

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Compound Podophyllin Paint B.P.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Podophyllum Resin B.P. 15.0% w/v

For excipients, see 6.1.

### **3. PHARMACEUTICAL FORM**

Medicinal Paint

### **4. CLINICAL PARTICULARS**

#### **4.1. Therapeutic Indications**

Anogenital and plantar warts

#### **4.2. Posology and Method of Administration**

##### **Plantar Warts**

Adults, the elderly and children over 5 years

Apply the minimum amount 2 or 3 times a week to affected areas, cover with a piece of plaster and leave until the wart is soft; dead skin may be removed at intervals by rubbing with a pumice stone. The product should be kept off normal healthy skin and away from sensitive areas such as the eyes.

Children under 5 years

Not recommended.

##### **Anogenital Warts**

The product should be applied in a genitourinary clinic, or at a general practitioner's surgery after screening for other sexually transmitted diseases.

### Adults and the elderly

Apply weekly to anogenital warts. Once applied the paint should be covered with soft paraffin and left for a maximum of 6 hours after which it should be washed off. During application care should be taken to avoid splashing the surrounding skin, which must be covered with soft paraffin as a protection.

### Children

Not recommended.

#### **4.3. Contra-indications**

Pregnancy and breastfeeding, facial warts, hypersensitivity to the product.

#### **4.4. Special Warnings and Precautions for Use**

The paint is very irritant to the eyes and tender parts of the skin. Avoid using on normal skin and broken skin.

Where there is a large number of warts, only a few should be treated at any one time as severe toxicity caused by absorption of podophyllum has been reported.

#### **4.5. Interactions with other Medicaments and other forms of Interaction**

None known.

#### **4.6. Pregnancy and Lactation**

Not to be used in pregnancy or lactation.

#### **4.7. Effects on Ability to Drive and Use Machines**

None known.

#### **4.8. Undesirable Effects**

Poisoning due to systemic absorption has been reported – where there are a large number of warts only a few should be treated at any one time.

May cause pain on application.

Podophyllum is strongly irritant to skin and mucous membranes and care must be taken to avoid healthy tissue.

#### **4.9. Overdose**

This preparation is for external use only. If ingested podophyllum has a drastic purgative action and produces violent peristalsis. Podophyllum may cause severe systemic toxicity after ingestion or extensive topical application. The toxic effects of podophyllum are usually reversible but fatalities have occurred. Symptoms of toxicity include nausea, vomiting, abdominal pain and diarrhoea. Thrombocytopenia, leucopenia, renal failure and hepatotoxicity have also been reported. Central effects are delayed in onset and prolonged in duration and include acute psychotic reactions, hallucinations, confusion, dizziness, stupor, ataxia, hypotonia, seizures and coma. EEG changes may persist for several days. Peripheral and autonomic neuropathies develop later and may result in paraesthesias, reduced reflexes, muscle weakness, tachycardia, apnoea, orthostatic hypotension, paralytic ileus and urinary retention. Neuropathy may improve but full recovery is unusual.

In addition to application to large areas with excessive amounts for prolonged periods, the risk of toxicity is increased by the treatment of friable, bleeding or recently biopsied warts and by inadvertent application to normal skin or mucous membranes.

Treatment is symptomatic and supportive with gastric lavage if needed. Anti-convulsant therapy may also be needed.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1. Pharmacodynamic Properties**

Not applicable.

#### **5.2. Pharmacokinetic Properties**

Not applicable.

### **5.3. Preclinical Safety Data**

No relevant data.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of Excipients**

Compound Benzoin Tincture B.P.

### **6.2. Incompatibilities**

None known.

### **6.3. Shelf Life**

Three years.

### **6.4. Special Precautions for Storage**

This preparation is flammable. Keep away from naked flames.

### **6.5. Nature and Contents of Container**

#### Dispensing Pack

100 ml ribbed amber glass bottle with plastic cap

Patient Packs

5 ml and 10 ml amber glass bottles with a polypropylene, unwadded cap, having a small spatula attached to the cap.

### **6.6. Instruction for Use/Handling**

No further data.

**7. MARKETING AUTHORISATION HOLDER**

Wise Pharmaceuticals Limited  
Hani Wells Business Park  
Unit 7  
Hardicker Street  
Manchester  
M19 2RB  
United Kingdom.

**8. MARKETING AUTHORISATION NUMBER**

PL 18374/0036

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF  
AUTHORISATION**

14<sup>th</sup> April 2005

**10. DATE OF REVISION OF THE TEXT**

14/04/2005