

### **1. Name of the Medicinal Product**

Podophyllin Cream 0.15% w/w

### **2. Qualitative and Quantitative Composition**

Each tube contains:

Podophyllotoxin 0.15% w/w

Cream Base q. s.

### **3. Pharmaceutical Form**

Topical Cream

### **4. Clinical Particulars**

#### **4.1 Therapeutic Indications**

Podophyllotoxin cream is commonly prescribed as a potent topical antiviral. It is used for the treatment of HPV infections with external warts as well as molluscum contagiosum infections.

#### **4.2 Posology and method of administration**

Use applicator provided. A small amount should be applied to each wart and allowed to air dry. Leave on briefly for the first treatment to assess for sensitivity, about 30 minutes or so. Thereafter the nonpregnant patient may thoroughly wash off the podophyllin in 1 to 4 hours.

#### **4.3 Contraindications**

Podophyllin is contraindicated in diabetics, patients using steroids or with poor blood circulation. Podophyllin should not be used on bleeding warts, moles, birthmarks or unusual warts with hair growing from them

#### **4.4 Special Warnings and Precautions for use**

Podophyllin is a powerful caustic and severe irritant. Keep away from the eyes; if eye contact occurs, flush with copious amounts of warm water and consult a physician or poison control center immediately for advice. Do not use podophyllin if the wart or surrounding tissue is inflamed or irritated.

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

Podophyllin has no noted severe interactions with any other drugs. Podophyllin has no noted serious interactions with any other drugs

#### **4.6 Pregnancy and lactation**

Pregnancy: There have been reports of complications associated with the topical use of podophyllin on condylomata of pregnant patients including birth defects, fetal death and stillbirth. In the absence of controlled safety studies, podophyllin remains contraindicated for use on pregnant patients.

#### **4.7 Effects on ability to drive and use machines**

Not Applicable.

#### **4.8 Undesirable effects**

- hives,
- difficulty breathing,
- swelling of the face, lips, tongue, or throat,
- severe burning,
- stinging,
- irritation,
- change in the mental state, confusion, agitation, seizure (convulsions), loss of consciousness;
- drowsiness or a light-headed feeling

#### **4.9 Overdose**

Podophyllin poisoning following both topical application and oral consumption has been reported in adults. Fatal dose of podophyllin resin for humans has been estimated to be 0.3 g to 0.6 g, or as little as one-half teaspoon of 25% podophyllin resin in benzoin tincture.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Cell division is arrested and other cellular processes are impaired, gradually resulting in the disruption of cells and destruction of the tissue.

Podophyllin is a cytotoxic agent that has been used topically in the treatment of genital warts. It arrests mitosis in metaphase, an effect it shares with other cytotoxic agents such as the vinca alkaloids. The active agent is podophyllotoxin, whose concentration varies with the type of podophyllin used.

#### **5.2 Pharmacokinetic properties**

Oral absorption: Podophyllum is very well and rapidly absorbed after ingestion. Dermal absorption: systemic poisoning was reported after topical application in some cases. Symptoms were delayed between 2-24 hr

### **5.3 Preclinical safety data**

NA

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

**White Soft Paraffin**

**Tween**

**Propylene Glycol**

**Purified Water**

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years from the date of manufacture.

### **6.4 Special precautions for storage**

Do not store above 30°C.

Store in the original packaging to protect from moisture

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

20 gm tube each packed in a carton along with the Pack Insert.

### **6.6 Special precautions for disposal and other Special handling**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7. REGISTRANT**

**Merit Organics Ltd**

Plot No 2104/2/A, G.I.D.C , Sarigam , Bhilad,

Dist- Valsad-396155, Gujarat , INDIA

## **8. MANUFACTURER**

**Merit Organics Ltd**

Plot No 2104/2/A, G.I.D.C , Sarigam , Bhilad,

Dist- Valsad-396155, Gujarat , INDIA

**9. DATE OF REVISION OF THE TEXT**

Applicable once the registration is obtained.