# Use of Topical Steroids in Wound Care Where an Excessive Inflammatory Response may be Present Dec 2020

**Off-label** (use of medicines outside the terms of the licence) **use of topical steroids in wounds, where an excessive inflammatory response may be present resulting in excessive degradation of the extracellular matrix and failure of progression of wound healing, is not recommended within the primary care setting unless instigated and overseen by a specialist service (e.g. Leg Ulcer Clinic, Community Tissue Viability Service, Local service/Specialist practitioner or Podiatry) using the Protocol for the specialist use of topical steroid preparation on wound beds within the community – please see page 3**

The rationale that should be considered before using a topical steroid:

- It should only be recommended when all other options have been tried and only following **review and initiation by a Specialist service** e.g. Leg Ulcer Clinic, Community Tissue Viability Service, Local service/Specialist practitioner or Podiatry
- Its use is for an unlicensed indication and therefore this should be discussed with the patient and must be documented in the notes - please see page 4 for further guidance
- The appropriate strength of steroid should be selected following clinical review by the **Specialist service**
- Appropriate documentation must be made in the notes and patient care plan to include frequency and quantity to be applied in fingertip units, duration of treatment and review/end date
- The wound should be regularly assessed to ensure there are no signs of infection
- If no improvement is demonstrated at review then the treatment must be stopped

Table 1: Cost of topical steroids +/- antibacterials +/- antifungal. Drug Tariff Dec 2020

| Product | Steroid | Antibacterial | Antifungal | Cost 30g |
|---|---|---|---|---|
| **Moderate steroid** | | | | |
| **Eumovate®** (Ointment & Cream) https://www.medicines.org.uk/emc/product/3808 https://www.medicines.org.uk/emc/product/3807 | Clobeta**sone** butyrate 0.05% (30g) | | | £1.86 |
| **Haelan®** (Cream) https://www.medicines.org.uk/emc/product/2696 | Fludroxycortide 0.0125%(60g) | | | £5.99 |
| **Potent steroid** | | | | |
| **Betnovate®** (Ointment & Cream) https://www.medicines.org.uk/emc/product/929/smpc https://www.medicines.org.uk/emc/product/931/smpc | Betamethasone valerate 0.1% (30g) | | | £2.10/£1.59 |

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|---|---|---|---|---|
| **Elocon®** (Ointment & Cream)<br>https://www.medicines.org.uk/emc/product/78<br>https://www.medicines.org.uk/emc/product/79/smpc | Mometasone Furoate 0.1% (30g) | | | £2.96/£3.24 |
| **Super-Potent steroid** | | | | |
| **Dermovate®** (Ointment & Cream)<br>https://www.medicines.org.uk/emc/product/939/smpc<br>https://www.medicines.org.uk/emc/product/940/smpc | Clobetasol propionate 0.05% w/w (30g) | | | £2.69 |
| **Moderate Steroid Combination Product (Not supported locally for off-label use in chronic wound management, please see alternatives above)** | | | | |
| **Trimovate®** Cream<br>https://www.medicines.org.uk/emc/product/9<br>**Not supported locally for off-label use in chronic wound management** | Clobeta**sone** butyrate 0.05% (30g) | Oxytetracycline 3% | Nystatin 100,000 units/g | £12.45 |

**The clinical evidence relating to the mode of action of topical steroids within wound bed management is limited. The protocol for the specialist use of topical steroid preparation on wound beds within the community has been developed by applying Nursing, Pharmacy and GP guidance on prescribing in order to promote safe nursing practice within the community**

| Action | Rationale |
|---|---|
| **Clear treatment objectives and rationale for use:-**<br>Is there evidence of a holistic patient assessment with a clear diagnosis requiring this specialist treatment?<br><br>Could treatment objectives be managed through the application of licensed Formulary dressing products and by optimising underlying disease processes/patient health? | **NMC Code October 2018**<br>https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf<br><br>6. Always practise in line with the best available evidence<br>7. Communicate clearly<br>10. Keep clear and accurate records relevant to your practice<br>18. Advise on, prescribe, supply, dispense or administer medicines within the limits of your training and competence, the law, our guidance and other relevant policies, guidance and regulations |
| **Ensuring safe administration:-**<br>Where possible gain and document patient informed consent for the unlicensed treatment.<br><br>Application of medication should be in line with a Patient-Specific Direction (PSD).<br><br>The prescribed steroid preparation is for single-patient use only. | **RPS Medicines Optimisation May 2013**<br>https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy/helping-patients-make-the-most-of-their-medicines.pdf<br><br>• ***Principle 2. Evidence based choice of medicines***<br>Ensure that the most appropriate choice of clinically and cost effective medicines (informed by the best available evidence base) are made that can best meet the needs of the patient.<br>• ***Principle 3. Ensure medicines use is as safe as possible***<br>The safe use of medicines is the responsibility of all professionals, healthcare organisations and patients, and should be discussed with patients and/or their carers. Safety covers all aspects of medicines usage, including unwanted effects, interactions, safe processes and systems, and effective communication between professionals. |

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|---|---|
| | **Guidance on Unlicensed Medicines**<br>https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities - accessed via RPS website Aug 2019<br><br>https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines<br><br>https://www.nhs.uk/conditions/medicines-information/ |
| **What topical steroid should be applied**:-<br><br>**Simple steroid topical creams and ointments should be used in preference to combination products, therefore avoiding unnecessary use of antifungal and antibacterial agents in combination with a steroid**<br><br>Please see Table 1 for examples<br><br>**The choice of formulation will be guided by a specialist service** | • **Topical Corticosteroids** https://www.nhs.uk/conditions/topical-steroids/<br>• **BNF Topical Corticosteroids** https://bnf.nice.org.uk/treatment-summary/topical-corticosteroids.html and https://bnf.nice.org.uk/drug-class/corticosteroids-topical.html |
| **How should the preparation be applied:-**<br><br>Using a sterile gloved fingertip. The topical steroid should be applied gently in a thin layer directly to the wound bed in line with treatment objectives and dressing regime.<br><br>If the wound is too painful to tolerate direct contact, thinly spread the steroid cream/ointment onto a non-contact dressing and place directly over the wound site. | • **BNF Topical Corticosteroids** https://bnf.nice.org.uk/treatment-summary/topical-corticosteroids.html and https://bnf.nice.org.uk/drug-class/corticosteroids-topical.html<br>• **Topical Corticosteroids** https://www.nhs.uk/conditions/topical-steroids/<br>• https://www.dermnetnz.org/topics/topical-steroid/ |

**A clear treatment period and end date-**

In the management of skin conditions, daily applications should be applied for up to a maximum of 4 weeks and if within this time there are signs of improvement, application frequency or steroid potency should be titrated accordingly. The 'dose' (in Finger Tip units) at each application should be entered on the care plan.

In wound care, an application of a topical steroid to the wound bed is required less frequently and is often in line with dressing changes. The prescribing or advising specialist is responsible for advising clinicians on the frequency, how to apply, where and treatment timescale. A community prescription sheet should be completed, which should clearly identify the end date.

Depending on the potency of application and the frequency of dressing change, **the maximum treatment period for the use of topical steroids is four weeks**. During this period the wound should be reviewed every 7 days or ***more frequently if indicated,*** and treatment stopped if there is no improvement. A wound reassessment and revised care plan to be completed.

Continuation of treatment at review at 4 weeks would be at the discretion of the specialist following clinical assessment. **Please see Emergency Steroid Card guidance**

Consider referral to Dermatology if not responding.

- Absorption is greatest where the skin is thin or raw, and from intertriginous areas; it is increased by occlusion (BNF accessed Aug 2019)
- The direct action of topical steroids on long-term wound and patient health is not clear. Therefore the controlled use of such treatment is deemed necessary in order to reduce the risk of potential side-effects:

| | |
|---|---|
| Skin thinning (Atrophy) | Easy bruising and tearing of skin |
| Allergy to the steroid cream | Enlarged blood vessels (Telangiectasia) |
| Susceptibility to increased bacterial loading | Masked inflammatory markers therefore disguising infection |

**Central serous chorioretinopathy**
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/637656/DSU-August_PDF.pdf
Central serous chorioretinopathy has been reported after local administration of corticosteroids including via topical dermal. The MHRA recommends that patients should be advised to report any blurred vision or other visual disturbances. Please see link above for more information.

**Emergency Steroid Card**
For consideration when treatment exceeds 4 weeks of 30 to 60g per month of very potent steroids or 60 to 120g per month of potent steroid
NPSA-Emergency-Steroid-Card-FINAL-2.3.pdf (england.nhs.uk)
PrescQIPP **Implementing the Steroid Emergency Card National Patient Safety Alert - Jan 21**

Further information is available via www.medicines.org.uk (SPC) and https://bnf.nice.org.uk/ (BNF)

## Evidence


**Summary**

- The cost of managing wounds is a significant burden to healthcare systems with expenses for wound dressings, supplies and the cost associated with use of healthcare systems, including hospitalisations. Prescribing of advanced wound and antimicrobial dressings accounts for about £110 million per year in primary care in England.
- Despite optimal management, some chronic wounds do not follow the expected pattern of healing in a timely manner. Evidence to support the interventions used for chronic wounds is often of poorer quality than in many other areas of prescribing.
- Topical corticosteroids have been used for a variety of indications in chronic wounds. Suppression of wounds with excessive inflammation is an example of a clinical scenario where a topical corticosteroid may be useful. Topical corticosteroids **Hydrocortisone** or **Haelan (Fludroxycortide)** Tape/Cream are already included in the DPC wound formulary for the treatment of over-granulating wounds (10)
- Trimovate® is a combination product containing clobetasone butyrate, oxytetracycline and nystatin. Tetracyclines have been used for their anti-inflammatory actions in skin conditions and this may confer additional benefit but evidence to support this assumption is lacking. Following an evaluation (2018) considering the efficacy, safety and cost effectiveness of Trimovate cream, the Basingstoke, Southampton and Winchester District Prescribing Committee do not support use of this preparation in chronic wound management. Its use would be off label and non-formulary and should therefore be considered only when recommended by specialists in **exceptional** circumstances.
- There is very limited data regarding the use of topical corticosteroids applied to chronic wounds. Although corticosteroid creams are generally well tolerated, concerns remain over a potential risk of infection with corticosteroid treatment in chronic wounds. Addition of topical antimicrobials needs further research to assess the benefits versus risks of treatment.


### Introduction

Chronic wounds do not follow the expected pattern of healing (inflammation, granulation and vascularisation, epithelialisation and wound contraction) in a timely manner (1). There are a variety of different risk factors (infection, ageing, immunosuppression etc.) that can contribute to the disruption of the healing process (2).

Chronic wounds represent a significant burden to the healthcare system, prescribing of advanced wound dressings and antimicrobial dressings accounts for about £110 million per year in primary care in England, with more than £20 million spent on silver dressings alone (1). Despite this the clinical evidence supporting the use of agents for the treatment of chronic wounds is often of poorer quality then in many other areas of prescribing.

### Indications

Topical corticosteroids have been used for a variety of different indications in wound healing including overgranulating wound beds, vasculitic ulcers and pyoderma gangrenosum (3).

For some patients an excessive inflammatory response may be present resulting in excessive degradation of the extracellular matrix and failure of progression of wound healing (5). The use of topical corticosteroids could therefore be a logical approach for treating these patients' wounds. Additionally, tetracyclines are thought to possess anti-inflammatory effects that may be beneficial where excessive inflammation is present (6).

## Efficacy

There is limited data regarding the efficacy of corticosteroids or combination preparations for the management of chronic wounds.
An evaluation prepared for the Basingstoke, Southampton and Winchester District Prescribing Committee (DPC) to consider the evidence for efficacy, safety and cost effectiveness of Trimovate cream in chronic wound management (Sept 2018) concluded there was data, albeit very limited, to suggest that application of topical corticosteroids may be beneficial in the treatment of chronic wounds, especially where there is chronic inflammation. There were, however, major limitations in the evidence that prevented conclusions being reached on the efficacy or safety of this practice, but the author suggested there may be a place in therapy for wounds that are not responsive to conventional management. Based on consideration of this evidence the DPC do not support use of Trimovate cream for chronic wound management. Its use would therefore be 'non-formulary' (note: this does not apply to use of Trimovate on a short term basis in accordance with the indications specified in the product SPC which is supported by the DPC).

## Safety

There is concern that corticosteroids could have a negative impact on the wound healing process, as systemic corticosteroid treatment has been shown to delay wound healing (7, 8). These findings have mainly been demonstrated in animal studies however and the results of a recent relatively larger longitudinal study showed a contradictory finding (9). The adverse effect profile of topical corticosteroid treatment is therefore unclear but some small studies appear to show that topical corticosteroids may be beneficial in certain circumstances.

Concerns remain regarding an increased infection risk with the use topical corticosteroids but this has not been quantified in the literature (5). The benefits/risks of using a combination product with an antimicrobial have also not been clarified.

## Guidelines

Topical corticosteroids **Hydrocortisone** or **Haelan (Fludroxycortide)** Tape/Cream are already included in the DPC wound formulary for the treatment of over-granulating wounds (10).

A protocol for the specialist use of topical steroid preparations on wound beds within the community of Oxfordshire states the use of Trimovate® or any other topical steroid preparation in chronic wound management without specialist team initiation and ongoing input is not advocated (11). This is mainly due to the lack of scientific evidence or consensus regarding the effects of their prolonged use on wound health. The guidelines suggest clobetasol propionate (Dermovate) as the steroid of choice, reducing down to mometasone furoate (Elocon), and restrict use of combination formulations (e.g. Daktacort, Fucibet, Trimovate) to dermatology specialist only.

## Conclusions

There is data to suggest that application of topical corticosteroids may be beneficial in the treatment of chronic wounds, especially where there is chronic inflammation. The available evidence on this subject has major limitations that prevent us from drawing conclusions on the efficacy or safety of this practice, however there may be a place in therapy for wounds that are not responsive to conventional management.

## References


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