NAME OF THE MEDICINE

WARTEC Cream contains podophyllotoxin as the active ingredient.

CAS number: 518-28-5

DESCRIPTION

WARTEC Cream is a white cream for topical use.

WARTEC Cream contains 0.15% w/w podophyllotoxin.

WARTEC Cream also contains purified water, stearyl alcohol, cetyl alcohol, isopropyl myristate, liquid paraffin, medium chain triglycerides, butylated hydroxyanisole (BHA), steareth-7, steareth-10, phosphoric acid, methyl hydroxybenzoate, propyl hydroxybenzoate and sorbic acid.

PHARMACOLOGY

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.

Pharmacokinetic properties

Systemic absorption of podophyllotoxin after topical application with a higher strength, 0.3% is low. Thus no study was performed on the present strength, 0.15%. The $C_{\text{max}}$ (1.0 – 4.7ng/mL) and $T_{\text{max}}$ (0.5 – 36 hrs) are comparable for the 0.3% cream and 0.5% solution in both males and females.
INDICATIONS
For the topical treatment of external condylomata acuminata (anogenital warts).

CONTRAINDICATIONS
− Application to open wounds (e.g. following surgical procedures) or bleeding sites.
− Use in children
− Hypersensitivity to podophyllotoxin
− Concomitant use with other podophyllotoxin containing preparations.
− Pregnancy and lactation

PRECAUTIONS
Avoid contact with the eyes. Should the cream accidentally come into the eyes, the eye should be thoroughly rinsed with water.

Prolonged contact with healthy skin must be avoided since the cream contains an active pharmaceutical substance, which could be harmful on healthy skin.

Use during Pregnancy and Lactation
The product is not for use in pregnancy or lactation.

Podophyllum resin has caused teratogenic effects and foetal death in humans when used in pregnancy.

Podophyllotoxin has the ability to condense with microtubular protein and interfere with the formation of cellular organelles and the spindle apparatus. It is because of these properties that podophyllotoxin may be teratogenic.

It is not known if the substance is excreted into breast milk.

INTERACTIONS WITH OTHER MEDICINES
None presently known.

ADVERSE EFFECTS
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. Tenderness, itching, smarting, erythema, superficial epithelial ulceration and balanoposthitis have been reported. Local irritation decreases after treatment.

DOSAGE AND ADMINISTRATION
The affected area should be thoroughly washed with soap and water, and dried prior to application.
Using a finger stall or gloves, the cream is applied twice daily for 3 days using only enough cream to just cover each wart.

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.

Where lesions are greater than 4cm², it is recommended that treatment takes place under the direct supervision of medical staff.

There is a possibility of relapse following treatment and in the event that this does occur, alternative treatment may need to be considered.

OVERDOSAGE

In cases of overdosage contact the Poisons Information Centre on 13 11 26.

There have been no reported overdosage with WARTEC Cream. However, excessive use of podophyllotoxin 0.5% solution has been reported as causing two cases of severe local reactions. In cases of excessive use of WARTEC Cream resulting in severe local reaction, the treatment should be stopped, the area washed and symptomatic treatment introduced.

No specific antidote is known. Since podophyllotoxin inhibits mitosis, overdose may cause severe gastroenteritis, multiple organ failure or pancytopenia. Treatment should be symptomatic and in severe oral overdose ensure the airway is clear. Give water (not milk) to reduce the caustic effects of podophyllotoxin, then give activated charcoal. Check and correct electrolyte balance, monitor blood gases and liver function. Blood count should be monitored for at least 5 days.

PRESENTATION AND STORAGE CONDITIONS

WARTEC Cream contains 0.15% w/w podophyllotoxin in a cream formulation for topical application. The product is presented in lacquered aluminium membrane sealed tubes fitted with a polyethylene cap. A small mirror is supplied with the pack.

Pack size: 5g* and 10g.

* - Currently marketed pack size.

Store below 30°C.

NAME AND ADDRESS OF THE SPONSOR

GlaxoSmithKline Australia Pty Ltd
Level 4
436 Johnston Street
Abbotsford, Victoria 3067
AUSTRALIA
DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

6 June 2001

Date of most recent amendment: 28 September 2011

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Version 3.0