1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of medicinal product

Podophyllin 0.15% cream w/w

2. Composition:

Each tube contains:
Podophyllin 0.15% w/w
Cream Base Q.S.

3. Pharmaceutical Form:

Topical

4. Clinical Particulars

4.1 Indication

For the topical treatment of condylomata acuminata affecting the penis or the external female genitalia.

4.2 Posology and Administration

The affected area should be thoroughly washed with soap and water, and dried prior to application.

Using a fingertip, the cream should be applied twice daily morning and evening (every 12 hours) for 3 consecutive days using only enough cream to just cover each wart. The cream should then be withheld for the next 4 consecutive days.

Application to the surrounding normal tissue should be avoided.

Residual warts should be treated with further courses of twice daily applications for three days at weekly intervals, if necessary for a total of 4 weeks of treatment.

Hands should be washed thoroughly after application.

4.3 Contraindication

Hypersensitivity to the active substance(s) or to any of the excipients.

4.4 Special Warning & precautions for use

Where the area of treatment is greater than 4 cm2, it is recommended that treatment takes place under the direct supervision of a healthcare professional.
Avoid applying the cream to warts occurring on mucous membranes of the genital area (including the urethra, rectum and vagina).
Avoid applying the cream to surrounding healthy tissue.
Avoid contact with eyes. Should the cream accidentally come into the eye, the eye should be thoroughly rinsed with water and medical advice sought.
Occlusive dressings should not be used on areas treated with the cream.
Local irritation may occur on the second or third day of application associated with the start of wart necrosis. In most cases, the reactions are mild. If severe local skin reactions occur

(bleeding, swelling, excessive pain, burning, itching) the cream should be washed immediately from the treatment area with mild soap and water, treatment discontinued and the patient advised to seek medical advice.
It is not recommended during pregnancy or in women of childbearing potential not using contraception.
It is recommended that patients refrain from sexual intercourse while treating warts with the cream and until the skin has healed. If a patient does engage in sexual intercourse, a condom must be used.

This cream contains:
• methyl and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).
• sorbic acid, stearyl alcohol and cetyl alcohol which may cause local skin reactions, (e.g. contact dermatitis).
• butyl hydroxyanisole which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies found.

4.6 Fertility, Pregnancy and lactation
Cream should not be used during pregnancy unless clearly necessary

4.7 Effects on ability to drive and use machines
Not known.

4.8 Undesirable effects
Local symptoms such as pruritus, skin exfoliation, application site pain, application site irritation, pigmentation disorder, skin burning sensation, erythema, scab, etc. may occur at the site of application.
These harmless symptoms must be distinguished from hypersensitivity reactions including rash, which are reported in sporadic cases and require discontinuation of therapy.
In case of accidental contact with the eyes terbinafine may be irritating to the eyes.
In rare cases the underlying fungal infection may be aggravated.

4.9 Overdose
While serious systemic effects have not been reported with the recommended dosage of topical podophyllotoxin, topical overdosage would be expected to increase systemic absorption of the drug and increase the potential for systemic effects, e.g. altered mental state and bone marrow suppression. Following oral ingestion, podophyllotoxin may also cause severe gastroenteritis.

Treatment

If topical overdosage occurs, podophyllotoxin should be washed immediately from the treatment area and symptomatic and supportive therapy initiated.

Treatment of oral podophyllotoxin poisoning is symptomatic and should include supportive care.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Chemotherapeutics for topical use, Antivirals

ATC code: D06BB

Podophyllotoxin is a metaphase inhibitor in dividing cells binding to at least one binding site on tubulin. Binding prevents tubulin polymerisation required for microtubule assembly. At higher concentrations, podophyllotoxin also inhibits nucleoside transport through the cell membrane.

The chemotherapeutic action of podophyllotoxin is assumed to be due to inhibition of growth and the ability to invade the tissue of the viral infected cells.

5.2 Pharmacokinetic properties

Systemic absorption of podophyllotoxin after topical application of 100 mg of 0.3% cream or 100 μL of 0.5% solution has been studied (extravaginally in 10 females, and within the preputial cavity in 10 males, each on 2 occasions separated by 8 hours). Cmax was at or below 4.7 ng/mL following all doses and Tmax ranged from 0.5 to 36 hrs; in some subjects concentrations were below the limit of detection. The Cmax and Tmax were comparable for the 0.3% cream and 0.5% solution in both males and females. It can be concluded that systemic absorption of recommended doses of podophyllotoxin cream or solution is expected to be low.

6. Shelf Life

36 months

7. Special precaution for Storage

Do not store above 30°C.

8. Nature and contents of container

20 gm tube packed in carton along with insert.

9. Marketing Holder

YOGI CARE PHARMACEUTICAL PRIVATE LIMITED

OFFICE-1113,1114, BINORI B SQUARE - 3, SINDHU BHAVAN

ROAD, NR. TRADE BULLS, Bodakdev, Ahmedabad, Ahmedabad,

Gujarat, 380054

10. Manufacturer

SPENSUS PHARMACEUTICALS PRIVATE LIMITED

Unit No. 1, survey No. 284, Ganeshpura, Gujarat - 382705