SUMMARY OF CHARACTERISTICS OF THE MEDICINAL PRODUCT

1. NAME OF THE MEDICINAL PRODUCT

CONDYLOX

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Podophyllotoxin 5 mg
in buffered ethanolic solution

For a complete list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous Solution
Clear, colourless

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of external genital warts (Condylomata Acuminatum).

4.2 Posology and method of administration

Posology

Treatment is carried out twice daily (at an interval of 12 hours) on three consecutive days. Then a treatment-free interval of four days should be observed. Therapy should be repeated until the condylomata disappear; the maximum duration of administration is four weeks.
If no success in treatment can be achieved after four treatment cycles, a different form of therapy must be chosen.

Method of administration

Application to skin

Prior to application, the body parts to be treated must be washed carefully with water and soap and subsequently dried with caution. The solution is applied with a cotton tipped applicator on the condylomata. The cotton pad may be used only once!
Take care that podophyllotoxin does not reach the surrounding healthy skin and/or mucosa. Condylox should not be applied to non-genital warts.
After application, let it dry for a few minutes.
Condylox 0.5% solution is left at the site of application and must not be washed off again. The treated spots must have dried before coming in contact with clothing.
After each treatment hands should be cleaned thoroughly.

Therapy with Condylox 0.5% solution may be carried out at home by the patients themselves. However, lesions in the female and lesions greater than 4cm² in the male should be treated under direct medical supervision.

Children
Condylox 0.5% solution is contraindicated in children under the age of 12 (See Section 4.3).

4.3 Contraindications

- Hypersensitivity to the active ingredient or to any of the excipients listed in section 6.1
- Inflamed or bleeding genital warts
- Concomitant use of other compounds containing podophyllotoxin
- Pregnancy and breast-feeding
- Children under 12 years of age

4.4 Special warnings and precautions for use

There are no data on the use of CONDYLOX 0.5% solution in adolescents aged 12 to 18 years.

CONDYLOX 0.5% solution is used exclusively for the treatment of condylomas and must not be applied to other warts or moles. Contact with healthy skin should be avoided.

CONDYLOX 0.5% solution must not be brought into contact with the eyes. If podophyllotoxin still gets into the eye, you must immediately rinse with water and contact the doctor.

Avoid alcohol consumption during treatment. Consuming alcohol during therapy can lead to a massive increase in adverse effects.

Male patients should wear condoms until complete healing. Partners should be advised to seek medical examination by a doctor as well.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant treatment with other podophyllin-containing medicinal products should be avoided, as these also contain podophyllotoxin.

4.6 Fertility, pregnancy and breast-feeding

Podophyllotoxin causes serious harm to the unborn child if used during pregnancy.
CONDYLOX 0.5% solution is contraindicated during pregnancy and breast-feeding (see 4.3). No impairment of fertility was observed in limited data from animal studies.

4.7 Effects on the ability to drive and use machines

CONDYLOX 0.5% solution has no or negligible effects on the ability to drive and use machines.

4.8 Side effects

Local irritation affects 35% to 40% of patients.

The following categories are used for the frequency information on side effects:

Very common:	≥ 1/10
Common:	≥ 1/100, < 1/10
Uncommon:	≥ 1/1,000, < 1/100
Rare:	≥ 1/10,000, < 1/1.000
Very rare:	< 1/10,000
Not known:	Frequency cannot be estimated from the available data

Skin and subcutaneous tissue disorders
Very common: local irritation of the treated mucosa such as itching, burning, pain, erythema, mucosal epithelial ulceration or erosions.

Reproductive system and mammary gland disorders
Not known: Phimoses, balanoposthitis

Since podophyllotoxin is only absorbed to a low degree when applied locally, no systemic effects are expected with the recommended route of administration and dosage.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il

4.9 Overdose

The risk of systemic toxicity after topical application is increased in case of extensive treatment with excessive amounts over a prolonged period of time or with treatment of bleeding or recently removed genital warts or accidental application to intact skin or mucous membranes.
After topical overdose, the skin should be thoroughly cleaned with soap and water. Thoroughly rinse eyes with water.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Chemotherapy agent for topical use, antiviral agents ATC code: D06BB04

Podophyllotoxin is the therapeutic ingredient of podophyllin, the resin from the rootstock of the pododphyllum species (Berberidaceae).
Podophyllotoxin has a marked antimitotic effect. Binding to tubulin prevents the formation of microtubules and thus spindle formation in the metaphase of cell division. Necrosis of the wart tissue is caused by blocked cell division.

In addition, podophyllotoxin has a tumour-destructive and anti-inflammatory effect.

5.2 Pharmacokinetic properties

Since podophyllotoxin is only absorbed to a low degree when applied locally, no systemic effects are expected with the recommended route of administration and dosage.
The absorbed amount of topically applied podophyllotoxin depends on the application volume. Amounts up to 50 µl of a 0.5% ethanolic solution (corresponds to Condylox) were not detectable in the serum. Patients treated with 100-1500 µl showed serum peak values of 1-17 ng/ml within 1 to 2 hours. There was no accumulation of the substance in the serum.
The half-life of podophyllotoxin is 1-4.5 hours.
Use of up to 250 µl twice daily for 3 days is considered safe and does not result in systemic toxicity.

5.3 Preclinical safety data

No teratogenic effect could be determined in reproductive studies. Nevertheless, the contraindication appears to be useful during pregnancy, as a distribution study in pregnant mice showed that podophyllotoxin crossed the placenta into the foetus.

Based on the long-standing clinical experience, no adverse effects other than those described in other sections of the SmPC are to be expected.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Lactic acid
Sodium lactate solution

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening: 6 weeks or expiry date whichever comes first.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package to protect from light.

6.5 Nature and contents of the container

The amber glass vial with child-proof screw top made of polypropylene contains a 3.5ml solution. The pack is supplied with disposable plastic applicators which have a small hole in one end that holds the solution.

6.6 Special precautions for disposal and other handling instructions

Any unused medicinal product or waste material should be disposed of in accordance with national requirements.
Condylox 0.5% Solution is flammable and should be kept away from naked flames.

7. MANUFACTURER

Takeda Austria GmbH
St.-Peter-Strasse 25
4020 Linz, Austria

8. REGISTRATION HOLDER

Takeda Israel Ltd., 25 Efal St., POB 4140, Petach - Tikva 4951125, Israel

9. REGISTRATION NUMBER

050-14-26541-00

Revised in August 2021 according to MOHs guidelines.