PATIENT GROUP DIRECTION (PGD)		
PGD 284(S)	**CATEPHEN (*Camellia sinensis* (green tea) leaf extract) 10% ointment for external genital and perianal warts**	**POM**

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

PROFESSIONAL(S) TO WHICH THIS PGD APPLIES:

Registered Nurses working in Integrated Sexual Health Service (ISHS) who have received training relating to the use/content of this direction.

CLINICAL CONDITION	
Indication	Cutaneous treatment of external genital and perianal warts (*condylomata acuminata*) in patients from the age of 18 years. **NOTE:** There are four treatments for above condition of which three are PGDs, and the fourth is cryotherapy which is a Standard Operating Procedure (SOP): • Catephen can be considered as an alternative for first line use with **external** vulval and penile warts. • Podophyllotoxin should be considered for first line use for non-keratinised warts affecting the penis or external female genitalia that are easy for patient to self-treat without risking damage to surrounding skin and preferable to Imiquimod for warts on glans penis or foreskin in uncircumcised males. • Imiquimod should be considered for all peri-anal warts, for keratinised or multiple warts, and if no response to Podophyllotoxin cream after 4-5 weeks treatment. • If fewer than 5 keratinised or peri-anal warts, consider cryotherapy
Inclusion Criteria	Patients aged 18 years of age and older.
Exclusion Criteria	• Patients under 18 years of age • Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received **Medical history** • Practitioner cannot accurately determine that the lesions are genital warts • Inflamed, ulcerated or broken skin • Warts on internal mucosal skin (vagina, anal canal, urethral meatus, cervix)

	• Extra-genital warts • Warts involving area more than 4cm^2 • Individuals with autoimmune conditions, on immunosuppressive or immunomodulatory treatment, or organ transplant recipients • Individuals who are unable to apply the preparation safely • Pregnancy or suspected pregnancy • Breast feeding mothers • Patients refusing treatment under this direction • Known hypersensitivity or allergy to *Camellia sinensis* (green tea) leaf extract or any other constituent or excipient of the medicine. • Patients with severe liver dysfunction (e.g. clinically relevant elevation of liver enzymes, increase of bilirubin, increase of INR) • Failed treatment within the same episode • Repeated presentations – received treatment from a nurse more than twice in 6 months
Cautions/Need for Further Advice	**Drug Interactions:** Check patient's current medication with the patient and eBNF before supplying. Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
Action if Patient Declines or is Excluded	• If a patient is excluded, explain the reasons for exclusion to the individual/carer and document in the patient notes and consider alternative treatment or refering to a doctor / non-medical prescriber. • Document advice given. If a patient with mental capacity declines treatment or referral, discuss potential consequences of not undertaking treatment and document full discussion in patient's records.

DRUG DETAILS	
Name, Form & Strength of Medicine	Catephen (*Camellia sinensis* (green tea) leaf extract) 10% ointment.
Route/Method	Topical to external warts. Not for intravaginal use.
Off-label Use	Not applicable – used within marketing authorisation.
Dosage/Frequency	Apply up to 250mg corresponding to 0.5cm of ointment strand to be applied three times per day.
Quantity	Initial supply: one 15g tube of ointment. Once opened, the product has a shelf life of 6 weeks. Second supply (after review once the first tube expired): one 15g tube of ointment.

Maximum Dosage	Three applications daily (750 mg total daily dose)
Duration of Treatment	Initial treatment: 6 weeks then review. A total of 12 weeks of treatment under the PGD, then refer to a prescriber. NOTE: Treatment with Catephen should be continued until complete clearance of all warts; however treatment should not exceed 16 weeks (week 13-16 under a prescriber) in total even if new warts develop during the treatment period. If <50% improvement in wart volume after 8 weeks, consider switching to an alternative.
Advice to Patient/Carer	The patient should be provided with a manufacturer's patient information leaflet and this should be documented including date and version number. The patient should also be advised: • How to use Catephen. • When to apply Catephen. • How to apply Catephen. • What to do if an application is missed. • What to do if undesirable effects occur. • Advice on sex while using Catephen. • Treatment duration. • When can benefits of Catephen be seen. • What to do during menstruation. • Where they can find more information. • Avoid contact with the eyes, nostrils, lips and mouth. • Catephen should not be applied to mucous membranes, open wounds, broken or inflamed skin. • 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 sexual activity. • 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. • Female patients using tampons should insert the tampon before applying Catephen. • 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. • 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. • Do not expose the treated area to sunlight or UV irradiation, as Catephen has not been tested under these conditions • 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. • In case a vesicular local reaction occurs, the patient should be advised to consult a doctor to exclude a genital herpes infection • Concomitant use of other local treatments in the wart area should be avoided (e.g. sitz baths, topically applied zinc or vitamin E etc.).Concomitant intake of high-dosed oral green tea extract preparations (food supplements) should be avoided. • After first opening use within 6 weeks Patients should also be given: • Information regarding aetiology of anogenital warts. • Advice on treatment, compliance and side effects supported by manufacturer's patient information leaflet • Advice regarding possible measures to reduce likelihood of recurrence. • Advice on safer sex in general for future sexual health.
Advice to Staff	• Therapy with Catephen is not recommended until the skin has completely healed from any previous surgical or drug treatment. • New warts may develop during treatment. • If the sexual partner of the patient is infected, treatment of the partner is advisable to prevent re-infection of the patient. • The use of an occlusive dressing should be avoided. • An interruption of the treatment may be indicated in case of more intense local skin reaction causing unacceptable discomfort or increase in severity or associated with a lymph node reaction. The treatment with Catephen can be resumed after the skin reaction has diminished. • Catephen contains propylene glycol monopalmitostearate which may cause skin irritations and isopropyl myristate which may cause irritation and sensitization of the skin. **Safeguarding**: Where there are any safeguarding concerns refer to local policies for safeguarding adults and children and/or seek advice from the safeguarding lead/team in the organisation. Document the concern and outcome in the healthcare record. DCHS: Safeguarding adults and children policies on DCHS intranet site DCHS Safeguarding Team: 01773 850000. **In the absence of a second checker self-check** correct product, dose selected and check expiry date. If the patient is receiving any concomitant medication or treatment it is the responsibility of the person identified in "Professional Group" to ensure that treatment with the drug detailed in this direction is appropriate.

	Check all concurrent medication with the patient and in the eBNF before supplying. Refer to a doctor if the patient is taking any medication that may interact with the intended treatment. If in any doubt advice should be sought and recorded before the drug is administered/supplied. ISHS doctor available for advice and support.
Record	• Assessment of competency to consent to treatment for patients at risk • Any discussion with doctor/ another professional • Verbal consent obtained • Diagnosis • Allergies • Drug, dose, form, route, quantity and length of course supplied / administered • Expiry date and batch number • Practitioner identifier for staff member who supplied the medication, and also, if relevant, identifier of staff who removed/discontinued the treatment • Advice given to patient (including side effects, contraception etc) • Referral arrangements (including self-care) • Any other relevant details of consultation • Supplied / administered via PGD See Clinical Record-Keeping Policy and Standards and Medicines Code.

REFERRAL ARRANGEMENTS AND AUDIT TRAIL	
Referral Arrangements	The nurse is expected to use their clinical judgment and refer patients to an appropriate senior or medical doctor for advice and management as they see fit.
Records/Audit Trail	In patient's record. Record PGD use.

CHARACTERISTICS OF STAFF	
Qualifications	A registered nurse working within ISHS who is deemed competent by their clinical line manager and authorised by their professional lead to undertake the clinical assessment of a patients leading to the identification of those suitable for management under this PGD.
Additional Local Training	Has undertaken the local training programme on the process, responsibilities and scope of PGDs.

	Has undertaken local training based on the use of this PGD. Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the 12 months. Undertakes Safeguarding Children Level 3 training annually.
Continuing Training & Education	Evidence of Continuing Professional Development in ISHS nurse role. Successful completion sexual health in-house training or sexual health module/course accredited or endorsed by the BASHH, CPPE, RCN or a university or advised in the RCN Sexual Health Education directory eg STIF. The nurse should be aware of any change to the recommendations for the medicines listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

ADDITIONAL INFORMATION	
References	1. British National Formulary http://www.bnf.org 2. Summary of product characteristics http://emc.medicines.org.uk (SPC last updated Oct 2022) 3. BASHH UK National Guidelines on the Management of Anogenital Warts (2015)
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC. However, in the event of an inadvertent or unavoidable deviation of temperature follow the Temperature Monitoring of Medicines Storage Rooms SOP.
Drug Interactions	Comprehensive lists of drug interactions are not described in each PGD, only the most significant are listed. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the eBNF www.bnf.org.
Identification & Management of Adverse Reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and eBNF www.bnf.org The following side effects have been observed with Catephen (but may not reflect all reported side effects):

	• Very common (≥1/10) Local reactions at the application site like erythema, pruritus, irritation/burning, pain, ulcer, oedema, induration and vesicles • Common (1 in 100 to <1 in 10): Local reactions at the application site like exfoliation, discharge, bleeding and swelling. • Inguinal lymphadenitis/lymphadenopathy • Phimosis See eMC for full details
Management of and Reporting Procedure for Adverse Reactions	• Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare Products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's medical record • Report any adverse reactions via DCHS incident policy.

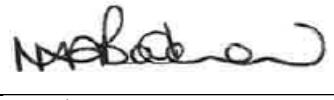
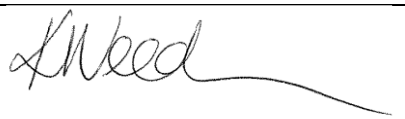
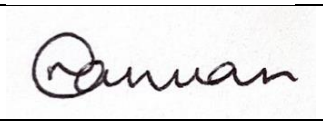
Review		
Date & Comments	**Name**	**Position**
December 2020 • Minor wording change to clarify Covid information.	Emily Stelmach	Advanced Pharmacist
February 2023 • Routine update in line with SPC PGDs for genital warts • Covid advice removed	Emily Stelmach Lisa Walton Dr Ade Apoola	Advanced Pharmacist ISHS Specialist Nurse Practitioner ISHS Lead Clinician

ANTIMICROBIAL SPECIALIST INPUT DURING REVIEW		
Advice/Comments	**Name**	**Position**
March 2023 Reviewed and aligned with DCHS Antibiotic PGD template	Cerina Nanuan	Advanced Pharmacist in IP&C

PATIENT GROUP DIRECTION AUTHORISATION

PGD approved by PGD Working Group on *23rd March 2023*

This PGD is authorised for use on behalf of DCHS by the following signatories.

Position of signatory	Name	Signature	Date
Director of Nursing, AHPs & Quality	Michelle Bateman		12/04/2023
Head of Medicines Management	Kate Needham		12/04/2023
Medical Director	Dr Ben Pearson		12/04/2023
Lead Clinician	Dr Ade Apoola		12/04/2023
Specialist in Antimicrobial Therapy	Cerina Nanuan		12/04/2023

PRACTITIONER AUTHORISATION SHEET

PGD: 284(S) Catephen
Version & Expiry Date: v2.0, **Expiry:** 31st March 2026

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Derbyshire Community Health Services for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet must be retained to serve as a record of those practitioners authorised to work under this PGD.