

Abbreviated prescribing information.

Refer to full Summary of Product Characteristics before prescribing.

Name: Catephen 10% Ointment **Presentation:** 15 g tube, 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 (-)-epigallocatechingallate. First extraction solvent: water. **Indication:** Catephen is indicated for the cutaneous treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years. **Dosage and administration:** Adults (> 18 years) Up to 250 mg Catephen ointment as total single dose, corresponding to about 0.5 cm of ointment strand to be applied three times per day to all external genital and perianal warts (750 mg total daily dose). **Duration of use** Treatment with Catephen should be continued until complete clearance of all warts, however, no longer than 16 weeks in total (max. duration), even if new warts develop during the treatment period. Paediatric population: the safety and efficacy of Catephen in children and adolescents below the age of 18 years have not been investigated. No data are available.

Older people: An insufficient number of older people were treated with Catephen ointment to determine whether they respond differently from younger subjects. Patients with hepatic impairment: Patients with severe liver dysfunction (e.g. clinically relevant elevation of liver enzymes, increase of bilirubin, increase of INR) should not use Catephen due to insufficient safety data.

Method of administration: A small amount of Catephen should be applied to each wart using the fingers, dabbing it on to ensure complete coverage and leaving a thin layer of the ointment on the warts (max. 250 mg in total for all warts/ per single dose).

Only apply to affected areas; any application into the vagina, urethra or anus must be avoided. Do not apply to mucous membranes. For cutaneous use only. If a dose is missed, the patient should continue with the normal treatment regimen. It is recommended to wash the hands before and after application of Catephen. It is not necessary to wash off the ointment from the treated area prior to the next application. Catephen should be washed off the treated area before sex

ual activity. Female patients using tampons should insert the tampon before applying Catephen. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions: Avoid contact with the eyes, nostrils, lips and mouth. Catephen should not be applied to open wounds, broken or inflamed skin. Therapy with Catephen is not recommended until the skin has completely healed from any previous surgical or drug treatment.

Catephen has not been evaluated for the treatment of urethral, intra-vaginal, cervical, rectal or intra-anal warts and must not be used for the treatment of these conditions. Female patients with genital warts in the vulvar region should use the ointment with caution as treatment in this area is associated more often with severe local adverse reactions. Accidental application into the vagina must be avoided. In case of accidental application into the vagina immediately wash off the ointment with warm water and mild soap. 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. ulceration, induration or increasing difficulty in retracting the foreskin) the treatment should be stopped.

New warts may develop during treatment. Condoms should be used until complete clearance of all warts as Catephen does not eliminate the HPV-virus and does not prevent transmission of the disease. Catephen may weaken condoms and vaginal diaphragms. Therefore, the ointment should be washed off the treated area before the use of condoms and sexual contact. Additional methods of contraception should be considered. If the sexual partner of the patient is infected, treatment of the partner is advisable to prevent re-infection of the patient. Do not expose the treated area to sunlight or UV irradiation, as Catephen has not been tested under these conditions.

The use of an occlusive dressing should be avoided. Catephen stains clothing and bedding.

Mild local skin reactions such as erythema, pruritus, irritation (mostly burning), pain and oedema at the site of application are very common and should not lead to discontinuation. They should decrease after the first weeks of treatment. An interruption of the treatment may be indicated in case of more intense local skin reaction causing unacceptable dis-

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comfort or increase in severity or associated with a lymph node reaction. The treatment with Catephen can be resumed after the skin reaction has diminished.

In case a vesicular local reaction occurs, the patient should be advised to consult a doctor to exclude a genital herpes infection. The effectiveness and safety in patients taking immunomodulatory medicines have not been investigated. Those patients should not use Catephen ointment. The safety and effectiveness for treatment beyond 16 weeks or for multiple treatment courses have not been investigated.

Patients with severe liver dysfunction (e.g. clinically relevant elevation of liver enzymes, increase of bilirubin, increase of INR) should not use Catephen due to insufficient safety data.

Catephen contains propylene glycol monopalmitostearate which may cause skin irritations and isopropyl myristate

effects: Very common (≥1/10) Local reactions at the application site like erythema, pruritus, irritation/burning, pain, ulcer, oedema, induration and vesicles. Common (≥1/100 to <1/10) Local reactions at the application site like exfoliation, discharge, bleeding and swelling, inguinal lymphadenitis/lymphadenopathy, Phimosis. Uncommon (≥1/1,000 to <1/100)

Local reactions at the application site like discoloration, discomfort, dryness, erosion, fissure, hyperaesthesia, anaesthesia, scar, nodule, dermatitis, hypersensitivity, local necrosis, papules, and eczema, Application site infection, application site pustules, genital herpes infection, staphylococcal infection, urethritis, vaginal candidiasis, vulvovaginitis, Dysuria, micturition urgency, pollakiuria, Balanitis, dyspareunia, Rash and papular rash. The maximum mean severity of local reactions was observed in the first weeks of treatment. **MA:** PL 39972/0003 (UK) PA 1748/3/1 (Ireland) **MA Holder:** Kora Corporation Ltd t/a Kora Healthcare, Swords Business Park, Swords Co. Dublin, Ireland **Legal category:** POM. **NHS Price:** 15g tube £39 (UK) **Date of preparation:** June 2015, CATUKIE_061503.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard (UK) or HPRARPharmacovigilance, Earlsfort Terrace, Dublin 2, Ireland. Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie
Adverse events should also be reported to Kora Healthcare on 0845 3038631 (UK) or 01-8900406 (Ire) or medinfo@korahealthcare.com

Catephen®

10% Ointment: extract (as dry extract, refined) from *Camellia sinensis* (L.) O.Kuntze, folium (green tea leaf) (24-56:1), corresponding to: 55-72 mg of (-)-epigallocatechingallate

Three Pillars of Warts Management:

Effective Clearance Low Recurrence Tolerability



Patient Advice



Catephen® Three Pillars of Warts Management

Patient Advice

What is Catephen?

Catephen is a medicinal ointment for skin use only. Its active substance is an extract from green tea leaves. Catephen is used to treat warts (Condylomata acuminata) on the surface of the genitals (sexual organs) and around the anus.

How do I 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. Always wash your hands before and after applying ointment.

When do I apply Catephen?

Apply Catephen three times per day.
The simplest way to use Catephen is to apply it:

1. Immediately after getting up
2. Early evening
3. Before going to bed

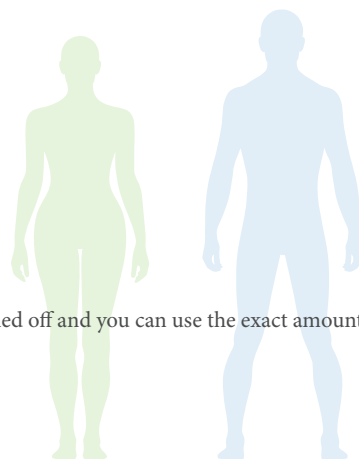
After application Catephen does not need to be washed off and you can use the exact amount that you need and reseal using the screw top lid.

How do I apply Catephen?

- Wash hands before and after applying 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.
- During each application do not apply more than a 0.5cm strand of ointment in total
- You can treat the clear area surrounding the warts, especially if there are a lot of warts

What should I do if I miss an application of Catephen?

Do not use a double dose to make up for a forgotten dose. Continue next dose when it's due.



What should I do if undesirable effects occur?

Mild local skin reactions such as redness, itching, irritation, mild 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. If you notice severe itching, severe burning or if blisters occur, stop treatment and contact your doctor or pharmacist. Your doctor may advise you to interrupt treatment. Treatment may be resumed after the local skin reaction has subsided.

Can I have sex while using Catephen?

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.

How long should you use Catephen before stopping?

Use Catephen for up to 16 weeks, if there are no improvements, please see your doctor.

How quickly can the benefit of Catephen be seen?

You should be able to see an improvement between 4 - 6 weeks.

What if I am menstruating?

If you are 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.

What if I am pregnant or breastfeeding?

There is insufficient data available on the use of Catephen in pregnant women. Therefore, as a precautionary measure, use of Catephen during pregnancy should be avoided.

It is not known if Catephen or its metabolites are excreted in breast milk. Therefore it is not known if there is a risk to a breastfed baby. However following application of the product to the mother's skin, the risk of adverse effects in the breastfed baby are likely to be low.

Where can I find more information?

Please refer to the information leaflet in the Catephen 10% ointment packaging for more information. If you have any concerns, please talk to your doctor or pharmacist.