



11 June 2024

## **Medicine Supply Alert Notice**

### **Imiquimod (Aldara®) 5% cream and podophyllotoxin (Warticon®) 0.5% solution and 0.15% cream**

**Priority: Level 2\***

**Valid until: mid-October 2024**

#### **Issue**

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

#### **Advice and Actions**

10. Prescribers 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.
11. Where people have insufficient supplies to last until the re-supply date(s), prescribers should consider:
  - prescribing an alternative product with reference to the licensed indication, ensuring that the person is not intolerant to any of the excipients and is counselled on dosing and administration (see Additional information);
  - whether supplies of fluorouracil (Efudix®) 5% cream need to be prioritised for certain 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 Additional information); and

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

- if the above options are not considered appropriate, advice should be sought from specialists on alternative management options.

## Additional Information

### Clinical Information

12. 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.

13. 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   |
|----------------------------------|--|--|
| <b>Actinic (solar) keratosis</b> |  |  |
| 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.  |

| Drug                        | Brand and presentation   | Indication   |
|-----------------------------|--|--|
| Tirbanibulin                | Klisyri® 10 mg/g ointment<br>( <i>This is a new product and is subject to additional monitoring</i> ). | Field treatment of non-hyperkeratotic, nonhypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.       |
| <b>Basal cell carcinoma</b> |  |  |
| Fluoruracil                 | Efudix® 5% cream   | Treatment of superficial basal-cell carcinoma  |
| <b>Anogenital warts</b>     |  |  |
| 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*

14. 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.
15. Unlicensed trichloroacetic acid 80-90% solution is used in a specialist clinic setting only.
16. 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 Actikeral® 5mg/g + 100mg/g cutaneous solution](#)

#### Guidance on ordering and prescribing unlicensed imports

17. 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
18. 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.

19. 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).

### **Specialist Pharmacy Service (SPS) website**

20. 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.

21. 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**

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