

DATA SHEET

NAME OF MEDICINE

Wartec® Cream

Podophyllotoxin 0.15% w/w

PRESENTATION

Wartec Cream contains podophyllotoxin in a white cream base for topical application.

USES

ACTIONS

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.

PHARMACOKINETICS

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_{max} (1.0-4.7ng/ml) and T_{max} (0.5-36 hrs) are comparable for the 0.3% cream and 0.5% solution in both males and females.

INDICATIONS

Wartec Cream is indicated for the topical treatment of external condylomata acuminata (anogenital warts).

DOSAGE AND ADMINISTRATION

Wartec Cream is for topical application only.

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

Using a fingerstall or disposable glove, 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 the 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.

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.

WARNINGS AND PRECAUTIONS

General Precautions

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

The hands should be thoroughly washed after each application. Prolonged contact with healthy skin must be avoided since the cream contains an active pharmaceutical substance, which could be harmful on healthy skin.

Presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

Teratogenicity/Embryotoxicity

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.

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.

INTERACTIONS

None presently known.

OVERDOSAGE

In cases of overdosage, contact the Poisons Information Centre on 0800 POISON (0800 764 766). 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 several 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 given activated charcoal. Check and correct electrolyte balance, monitor blood gases and liver function. Blood count should be monitored for at least 5 days.

PHARMACEUTICAL PRECAUTIONS

Storage Condition

Wartec Cream should be stored at temperatures not exceeding 30°C.

Shelf Life

According to stability results, Wartec Cream has a shelf life of three years from the date of manufacture, when stored at the recommended conditions.

INCOMPATIBILITIES (MAJOR)

None.

MEDICINE CLASSIFICATION

Prescription Medicine.

PACKAGE QUANTITIES

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.

FURTHER INFORMATION

Excipients

Wartec Cream also contains purified water, stearyl alcohol, cetyl alcohol, isopropyl myristate, liquid paraffin, fractionated coconut oil, butylated hydroxyanisole (BHA), steareth-7, steareth-10, phosphoric acid, methyl hydroxybenzoate, propyl hydroxybenzoate and sorbic acid.

Trade Mark

Wartec is a registered trade mark of Stiefel Laboratories, Inc.

NAME AND ADDRESS

Manufacturer

Stiefel Laboratories (Ireland) Limited
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Ireland

Mfr Licence No:M144

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NEW ZEALAND

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