

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Phytex Paint Cutaneous Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Solution contains Tannic Acid 4.886% w/v, Boric Acid 3.124% w/v, 1.45% w/v salicylates (as Salicylic Acid 0.89% w/v and Methyl Salicylate 0.526% w/v).

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous Solution

A clear pale straw-coloured cutaneous solution with a characteristic odour.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the treatment of infections of the skin and nails due to superficial dermatophytes of Candida.

### 4.2 Posology and method of administration

For adults, including the elderly, and children over five years:

The tincture is painted onto the affected areas morning and evening and after washing. Several weeks of treatment may be required to prevent relapse.

Children under five years:

Contraindicated.

### 4.3 Contraindications

Known sensitivity to any of the ingredients. Do not use in children under five. Should not be used on broken or inflamed skin. Use in pregnancy.

### 4.4 Special warnings and precautions for use

Do not use for longer than 10 days without consulting a doctor. For use on nail areas and feet only. Phytex should be used with caution in patients with impaired circulation and diabetics. Phytex is for topical use only and may be harmful if taken internally.

### 4.5 Interaction with other medicinal products and other forms of interaction

None stated.

## 4.6 Fertility, pregnancy and lactation

Contraindicated.

## 4.7 Effects on ability to drive and use machines

Not applicable.

## 4.8 Undesirable effects

Slight stinging may occur on application. Any further discomfort caused by dryness of the skin may be due to the astringent nature of the product.

## 4.9 Overdose

Not applicable.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Borotannic complex possesses bacteriostatic and fungistatic properties. After application the solvent evaporates to leave a clear film over the infected area. Perspiration subsequently dissolves the active complex which ionises producing a low pH (about 2.0) that is fungicidal. Salicylic acid facilitates penetration of infected skin.

## 5.2 Pharmacokinetic properties

Salicylic acid and methyl salicylate are absorbed through the skin; however, the quantities present in Phytex would make the possibility of systemic salicylate poisoning remote. Unbound boric acid or tannic acid may be absorbed through damaged skin. The quantities present in Phytex would indicate that systemic effects are highly unlikely.

## 5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Glacial acetic acid  
Industrial methylated spirit  
Ethyl acetate

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

3 years.

## **6.4 Special precautions for storage**

Do not store above 25°C. Keep bottle tightly closed.

## **6.5 Nature and contents of container**

Amber glass bottle with polypropylene screw cap and applicator brush, containing 25 ml.

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Wynlit Laboratories Limited  
7 Birchington Road  
London  
N8 8HR  
UK

## **8 MARKETING AUTHORISATION NUMBER**

PA 283/2/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 April 1977

Date of last renewal: 01 April 2008

## **10 DATE OF REVISION OF THE TEXT**

June 2011