm		
Folded Size	-----		
No. of Folds	-----		
GSM	40 gsm		
Paper	Bible Paper		
Specification No.	-----		
Colour	 Pantone Black C		
SAP Code:		Supersedes SAP Code: -----	
Location: Waluj-South Africa		Prepared On: 04-09-2023	
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