SUMMARY OF PRODUCT CHARACTERISTICS

Pitrex®

1. Name of the medicinal product

Pitrex®

Cream

2. Qualitative and quantitative composition

Tolnaftate 1.0% w/w

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Cream

Pure white, smooth homogeneous cream, free from specks and the like.

4. Clinical particulars

4.1 Therapeutic indications

Topical treatment of superficial dermatomycoses.

4.2 Posology and method of administration

Apply a thin layer on the affected area 2-3 times daily.

Do not exceed the recommended dosage.

This medicine is not usually intended for administration to children and infants under 2 years of age.

If there is no improvement in the condition within 10 days, the patient should refer to the doctor.

4.3 Contraindications

Contraindicated in nail or scalp infections.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For external use only.

Keep out of eyes.

If symptoms do not improve within 10 days, discontinue use and consult your doctor.

Keep out of the reach and sight of children.

The product contains butylated hydroxytoluene (E 321) which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. If irritation or rash occurs, use of the product should be discontinued and medical advice should be sought.

4.5 Interaction with other medicinal products and other forms of interaction

Not relevant to topical use

4.6 Pregnancy and lactation

No known restrictions.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Adverse reactions have been ranked under headings of frequency using the following convention:		
Very common	≥ 1/10	
Common	≥ 1/100 to ≥ 1/10	
Uncommon	≥ 1/1,000 to < 1/100	
Rare	≥ 1/10,000 to < 1/1,000	
Very rare	<1/10,000	
Not known	(cannot be estimated from the available data)	
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.		
System Organ Class	**Frequency**	**Adverse Events**
Skin and subcutaneous tissue disorder	Unknown	Skin reactions Skin irritation Pruritus Contact dermatitis

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.9 Overdose

Symptoms:

There have been no reports of over dosage with the use of this product.

Management:

In the case of over dosage, treatment should be symptomatic and supportive.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Tolnaftate is a topical antifungal agent (ATC Classification: D01AE 18)

5.2 Pharmacokinetic properties

Not applicable for a topical dosage form of this type

5.3 Preclinical safety data

None stated

6. Pharmaceutical particulars

6.1 List of excipients

Polyethylene glycol 400

Polyethylene glycol 4000

White petrolatum

Titanium dioxide

Butylated hydroxytoluene (E 321)

6.2 Incompatibilities

None stated.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

Once opened, use until the expiry date

6.4 Special precautions for storage

Store in a cool place, below 25°C.

6.5 Nature and contents of container

15g cream in an aluminum tube.

6.6 Special precautions for disposal and other handling

No special precautions required

7. Licence Holder And Manufacturer

Teva Israel Ltd.,
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8. Registration Number

026.52.21118.00

This leaflet was prepared in December 2021 according to MOHs guidelines.