



Medicine Supply Notification

MSN/2024/069

Imiquimod (Aldara[®]) 5% cream and podophyllotoxin (Warticon[®]) 0.5% solution and 0.15% cream

Tier 2 – medium impact*

Date of issue: 05/06/2024

Link: [Medicines Supply Tool](#)

Summary

- Imiquimod (Aldara[®]) 5% cream will be out of stock from mid-June 2024 until late July 2024.
- Podophyllotoxin (Warticon[®]) 0.5% solution is out of stock until mid-June 2024.
- Podophyllotoxin (Warticon[®]) 0.15% cream is out of stock until mid-October 2024.
- Imiquimod (Zyclara[®]) 3.75% cream remains available and can support a partial increase in demand.
- Imiquimod (Bascellex[®]) 50 mg/g cream remains available and can support a partial increase in demand.
- Fluorouracil (Efudix[®]) 5% cream remains available, however, cannot support any increase in demand.
- Diclofenac (Solaraze[®]) 3% gel, fluorouracil with salicylic acid (Actikerall[®]) cutaneous solution and tirbanibulin (Klisyri[®]) ointment remain available and can support an increase in demand.
- Camellia sinensis (Catephen[®]) 10% ointment remains available and can support a partial increase in demand.
- Unlicensed supplies of imiquimod 5% cream may be sourced, lead times vary.

Actions Required

Clinicians should not initiate new patients on imiquimod (Aldara[®]) 5% cream or podophyllotoxin (Warticon[®]) 0.5% solution or 0.15% cream until the shortages have resolved.

Where patients have insufficient supplies to last until the re-supply date(s), clinicians should consider:

- prescribing an alternative product with reference to the licensed indication, ensuring that the patient is not intolerant to any of the excipients and is counselled on dosing and administration (see Supporting information);
- whether supplies of fluorouracil (Efudix[®]) 5% cream need to be prioritised for certain patient groups to ensure stock is not depleted through use for conditions that can be treated with other products;
- 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, advice should be sought from specialists on alternative 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

Clinical Information

Imiquimod (Aldara®) 5% Cream is licensed for the 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 the face or scalp in immunocompetent adult patients when size or number of lesions limit the efficacy and/or acceptability of cryotherapy and other topical treatment options are contraindicated or less appropriate.

Podophyllotoxin (Warticon®) cream and solution are licensed for the topical treatment of condylomata acuminata affecting the penis or the external female genitalia.

Table 1: Alternative licensed topical preparations

Drug	Brand and presentation	Indication
Actinic (solar) keratosis		
Imiquimod	Bascellex® 50 mg/g cream	Treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adult patients when size or number of lesions limit the efficacy and/or acceptability of cryotherapy, and other topical treatment options are contraindicated or less appropriate.
Imiquimod	Zyclara® 3.75% cream*	Treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate.
Diclofenac sodium gel	Solaraze® 3% gel	Treatment of actinic keratosis.
Fluorouracil	Efudix® 5% cream	Treatment of keratoses including senile, actinic and arsenical forms.
Fluorouracil with salicylic acid	Actikerall® 5mg/g + 100mg/g Cutaneous Solution	Treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients.
Tirbanibulin	Klisyri® 10 mg/g ointment▼ (This is a new product and is subject to additional monitoring).	Field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.
Basal cell carcinoma		
Fluoruracil	Efudix® 5% cream	Treatment of superficial basal-cell carcinoma
Anogenital warts		
Camellia sinensis	Catephen® 10% Ointment	Treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years.

*In the USA, Zyclara® 3.75% cream is approved to treat external genital and perianal warts/condyloma acuminata in patients 12 years or older

Unlicensed treatments for anogenital warts

Cryotherapy or other forms of physical ablative therapy (e.g., surgery, laser treatment) may also 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.

Links to further information

[BNF treatment summary - Photodamage](#)

[BNF treatment summary - Anogenital warts](#)

[BASHH guidelines: anogenital warts](#)

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

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

[SmPC Imiquimod preparations](#)

[SmPC Solaraze® 3% Gel](#)

[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](#)

Guidance on ordering and prescribing unlicensed imports

The following specialist importers have confirmed they can source unlicensed imiquimod 5% cream (please note there may be other companies that can also source supplies):

- Alium Medical
- Mawdsleys

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:
 - 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**”.

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.

REGION	Lead RPPS	Email	Associate RPPS	Email
Midlands	Andi Swain	andi.swain@nhs.net	vacant	
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All other organisations should send enquiries about this notice to the DHSC Medicine Supply Team quoting reference number MSN/2024/069

Email: DHSCmedicinesupplyteam@dhsc.gov.uk.