



11 December 2024

Medicine Supply Alert Notice

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

Priority: Level 2*

Valid until: mid-January 2025

Issue

1. Imiquimod (Aldara®) 5% cream 250mg sachets are out of stock until mid-January 2025.
2. Imiquimod (Bascellex®) 50 mg/g cream 250mg sachets are out of stock until early January 2025.
3. Podophyllotoxin (Warticon®) 0.15% cream is out of stock until late January 2025 (see also [MSAN\(2024\)34](#)).
4. Efudix® (fluorouracil 5%) cream remains available, however it cannot support an uplift in demand.
5. Alternative products remain available, and where these are not suitable, unlicensed supplies may be sourced, lead times vary.

Advice and Actions

6. Clinicians should not initiate new patients on imiquimod (Aldara® 5% or Bascellex® 50mg/g) cream until the shortages have resolved.
7. 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 Additional 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 Additional information); and
 - if the above options are not considered appropriate, advice should be sought from specialists on management options.

Additional Information

Clinical Information

8. 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.

*<https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf>

- 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.

9. Imiquimod (Bascellex®) 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.

Table 1: Alternative licensed topical preparations

Drug	Brand and presentation	Licensed indication	Ability to support
Actinic (solar) keratosis			
Imiquimod 3.75%	Zyclara® cream*	Topical 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	Topical treatment of keratoses including senile, actinic and arsenical forms	Unable to support**
Fluorouracil 5mg/g with salicylic acid 100mg/g	Actikeral® Cutaneous Solution	Topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients.	Partially support
Tirbanibulin 10 mg/g	Klisyri® ointment (<i>This is a new product ▼subject to additional monitoring</i>).	Field treatment of non-hyperkeratotic, nonhypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.	Partially support
Basal cell carcinoma			
Fluorouracil 5%	Efudix® 5% cream	Topical treatment of superficial basal-cell carcinoma	Unable to support**
Anogenital warts			
Podophyllotoxin 0.5%	Warticon® solution	Topical 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 (<i>condylomata acuminata</i>) 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

10. 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.
11. Unlicensed trichloroacetic acid 80-90% solution is used in a specialist clinic setting only.
12. Off label use of fluorouracil cream is not recommended for *routine* management of genital warts.

Guidance on ordering and prescribing unlicensed imports

13. 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
14. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health Board 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).

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 medicine supply tool](#) (registration to access the website required)

Specialist Pharmacy Service (SPS) website

15. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the [SPS website](#). Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
16. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

17. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or NSS.NHSSMedicineShortages@nhs.scot (secondary care).