



## Medicine Supply Notification

MSN/2024/109

Imiquimod (Aldara<sup>®</sup> 5% and Bascellex<sup>®</sup> 50mg/g) cream 250mg sachets

Tier 2 – medium impact\*

Date of issue: 26/11/2024

Link: [Medicines Supply Tool](#)

### Summary

- Imiquimod (Aldara<sup>®</sup>) 5% cream 250mg sachets are out of stock until mid-January 2025.
- Imiquimod (Bascellex<sup>®</sup>) 50 mg/g cream 250mg sachets are out of stock until early January 2025.
- Podophyllotoxin (Warticon<sup>®</sup>) 0.15% cream is out of stock until late January 2025 (reported in [MSN/2024/069](#)).
- Efudix<sup>®</sup> (fluorouracil 5%) cream remains available, however it cannot support an uplift in demand.
- Alternative products remain available, and where these are not suitable, unlicensed supplies may be sourced, lead times vary.

### Actions Required

Clinicians should not initiate new patients on imiquimod (Aldara<sup>®</sup> 5% or Bascellex<sup>®</sup> 50mg/g) 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 and local guidelines/formulary, if appropriate, ensuring that the patient is not intolerant to any of the excipients 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, advice should be sought from specialists on management options.

### Supporting information

#### Clinical Information

Imiquimod (Aldara<sup>®</sup>) 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.

Imiquimod (Bascellex<sup>®</sup>) 50mg/g cream is licensed for the topical 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.

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

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

Table 1: Alternative licensed topical preparations

Drug	Brand and presentation	Licensed indication	Ability to support
<b>Actinic (solar) keratosis</b>			
Imiquimod 3.75%	Zyclara® 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.	Unable to support
Diclofenac 3%	Solaraze® gel	Treatment of actinic keratosis in adults.	Partially support
Fluorouracil 5%	Efudix® cream	Treatment of keratoses including senile, actinic and arsenical forms	Unable to support**
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
Tirbanibulin 10 mg/g	Klisryi® ointment ( <i>This is a new product ▼ 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	Unable to support**
<b>Anogenital warts</b>			
Podophyllotoxin 0.5%	Warticon® solution	Treatment of condylomata acuminata affecting the penis or the external female genitalia.	Partially support
Camellia sinensis 10%	Catephen® Ointment	Treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years.	Partially support

\*In the USA, imiquimod (Zyclara®) 3.75% cream is also approved to treat external genital and perianal warts in patients 12 years or older.

\*\* Fluorouracil (Efudix®) 5% cream stock should not be used for conditions that can be treated with other products to avoid impacting its supply.

### 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.

### 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
- Genetech Pharmaceuticals
- Durbin
- Target Healthcare
- 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**”.

#### 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](#)

[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](#)

[Shortage of Podophyllotoxin \(Warticon\) 0.15% cream and 0.5% solution – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

**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	<a href="mailto:andi.swain@nhs.net">andi.swain@nhs.net</a>	Dav Manku	<a href="mailto:Dav.Manku@uhb.nhs.uk">Dav.Manku@uhb.nhs.uk</a>
East of England	James Kent	<a href="mailto:james.kent@nhs.net">james.kent@nhs.net</a>	Tracy McMillan	<a href="mailto:tracy.mcmillan2@nhs.net">tracy.mcmillan2@nhs.net</a>
London	Jackie Eastwood	<a href="mailto:jacqueline.eastwood@gstt.nhs.uk">jacqueline.eastwood@gstt.nhs.uk</a>	Daniel Johnson	<a href="mailto:Daniel.Johnson@gstt.nhs.uk">Daniel.Johnson@gstt.nhs.uk</a>
North East and Yorkshire	David Allwood	<a href="mailto:davidallwood@nhs.net">davidallwood@nhs.net</a>	Penny Daynes	<a href="mailto:penny.daynes@nhs.net">penny.daynes@nhs.net</a>
North West	Richard Bateman	<a href="mailto:richard.bateman@liverpoolft.nhs.uk">richard.bateman@liverpoolft.nhs.uk</a>	Andy Stewart	<a href="mailto:Andrew.stewart@liverpoolft.nhs.uk">Andrew.stewart@liverpoolft.nhs.uk</a>
South East	Alison Ashman	<a href="mailto:Alison.Ashman@berkshire.nhs.uk">Alison.Ashman@berkshire.nhs.uk</a>	Melanie Renney	<a href="mailto:melanie.renney@berkshire.nhs.uk">melanie.renney@berkshire.nhs.uk</a>

<b>South West</b>	Danny Palmer	<a href="mailto:danny.palmer@uhbw.nhs.uk">danny.palmer@uhbw.nhs.uk</a>	Natalie Bryson	<a href="mailto:Natalie.Bryson@uhbw.nhs.uk">Natalie.Bryson@uhbw.nhs.uk</a>
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**Scotland:** [nss.nhssmedicineshortages@nhs.scot](mailto:nss.nhssmedicineshortages@nhs.scot)

**Wales:** [MedicinesShortages@gov.wales](mailto:MedicinesShortages@gov.wales)

**Northern Ireland:** [RPHPS.Admin@northerntrust.hscni.net](mailto:RPHPS.Admin@northerntrust.hscni.net)

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

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