

PACKAGE LEAFLET: INFORMATION FOR THE USER

CATEPHEN[®] 10% OINTMENT

Extract from green tea leaves

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Catephen is and what it is used for
2. What you need to know before you use Catephen
3. How to use Catephen
4. Possible side effects
5. How to store Catephen
6. Contents of the pack and other information

1. WHAT CATEPHEN IS AND WHAT IT IS USED FOR

Catephen is an herbal medicinal product for skin use only. Its active substance is an extract from green tea leaves. Catephen is used to locally treat warts (*Condylomata acuminata*) on the surface of the genitals (sexual organs) and around the anus. Catephen is used in adults with normal function of their immune system.

You should talk to a doctor if you do not feel better or if you feel worse after 4-6 weeks of treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CATEPHEN

Talk to your doctor before using Catephen.

Do not use Catephen

- If you are allergic (hypersensitive) to green tea extract or any of the other ingredients of this medicine (listed in section '6. Contents of the pack and other information').

Warnings and precautions

- Talk to your doctor if you have any problems with your liver or immune system. Catephen should not be used if your liver function is impaired (e.g. abdominal dropsy, yellow skin due to liver dysfunction) or when your immune system is compromised (either due to illness or due to other medicines you are taking).
- Do not use Catephen until the area to be treated has completely healed after previous drug or surgical treatment.
- Avoid contact with the eyes, nostrils, lips and mouth. If the ointment gets on any of these areas inadvertently, it should be wiped off and/or rinsed off with water.
- Do not apply to open wounds, broken or inflamed skin.
- Catephen must not be applied on mucous membranes, so it is not a treatment for warts in the vagina, cervix, urethra or inside the anus.
- Female patients with genital warts in the vulvar region should use the ointment with caution as treatment in this area can cause severe local adverse reactions more often.
- Uncircumcised male patients treating warts under the foreskin should retract the foreskin and clean the area daily to prevent phimosis. When early signs of stricture occur (e.g. open sores, hardening of the skin or increasing difficulty in retracting the foreskin), you should stop the treatment and consult your doctor.
- Catephen does not eliminate the HPV-virus or prevent transmission of the disease, therefore special care should be taken before sexual activity; see section '3. How to use Catephen' of this leaflet.
- In case your sexual partner is infected with genital warts his/her treatment is advisable and will help to prevent reinfection. You can ask your doctor for advice.
- Do not expose the treated area to sunlight and do not use sunlamps and tanning beds.
- Catephen stains clothing and bedding.
- Mild local skin reactions such as redness, itching, irritation (mostly burning), pain and swelling at the site of application are very common and should not lead to discontinuation. They should decrease after the first weeks of treatment; see section '4. Possible side effects'.

Children and adolescents

Catephen is not recommended for use in children and adolescents below the age of 18 years.

Other medicines and Catephen

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine or if you have recently had other treatments for warts around the sexual organs or the anus. Catephen should not be used together with other treatment at the wart area. Catephen should not be used until your skin has healed from other treatments.

Catephen with food and drink

There is no interaction with food and drink.

Catephen should not be used with food supplements containing high amounts of extract from green tea leaves.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

There are no or limited amount of data from the use of Catephen in pregnant women. Studies in animals have shown reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Catephen during pregnancy, although systemic exposure to epigallocatechingallate is expected to be low following dermal application (see section '3. How to use Catephen').

Breast-feeding

It is unknown whether Catephen or its metabolites are excreted in human milk. A risk to the suckling child cannot be excluded.

No effects on the breastfed newborn / infant are anticipated since systemic exposure to epigallocatechingallate is expected to be low following dermal application of Catephen.

Fertility

There is no evidence for an effect on the fertility if you use Catephen as prescribed.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed. However it is unlikely that treatment will have an effect on the ability to drive or use machines.

Catephen contains isopropyl myristate and propylene glycol monopalmitostearate

Catephen contains, among other ingredients, high amounts of isopropylmyristate (IPM), which can cause irritation and sensitization of the skin, and propylene glycol monopalmitostearate which may cause skin irritations.

3. HOW TO USE CATEPHEN

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is up to 0.5 cm of ointment strand (corresponding to 250 mg) for all warts together, applied three times daily (in the morning, at noontime and in the evening).

- **Wash hands before and after applying** the ointment.
- Apply a small amount of Catephen to each wart using the fingers, dabbing it on to ensure complete coverage and leaving a thin layer of the ointment on the warts. Do not apply the ointment internally (into the anus, urethra or into the vagina).
- Do not cover the treated area with bandages after you have applied the ointment.
- It is not necessary to wash off the ointment from the treated area prior to the next application. When you wash the treatment area or bathe, apply the ointment afterwards.
- Apply Catephen **three times per day** (in the morning, at noontime and in the evening).
- New warts may develop during treatment, which need to be treated in the same way.
- Genital warts are a sexually transmitted disease; therefore you may infect your partner by sexual activity. Condoms should be used until complete clearance of all warts. The use of condoms prevents reinfection as well.
- Catephen may weaken condoms and vaginal diaphragms. Before sexual activity, wash off the ointment carefully with warm water and mild soap and apply a condom thereafter. Ask your doctor for additional methods of contraception.
- Female patients during menstruation using tampons: insert the tampon before applying the ointment. If you need to change your tampon while the ointment is on your skin, avoid getting the ointment into the vagina. In case of accidental application immediately wash-off the ointment with warm water and mild soap.
- Duration of treatment with Catephen should be continued until complete clearance of all warts,

however **no longer than 16 weeks**, even if new warts develop during the treatment period. If the warts do not go away or if they come back after treatment please consult your doctor.

Use in children and adolescents (below the age of 18 years)

Catephen is not approved for use in children and adolescents below the age of 18 years.

Older people

There is limited experience for the use of Catephen in older people.

Hepatic impairment

You should not use Catephen if your liver function is impaired (e.g. abdominal dropsy, yellow skin due to liver dysfunction).

If you use more Catephen than you should

You may experience more intense local reactions (see sections '2. What you need to know before you use Catephen' and '4. Possible side effects').

Wash off the extra ointment with mild soap and water.

If you have accidentally swallowed the ointment you should contact your doctor.

If you forget to use Catephen

Continue with normal regimen. Do not take a double dose to make up for a forgotten dose.

If you stop using Catephen

Clearance of warts may not be achieved.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the side effects of Catephen are due to its local action on the skin and occur on or around the treated wart area. Many patients experience redness, itching, irritation, pain or swelling. Mild reactions are expected and should ease after the first weeks of treatment. If however, the intensity of local skin reactions is affecting your daily activities or if vesicles occur, please consult your doctor. It may be necessary to interrupt treatment. Treatment can be resumed after the skin reaction has subsided. In case of vesicular local reactions please consult your doctor. If you experience severe local reaction causing unacceptable discomfort e.g. local inflammation/infection, open sore, swelling of lymph nodes or any other serious reaction (e.g. constriction of foreskin or urethra, difficulty passing urine or severe pain) you should stop treatment, wash off the ointment with warm water and mild soap and consult your doctor straight away.

For the assessment of the side effects the following frequency rating was used:

Very common	In more than 1 in 10 patients treated
Common	In less than 1 in 10, but more than 1 in 100 patients treated
Uncommon	In less than 1 in 100, but more than 1 in 1,000 patients treated

Very common:

- Local skin reactions at the wart site where you have applied Catephen including: redness, itching, irritation/burning, pain, swelling, open sores, hardening of the skin, and blisters.

Common:

- Local skin reactions like flakiness, discharge, bleeding, swelling
- Inguinal Lymph node swelling
- Constriction of the foreskin of the penis

Uncommon:

- Local scarring, fissure, skin dryness, discomfort, erosion, increase or loss of sensation, nodule, papules, inflammation of the skin, and changes in skin colour at the application site, local necrosis, eczema
- Pustules at the application site, infections at the application site, genital herpes infection, staphylococcal infection, fungal infection of the vagina, inflammation of the urethra or of the vulva and vagina
- Pain, high frequency or urgency in urinating
- Inflammation of the foreskin and head of the penis, painful sexual intercourse
- Rash, hypersensitivity

Adverse reactions that were observed with a higher strength (Catephen 15%) ointment only:

- Pyoderma, vulvitis
- Constriction of the urethra/difficulty passing urine, vaginal discharge

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via

IRELAND

HPRA Pharmacovigilance,
Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

UK

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CATEPHEN

Keep this medicine out of the sight and reach of children

Do not store above 25°C

Use within 6 weeks after first opening of the tube

Do not use this medicine after the expiry date which is stated on the tube and carton label after {EXP}. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Catephen contains

The active substance is an extract from green tea leaves. 1 g of the ointment contains 100 mg of extract (as dry extract, refined) from *Camellia sinensis* (L.) O. Kuntze folium (green tea leaf) (24-56:1), corresponding to: 55-72 mg of (-)-epigallocatechin gallate. First extraction solvent: water

The other ingredients are:

White soft paraffin (contains all-*rac*- α -tocopherol), white beeswax, isopropyl myristate, oleyl alcohol, propylene glycol monopalmistearate.

What Catephen looks like and contents of the pack

Catephen is a brown, smooth ointment, free from gritty particles presented in 2 tube sizes: 15 g and 30 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Kora Corporation Ltd t/a Kora Healthcare
Swords Business Park, Swords, Co. Dublin, Ireland

Manufacturer:

Medigene AG
Lochhamer Strasse 11
D-82152 Planegg / Martinsried, Germany.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Veregen 10% Salbe
Belgium:	Veregen pommade
Bulgaria:	Veregen 10% маз
Croatia:	Veregen 100 mg/g mast
Cyprus:	Veregreen 10% Αλοιφή
Czech Republic:	Veregen 10% mast
Denmark:	Veregen, salve
Estonia:	Veregen
Finland:	Veregen voide
France:	Veregen 10%, pommade
Germany:	Veregen 10% Salbe
Greece:	Veregreen 10% Αλοιφή
Hungary:	Veregen 10% kenőcs
Ireland:	Catephen
Italy:	Veregen
Latvia:	Veregen 100 mg/g ziede
Lithuania:	Veregen 100 mg/g tepalas
Luxembourg:	Veregreen 10 %
Netherlands:	Veregen 10%, zalf
Norway:	Veregen salve
Poland:	Veregen 100 mg/g maść
Portugal:	Veregen
Romania:	Veregen 100 mg/g unguent
Slovak Republic:	Veregen 100 mg/g mast
Slovenia:	Veregen 100 mg/g mazilo
Spain:	Veregen 100 mg/g pomada
Sweden:	Veregen salva
United Kingdom:	Catephen

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