



# Medicine Supply Notification

MSN/2024/109U

## UPDATE:

Updates to communication (MSN/2024/109) issued 26 November 2024 **in bold**

## **Camellia sinensis extract (Catephen®) 10% ointment**

## **Fluorouracil (Efudix®) 5% cream**

Imiquimod (Aldara® 5% and **Zyclara® 3.75%**) cream 250mg sachets

Tier 2 – medium impact\*

Date of issue: 03/02/2025

Link: [Medicines Supply Tool](#)

## Summary

<b>Camellia sinensis extract (Catephen®) 10% ointment</b>	<b>In limited supply until mid-February 2025 and then out of stock until late April 2025</b>
<b>Fluorouracil (Efudix®) 5% cream</b>	<b>In limited supply until March 2025.</b>
<b>Imiquimod (Zyclara®) 3.75% cream 250mg sachets</b>	<b>Out of stock until mid-April 2025.</b>
Imiquimod (Aldara®) 5% cream 250mg sachets	Out of stock until <b>mid-April 2025.</b>
Podophyllotoxin (Warticon®) 0.15% cream	Out of stock until <b>mid-March 2025</b> (reported in <a href="#">MSN/2024/069</a> ).

*New/updated information in bold*

- **Limited supply of alternative products** (see Supporting Information).
- Unlicensed supplies may be sourced; lead times vary.

## Actions Required

Clinicians should not initiate new patients on imiquimod (Aldara® 5% or **Zyclara® 3.75%**) cream or **Catephen® 10% ointment** until the shortages have resolved.

Where patients have insufficient supplies to last until the re-supply dates, clinicians should consider:

- **prioritising available supply of Efudix® 5% cream for treatment of patients in need of urgent treatment;**
- **delaying non-urgent treatment until the shortages of Efudix® 5% and Aldara 5% have resolved;**
- prescribing an alternative product in line with the product's licensed indication and local guidelines/formulary.
- ensure that the patient is not intolerant to any of the excipients of any alternative product and is counselled on dosing and administration (see Supporting information);
- prescribing unlicensed products only where licensed alternatives are not appropriate, working with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see Supporting information); and
- if the above options are not considered appropriate, or off-label use of a product is being considered, advice should be sought from specialists on management options.

\*Classification of Tiers can be found at the following link:

<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

## Supporting information

### Imiquimod (Aldara®) 5% Cream

Licensed for topical treatment of:

- external genital and perianal warts (condylomata acuminata) in adults.
- small superficial basal cell carcinomas in adults.
- clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on face or scalp in immunocompetent adult patients when size or number of lesions limit efficacy and/or acceptability of cryotherapy and other topical treatment options are contraindicated or less appropriate.

### Imiquimod (Zyclara®) 3.75% cream

**Licensed for topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis of full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate.**

### Camellia sinensis extract (Catephen®) 10% ointment

**Licensed for topical treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from age of 18 years.**

Table 1: Availability of alternative licensed topical preparations

Drug	Brand and presentation	Licensed indication	Ability to support
<b>Actinic (solar) keratosis</b>			
Diclofenac 3%	Solaraze® gel	Treatment of actinic keratosis in adults.	Partially support
Fluorouracil 4%	Tolak® cream	Treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade I and II) of the face, ears, and/or scalp in adults.	Partially support
Fluorouracil 5%	Efudix® cream	Treatment of keratoses including senile, actinic and arsenical forms	Limited supply, see actions.
Fluorouracil 5mg/g with salicylic acid 100mg/g	Actikerall® Cutaneous Solution	Treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients.	Partially support
Imiquimod 50mg/g	Bascellex® cream	Treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on face or scalp in immunocompetent adult patients when size or number of lesions limit efficacy and/or acceptability of cryotherapy, and other topical treatment options are contraindicated or less appropriate	Partially support
Tirbanibulin 10 mg/g	Klisyri® ointment ( <i>new product</i> ▼ <i>subject to additional monitoring</i> ).	Field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.	Partially support
<b>Basal cell carcinoma</b>			
Fluorouracil 5%	Efudix® 5% cream	Treatment of superficial basal-cell carcinoma	Limited supply, see actions.
<b>Anogenital warts</b>			
Podophyllotoxin 0.5%	Warticon® solution	Treatment of condylomata acuminata affecting the penis or the external female genitalia.	Partially support

### Unlicensed treatments for anogenital warts

Cryotherapy or other forms of physical ablative therapy (e.g., surgery, laser treatment) may be considered for anogenital warts, particularly for patients with a small number of low-volume warts, irrespective of type.

Unlicensed trichloroacetic acid 80-90% solution is used in a specialist clinic setting only.

Off label use of fluorouracil cream is not recommended for *routine* management of genital warts.

### Guidance on ordering and prescribing unlicensed imports

The following specialist importers have confirmed they can source unlicensed supplies of the listed products (please note there may be other companies that can also source supplies)

- Alium Medical (**fluorouracil 5% cream, imiquimod 3.75% and 5% cream**)
- Chemys (**fluorouracil 5% cream**)
- Durbin (**fluorouracil 5% cream, imiquimod 3.75% and 5% cream**)
- Genetech Pharmaceuticals (**fluorouracil 5% cream, imiquimod 5% cream**)
- Mawdsleys (**fluorouracil 5% cream, imiquimod 3.75% and 5% cream**)
- Target Healthcare (**fluorouracil 5% cream, imiquimod 5% cream**)

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.

Please see the links below for further information:

- [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
- [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
- [Prescribing unlicensed medicines](#), General Medical Council (GMC),

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

- Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:
  - fluorouracil 5% cream (imported)
  - imiquimod 3.75% cream (imported)
  - imiquimod 5% cream (imported)

Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: “**special order**”.

### Links to further information

[BNF treatment summary - Photodamage](#)

[BNF treatment summary - Anogenital warts](#)

[BASHH guidelines: anogenital warts](#)

[CKS- anogenital warts](#)

[British Association of Dermatologists' guidelines: actinic keratosis](#)

[Primary Care Dermatology Society: clinical guidance- actinic keratosis](#)

[British Association of Dermatologists guidelines: basal cell carcinoma](#)

[SmPC Imiquimod preparations](#)

[SmPC Solaraze® 3% Gel](#)

[SmPC Tolak 40 mg/g cream](#)

[SmPC Efudix® 5% cream](#)

[SmPC Warticon® cream and solution](#)

[SmPC Catephen® 10% ointment](#)

[SmPC Klisyri® 10 mg/g ointment](#)

[SmPC Actikerall® 5mg/g + 100mg/g cutaneous solution](#)

[SPS: Shortage of Podophyllotoxin \(Warticon\) 0.15% cream and 0.5% solution](#)

**Enquiries** Enquiries from NHS Trusts in England should in the first instance be directed to your Regional Pharmacy Procurement Specialist (RPPS) or Associate RPPS, who will escalate to national teams if required.

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All other organisations should send enquiries about this notice to the DHSC Medicine Supply Team quoting reference number MSN/2024/109U

Email: [DHSCmedicinesupplyteam@dhsc.gov.uk](mailto:DHSCmedicinesupplyteam@dhsc.gov.uk).