Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Warticon Solution 0.5% w/v Cutaneous Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Podophyllotoxin 0.5% w/v

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.
A blue coloured solution for cutaneous use.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of anogenital warts (Condylomata Acuminata)

4.2 Posology and method of adminstration

The following doses and schedules are applicable to adults and the elderly.

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

Using the applicator provided, the warts should be painted twice daily for three days.

The treated area should be allowed to dry.

Residual warts should be treated with further courses of twice daily applications for 3 days after a 4 day treatment-free period. Normally 3 - 4 treatment courses are sufficient.

The majority of patients will not require in excess of 30 loops for each application, however, a maximum of 50 loops per application (equivalent to 250µl of Warticon solution) may be applied. Where lesions are greater in area than $4cm^2$, it is recommended that treatment takes place under the direct supervision of medical staff.

4.3 Contraindications

Open wounds following surgical procedures should not be treated with podophyllotoxin. Hypersensitivity to podophyllotoxin is a contraindication.

4.4 Special warnings and special precautions for use

Be careful to apply Warticon solution to the warts only; if any spreads onto healthy skin it should be washed off with soap and water.

Avoid contact with the eyes. Following accidental spillage the skin should be washed well with soap and water. In the

event of the preparation entering the eye, the eye should be bathed thoroughly with water.

4.5 Interaction with other medicinal products and other forms of interaction

None Known

4.6 Pregnancy and lactation

The product should not be used during pregnancy and lactation

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Local irritation may occur on the second or third day of application, associated with the start of wart necrosis. In the majority of cases the reactions are mild. Tenderness, smarting, erythema, superficial epithelial ulceration and balanoposthitis have been reported. Local irritation decreases after treatment.

4.9 Overdose

There have been no reported overdoses with Warticon Solution. No specific antidote is known. Following accidental spillage, wash the skin well with soap and water. In the event of accidental ingestion give an emetic or stomach washout. Treatment should be symptomatic; in the event of severe oral overdosage, ensure that the airway is clear, give fluids, check and correct electrolyte balance, monitor blood gases and liver function. Blood count should be monitored for at least 5 days.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 administration is low. C_{max} is 1.0 - 4.7 ng/ml and T_{max} 0.5 - 36 hours.

5.3 Preclinical safety data

No relevant findings.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphoric acid
Patent blue V (E131)
Ethanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

(a) For the product as packaged for sale

Three years

(b) After first opening the container

Comply with expiry date

6.4 Special precautions for storage

Do not store above 25^0 C. Store in original container.

6.5 Nature and contents of container

Amber glass bottles containing 3ml fitted with screw caps.
A supply of applicators is included in the pack.

6.6 Instructions for use and handling

Keep away from naked flame.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 144/40/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 17 November 2003

10 DATE OF REVISION OF THE TEXT

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