

Guide for Primary Care on the use of off-label topical steroids for inflammatory oral conditions within the Oral Medicine Department

Background

Recurrent oral ulceration, oral lichen planus, and immunobullous conditions are disorders seen and managed within the Oral Medicine clinic. There are very few pharmaceutical products licensed to treat these conditions. Therefore, Oral Medicine has traditionally used several treatments off-label, particularly topical steroids. The following off-label regimens have been approved for use in Bristol, North Somerset and South Gloucestershire (BNSSG) for these indications.

The formulation and delivery route chosen for topical treatment depends on patient specific factors. For example, a mouthwash is preferred in cases of widespread or large areas of ulceration whereas a discrete small ulcer may be better managed with a spray or gel.

TREATMENT OPTIONS AS PER BNSSG FORMULARY

Analgesic and NSAID preparations

Benzydamine hydrochloride 0.15% (mouthwash and spray) (Difflam®)

TLS GREEN – for recurrent oral ulceration and non-specific oral ulceration and inflammation

Difflam Oral Rinse® and Difflam Spray® are available to buy over-the-counter. Patients may be advised to self-medicate. If a prescription is deemed necessary, Benzydamine hydrochloride 0.15% (mouthwash and spray) (Difflam®) can be prescribed in primary and secondary care within the competencies of the prescriber.

Benzydamine oromucosal spray 0.15% (Difflam 0.15% spray®)

- Apply 4-8 sprays every 1.5 - 3 hours to affected area as required

Benzydamine mouthwash 0.15% (Difflam Oral Rinse 0.15% solution®)

- 15ml rinse every 1.5 - 3 hours as required (can dilute with an equal measure of water if stinging occurs)

Steroid Mouthwashes

Mouthwashes are useful in treating large areas of the mouth and lesions that are not accessed easily by ointments or sprays.

1st line* - Betamethasone 500 microgram soluble tablets (for use as a mouthwash, please note use is unlicensed)

TLS GREEN – for recurrent oral ulceration and non-specific oral ulceration and inflammation

Prescription Only Medicine - Appropriate for prescribing in primary and secondary care and within the competencies of the prescriber

TLS AMBER 1 month – for oral lichen planus and immunobullous disease

Appropriate for shared care – responsibility for prescribing may be transferred from secondary to primary care with agreement of GP after one month

Betamethasone 500 microgram soluble tablets

- Disperse 2 tablets in 20mL of water, rinse around the mouth for 3 - 4 minutes and spit out BD, as required

From clinical experience, the second regimen (2 tablets dissolved and used BD) is more effective and improves patient compliance.

* Betamethasone soluble tablets are unlicensed for use in oral ulceration and are therefore used first line in Primary Care. If this product is unavailable, or patient is intolerant, dexamethasone 2mg soluble tablets may be used off-label.

*The NPSA has identified several incident reports where betamethasone soluble tablets have been taken orally in error despite being prescribed as a mouthwash. One particular report details a hospital admission resulting from adrenal crisis due to this administration error.

Please ensure dental and medication practitioners specify detailed instructions on how to make up the mouthwash using soluble steroid tablets. Please ensure that the patient is counselled on how to prepare the mouthwash using soluble steroid tablets.

Dexamethasone 2mg soluble tablets (for use as a mouthwash)

TLS AMBER 1 month – Specialist Recommended for topical management of recurrent oral ulceration, oral lichen planus and immunobullous disease

Appropriate for shared care – responsibility for prescribing may be transferred from secondary to primary care with agreement of GP after one month

Dexamethasone 2mg sugar free soluble tablets

- Disperse 1 tablet in 10 – 20mL of water, rinse around the mouth for 3 – 4 minutes and spit out once daily , as required

Steroid Gel

A steroid gel is useful for targeting specific lesions, or for lesions found at the anterior portion of the mouth and/or tongue.

Fluocinolone acetonide 0.025% gel (Synalar®)

TLS AMBER 1 month – Specialist Recommended – for topical management of oral ulceration/oral lesions and inflammation.

The decision to initiate must be taken by the specialist team, however the first prescription may be written by the specialist or the GP may be asked to provide the first and ongoing prescriptions

Fluocinolone acetonide 0.025% gel (Synalar®)

- A small amount (pea-sized) to be applied to the affected area using either a clean finger or a cotton bud, to be used maximum twice daily, as required

If a referral to secondary care is indicated, the first prescription for 28 days will be issued from the oral medicine clinic. The GP may then be asked to provide repeated courses with clear instruction from secondary care.

Please note: Regular use of topical steroids within the oral cavity can result in the development of oral thrush (oral candidiasis). If this occurs, advise the patient to withhold topical steroid treatment until oral thrush resolves. The patient could be advised to visit their local pharmacist for the provision of Miconazole oral gel. Alternatively, Nystatin oral suspension can be prescribed if appropriate.

CLINICAL GUIDELINE

Recurrent Oral Ulceration

Repeated episodes of self-limiting ulceration:

- Labial, buccal or ventral tongue
- Oval shape
- Size <10mm
- Resolve <14 days
- Sites of ulcers vary
- Mucosa normal once ulcers heal



Features that require referral to secondary care:

Recurrent ulceration that is inadequately managed by first line management as outlined

Unexplained other features such as:

- systemic upset
- gastrointestinal problems
- fevers
- genital ulceration
- joint problems
- skin rashes

Management in Primary Care:

- *Benzydamine hydrochloride 0.15% spray or mouthwash*
- *Betamethasone soluble tablets for use as a mouthwash*

OR

Dexamethasone soluble tablets for use as a mouthwash

See accompanying Betamethasone and Dexamethasone mouthwash Patient Information Leaflets



- eye soreness or redness

Oral Lichen Planus

- Reticulated or plaque-like hyperkeratosis with variable redness and/or ulceration (may be none).
- Symmetrical involvement of the posterior buccal mucosa is common, but any site may be involved.
- Desquamative gingivitis can be present.
- Lesions may be unilateral/adjacent to dental restorative materials



Features that require referral to secondary care:

- Soreness that is inadequately managed by first line management as outlined.
- Features that do not fit the typical oral presentation
- Unexplained other features such as:
 - skin rash
 - nail changes
 - genital ulceration
 - scalp soreness or acute hair loss
 - Widespread oral involvement

Note: cancer development is <1 in 100 in individuals who have oral lichen planus for 10 years or more.

Management in Primary Care:

- *Benzydamine hydrochloride 0.15% spray or mouthwash*
 - *Betamethasone soluble tablets for use as a mouthwash*
- OR**
- *Dexamethasone soluble tablets for use as a mouthwash*

See accompanying Betamethasone and Dexamethasone mouthwash Patient Information Leaflets



<h2 style="text-align: left; margin: 0;">Desquamative Gingivitis</h2>	
<p>Bright band of redness of the attached gingivae that:</p> <ul style="list-style-type: none"> - Cannot be attributed to dental plaque. - May be generalised or localised. - May be diffuse & patchy or well-defined. - May be associated with superficial ulceration. <div style="text-align: center;">  </div> <p>May occur with other oral mucosal lesions. Persists for weeks or months without settling.</p> <p>Features that require referral to secondary care:</p> <p>Soreness that is inadequately managed by first line management as outlined</p> <ul style="list-style-type: none"> - Features that do not fit the typical oral presentation - Unexplained other features such as: <ul style="list-style-type: none"> - systemic upset - eye soreness or redness - genital ulceration - nasal soreness - skin rashes 	<p>Management in Primary Care:</p> <ul style="list-style-type: none"> • <i>Recommend review by GDP to exclude periodontal disease</i> • <i>Benzydamine hydrochloride 0.15% spray or mouthwash</i> • <i>Betamethasone soluble tablets for use as a mouthwash</i> <p style="text-align: center;">OR</p> <p style="text-align: center;"><i>Dexamethasone soluble tablets for use as a mouthwash</i></p> <p style="text-align: center;"><i>*See accompanying Betamethasone and Dexamethasone mouthwash Patient Information Leaflets*</i></p>
<h2 style="text-align: left; margin: 0;">Persistent Superficial Ulceration</h2>	
<ul style="list-style-type: none"> - Often present at multiple sites - Shallow ulcers surrounded by inflammation - Ulcers of variable size - Soft on palpation - Present for several weeks or even months without improvement 	<p>Management in Primary Care:</p> <ul style="list-style-type: none"> • <i>Referral to secondary care</i> • <i>Benzydamine hydrochloride 0.15% spray or mouthwash</i>



All cases should be referred

- *Betamethasone soluble tablets for use as a mouthwash*

OR

Dexamethasone soluble tablets for use as a mouthwash

See accompanying Betamethasone and Dexamethasone mouthwash Patient Information Leaflets