NHS Circular: MSAN (2025) 07

Chief Medical Officer Directorate Pharmacy and Medicines Division



5 February 2025

Medicine Supply Alert Notice

Camellia sinensis extract (Catephen®) 10% ointment Fluorouracil (Efudix®) 5% cream Imiquimod (Aldara® 5% and Zyclara® 3.75%) cream 250mg sachets - UPDATE

Priority: Level 2*

Valid until: late April 2025

Issue

- 1. Camellia sinensis extract (Catephen®) 10% ointment is in limited supply until mid-February 2025 and then out of stock until late April 2025.
- 2. Fluorouracil (Efudix®) 5% cream is in limited supply until March 2025.
- 3. Imiguimod (Aldara®) 5% cream 250mg sachets are out of stock until mid-April 2025.
- Podophyllotoxin (Warticon[®]) 0.15% cream is out of stock util mid-April 2025 (see also MSAN(2024)34).
- 5. **Limited supply of alternative products** (see Additional Information section), and where these are not suitable, unlicensed supplies may be sourced, lead times vary.
- 6. This MSAN supersedes MSAN(2024)66, issued on 11 December 2024. New / updated information is in bold.

Advice and Actions

- 7. Clinicians should not initiate new patients on imiquimod (Aldara® 5% or **Zyclara® 3.75%**) cream or **Catephen® 10% ointment** until the shortages have resolved.
- 8. Where patients have insufficient supplies to last until the re-supply date(s), 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 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.

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

Additional Information

Clinical Information

Imiquimod (Aldara®) 5% Cream

- 9. 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 (Zyclara®) 3.75% cream

10. 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

11. 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
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
Tirbanibulin10 mg/g	Klisyri® ointment (new product subject to additional monitoring).	Field treatment of non-hyperkeratotic, nonhypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.	Partially support

Fluorouracil 5%	Efudix® 5% cream	Treatment of superficial basal-cell carcinoma	Limited supply, see actions.
Podophyllotoxin 0.5%	Warticon® solution	Treatment of condylomata acuminata affecting the penis or the external female genitalia.	Partially support

Unlicensed treatments for anogenital warts

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

Guidance on ordering and prescribing unlicensed imports

- 15. 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 (fluorouracil 5% cream, imiguimod 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)
- 16. 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:
 - <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA)
 - <u>Professional Guidance for the Procurement and Supply of Specials</u>, 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

- 17. 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.
- 18. 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

19. 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).