

NEW ZEALAND DATA SHEET

1. CONDYLINE®

Topical solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Podophyllotoxin 5mg/ml solution

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Condyline® is a topical solution which contains podophyllotoxin 5mg/ml as its active ingredient in an ethanol solution. A clear, colourless solution with a smell of alcohol.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

External condylomata acuminata in adults.

4.2 Dosage and method of administration

Apply Condyline® carefully on the condylomata with one of the plastic stick applicators enclosed in the package, and allow to dry.

Take care that the preparation does not come into contact with the healthy skin.

Condyline® should be applied twice a day for 3 consecutive days. This treatment can be repeated every week, for a maximum of 5 successive weeks.

4.3 Contraindications

Condyline® should not be used during pregnancy and lactation or in children. Condyline® may not be used in combination with any other podophyllin preparation because of possible symptoms of toxicity.

4.4 Special warnings and precautions for use

Condyline® should be allowed to dry thoroughly after application in order to avoid inadvertent spreading. This particularly applies to condylomata which are localized on the preputium.

Condyline® should not come into contact with the eyes as it will cause very severe irritation. Should this accidentally happen rinse the eyes immediately and for a long time with water.

Local irritation and/or ulceration of healthy mucosa of the skin in the vicinity or at the base of the condylomata through inadvertent contact with Condyline® can be prevented by applying a protective layer of neutral cream, vaseline or zinc ointment on the surrounding skin prior to treatment.

Application of this preparation on relatively large mucosal surfaces may lead to general reactions and should be avoided. In addition (as has been mentioned under **Dosage and method of administration**) each contact of the substance with the healthy surrounding skin or mucosa should be avoided.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been conducted.

4.6 Fertility, pregnancy and lactation

Human studies have indicated that the compound may be harmful during pregnancy. Therefore, Condylin[®] should not be used during pregnancy.

It is unknown whether podophyllotoxin and/or its metabolites are excreted via breast-milk. In view of the cytostatic properties of podophyllotoxin, harm to the infant cannot be ruled out. Therefore, Condylin[®] should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

There is no data concerning the effect of Condylin[®] on the ability to drive and use machines, but Condylin[®] is not expected to exert any influence.

4.8 Undesirable effects

Local side-effects do occur, mainly with an optimal therapeutic effect and usually on the second or third day of treatment when necrosis of the condylomata starts. These adverse reactions are generally mild and well tolerated by the patients if this possibility is discussed with them beforehand. Redness with slight pain and/or superficial ulceration of the epithelium in the treated area can be expected and the application of Condylin[®] may therefore be painful. Oedema and balanoposthitis have been observed in some patients with large warts in the preputial cavity. Such local effects improve after a few days of anti-inflammatory therapy, i.e. with a topical corticosteroid.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

Overdosage may result in systemic toxicity. Systemic toxicity is only to be expected if more than one bottle is used. Symptoms of intoxication include: nausea, vomiting, diarrhoea, tachycardia, hypotension, tachypnoea (also respiratory insufficiency) and CNS symptoms like dizziness, stupor, coma and peripheral neuropathy. Symptomatic treatment is indicated in such cases. If coma occurs hemoperfusion over active charcoal maybe useful, although its effectiveness has not been proven sufficiently.

Contact the Poisons Information Centre on 0800 POISON or 0800 764 766 for further advice on overdose management.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Podophyllotoxin is the most active component of podophyllin which is prepared from plant extracts. It has marked antimetabolic and cytolytic activities which induce necrosis of condylomata acuminata. Condylin[®] works more rapidly and reliably than podophyllin due to the purified and standardized form of podophyllotoxin. As Condylin[®] can be accurately dosed, there is a reduced risk of severe side-effects and treatment at home is possible. High cure rates are obtained.

5.2 Pharmacokinetic properties

Absorption

Absorption tests in patients treated with 0.5% podophyllotoxin showed that the application of 0.01-0.05 ml for 3 days to 10 patients, produced no demonstrable levels of podophyllotoxin in the serum ½-1 hour after treatment.

A dose of 0.1 ml (condylomata with a total surface of >4cm²) produced a serum level of ≤5ng/ml after 1-2 hours which decreased to ≤3ng/ml after 4 hours. With a dosage of 0.15ml, nearly comparable values were obtained, however, a level of ≤1ng/ml remained (in 5 patients) 12 hours after application. In 7 patients with extremely large lesions who applied 0.1-1.5ml, peak levels of 1-17ng/ml were noted after 1-2 hours. Tests in 52 patients showed that concentrations greater than 0.1ml are rarely necessary for the treatment of condylomata.

Distribution, biotransformation and excretion

A relatively long clearance after application of 0.1 ml 0.5% podophyllotoxin twice daily may be an indication that distribution occurs according to the 2 compartment model.

From the data obtained from absorption tests it may be concluded that the serum half-life of podophyllotoxin is somewhere between 1 and 4½ hours. Accumulation of podophyllotoxin did not occur.

5.3 Preclinical safety data

No specific data are available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol, lactic acid, sodium lactate and purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

Condyline[®] should not be used after the expiry date. At the recommended storage temperature and in the pack in which it is sold, Condyline[®] expires 3 years after the date of manufacture.

6.4 Special precautions for storage

Store below 25°C until the expiry date indicated on the pack.

6.5 Nature and contents of container

Condyline[®] is supplied in a glass bottles containing 3.5ml.

7. MEDICINE SCHEDULE

Prescription Medicine.

8. SPONSOR

AFT Pharmaceuticals Ltd
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9. DATE OF FIRST APPROVAL

20 October 1988

10. DATE OF REVISION OF THE TEXT

12 May 2017

Summary Table of Changes

Section changed	Summary of new information
Format of DS	Updated to SPC format as per Medsafe requirements
8	Change in Sponsor details