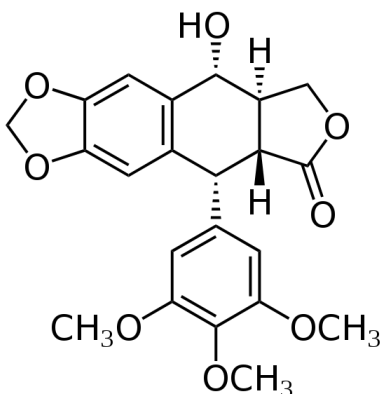


PRODUCT INFORMATION

CONDYLINE[®] PAINT

NAME OF THE MEDICINE

Active ingredient:	podophyllotoxin
Chemical name (CAS):	(5R,5aR,8aR,9R)-5,8,8a,9-tetrahydro-9-hydroxy-5-(3,4,5-trimethoxy-phenyl)furo[3'4':6,7]naphtho[2,3-d]-1,3-dioxol-6(5aH)-one
Molecular Formula:	C ₂₂ H ₂₂ O ₈
CAS number:	518-28-5
Molecular weight:	414.41
Structural formula:	



DESCRIPTION

CONDYLINE[®] Paint is a clear, colourless alcoholic solution for topical application.

CONDYLINE[®] Paint contains 0.5% w/v podophyllotoxin.

CONDYLINE[®] Paint also contains lactic acid, sodium lactate, ethanol and purified water.

PHARMACOLOGY

The exact mode of action of CONDYLINE[®] Paint is not known, however the antimitotic activity of podophyllotoxin causes necrosis of wart tissue. The podophyllotoxin binds to the tubulin and prevents the formation of microtubules which are needed in mitotic spindle formation. As a result mitosis is stopped along with other cellular functions controlled by the microtubules.

INDICATIONS

For the treatment of anogenital warts.

CONTRAINDICATIONS

CONDYLINE® Paint is contraindicated in:

- patients with a hypersensitivity to podophyllotoxin or any of its ingredients;
- patients with open wounds following surgical procedures;
- patients with inflamed or bleeding lesions;
- combination with other podophyllin containing preparations;
- pregnant or breast-feeding women;
- children.

PRECAUTIONS

Avoid contact with the healthy skin as well as the eyes and face because of severe irritation.

Lesions in the female and lesions greater than 4 cm² in the male should be treated under direct medical supervision.

The risk of toxicity is increased during simultaneous treatment with other podophyllin containing preparations since these also contain podophyllotoxin and should therefore be avoided (see CONTRAINDICATIONS).

The risk of systemic toxicity after topical application is increased by the treatment of large areas with excessive amounts for prolonged periods, by the treatment of friable, bleeding, or recently removed warts, and by inadvertent application to normal skin or mucous membranes (see CONTRAINDICATIONS).

Use in Pregnancy

Podophyllotoxin should not be used during pregnancy (see CONTRAINDICATIONS). Females of child bearing age should use effective contraception while using CONDYLINE® Paint.

Use in Lactation

Podophyllotoxin should not be used during breast-feeding (see CONTRAINDICATIONS).

Paediatric use

Podophyllotoxin should not be used in children (see CONTRAINDICATIONS).

INTERACTIONS WITH OTHER MEDICINES

None known.

ADVERSE EFFECTS

Disorders of the reproductive system and breast

Podophyllotoxin may induce balanoposthitis.

Skin & subcutaneous tissue disorders

Podophyllotoxin may provoke local irritations (of the mucous membranes) usually mild and include itching, burning, pain, erythema or epithelial ulceration.

DOSAGE & ADMINISTRATION

CONDYLINE® Paint is to be used by applying directly to the wart, using the applicator provided.

CONDYLINE® Paint is to be applied twice daily for three days and this may be repeated weekly for a total of five weeks.

Only a small area or number of warts should be treated at anyone time.

OVERDOSAGE

Symptoms

The risk of systemic toxicity after topical application is increased by the treatment of large areas with excessive amounts for prolonged periods, by the treatment of friable, bleeding, or recently removed warts, and by inadvertent application to normal skin or mucous membranes. Symptoms include nausea, vomiting, abdominal pain and diarrhoea; thrombocytopenia, leucopenia, hepatotoxicity or renal failure may occur. CNS-related adverse events are delayed in onset and prolonged in duration and include acute psychotic reactions, hallucinations, confusion, dizziness, stupor, ataxia, hypotonia, seizures, and coma. Peripheral and autonomic neuropathies develop later and may result in paraesthesias, reduced reflexes, muscle weakness, tachycardia, apnoea, orthostatic hypotension, paralytic ileus, and urinary retention.

Treatment

In topical overdose, wash well with soap and water; if the eyes are involved, rinse thoroughly with water or if available, with an appropriate eye-cleaning solution. If accidentally ingested, give stomach washout and monitor electrolyte balance, blood gases, liver function, and blood picture.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

PRESENTATION AND STORAGE CONDITIONS

CONDYLINE® Paint is supplied in an amber glass bottle fitted with a child resistant closure containing 3.5 mL solution, and a suitable quantity of specific applicators.

Store below 25°C.

NAME AND ADDRESS OF THE SPONSOR

Takeda Pharmaceuticals Australia Pty Ltd
Level 5
2 Chifley Square
Sydney NSW 2000

POISON SCHEDULE OF THE MEDICINE

Prescription Medicine (S4)

**DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS
(the ARTG)**

7 February 1992

DATE OF MOST RECENT AMENDMENT

3 November 2017