



CLINICAL GUIDELINE

Spiroinolactone for Persistent Acne in Women in Primary Care

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The Intranet version of this document is the only version that is maintained. Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Spironolactone for Persistent Acne in Women in Primary Care

Aim of Guideline.....	2
Introduction	2
Scope	2
Indications.....	3
Contraindications	3
Dosage	3
Monitoring	3
Side Effects.....	3
Considerations in Women of Child Bearing Age.....	4
Concomitant Prescribing of Other Acne Treatments	4
Spironolactone and Sport.....	4

AIM OF GUIDELINE

This guideline aims to provide guidance on the initiation, dose titration and monitoring of spironolactone for treatment of acne vulgaris in women which has not responded to first line treatments or where first line treatments have not been tolerated.

INTRODUCTION

Acne vulgaris is a common skin condition with a multifactorial aetiology, including hormonal influences. Spironolactone is a potassium-sparing diuretic with anti-androgenic properties which has been widely used off-license for acne in women due to its demonstrated efficacy in reducing androgen-driven sebum production. Spironolactone can be particularly useful for the treatment of hormonal acne or where there are other symptoms of hyperandrogenism such as hirsutism and female-pattern hair loss. It can be used as monotherapy or alongside other acne treatments (*see: concomitant prescribing of other acne treatments*).

The recent 'Spironolactone for acne in females' (SAFA) study ^[1] has shown that spironolactone is a safe and effective treatment for persistent acne in adult females. Spironolactone was superior to placebo in treatment of acne as measured by Acne QoL symptom score at 12 weeks, with greater differences seen at 24 weeks. Patient self-assessed improvement was 72% at 12 weeks and 82% at 24 weeks. Doses of 50-100mg were well tolerated with mild side effects similar to placebo.

Historically, patient access to spironolactone therapy has been via secondary care Dermatology services. Current referral wait times often mean patients have significant delay in starting effective treatment for their acne when they have not responded to first line treatments. Spironolactone is a well-tolerated treatment with minimal monitoring requirements in most patient groups therefore has been granted a GG&C formulary change to include "treatment of persistent acne in adult females" as an approved indication for prescribing in general practice.

SCOPE

This guideline is intended for use by prescribers in general practice involved in the management of acne in women aged 18 years and older.

INDICATIONS

Spironolactone can be considered in women > 18 years with persistent (defined as > 6 months) moderate to severe acne who have failed to respond to or not tolerated at least one topical and one systemic agent (e.g. antibiotic or COCP) as per NICE guidance.

CONTRAINDICATIONS

- Acute renal insufficiency, significant renal compromise, anuria
- Addison's disease
- Hyperkalaemia
- Hypersensitivity to spironolactone or to any of its excipients
- Concomitant use of other potassium sparing diuretics.
- Pregnancy and breastfeeding

DOSAGE

Initially 50mg daily, titrating to 100mg daily after two weeks. Dose can be increased up to 200mg daily as tolerated in 50mg increments every 4 weeks.

If there is no improvement after three months treatment should be stopped. Patients should be counselled that full effect is often not seen until 6 months of treatment. Treatment can be continued indefinitely while effective and tolerated.

MONITORING

All patients should have baseline urea & electrolytes and baseline blood pressure checked prior to therapy. Serum potassium must be < 5 mmol/L prior to initiation.

No drug monitoring is required except in patients:

- > 45 years
- With pre-existing renal, cardiac or liver conditions
- Concomitant prescription of other drugs known to cause hyperkalaemia

The above patients should have U&Es checked one week following initiation of treatment or dose increase → monthly for three months → three monthly for one year → six monthly.

SIDE EFFECTS

- Postural hypotension
- GI disturbance
- Irregular menstrual periods
- Breast tenderness/ enlargement
- Skin rashes / pruritus
- Increased urinary frequency

CONSIDERATIONS IN WOMEN OF CHILD BEARING AGE

Effective contraception should be offered to all women of child bearing age due to the risk of feminisation of the male foetus in pregnancy. Women should be counselled regarding the risk of menstrual disorders which can occur with spironolactone; these are likely to settle with ongoing treatment, but can also be managed by the addition of an oral contraceptive pill.

CONCOMITANT PRESCRIBING OF OTHER ACNE TREATMENTS

Spironolactone can be used as monotherapy or in combination with other acne treatments including:

- Any licensed topical acne preparation (no antibiotic containing preparation should be used at the same time as an oral antibiotic)

AND / OR

- Lyme cycline 408mg caps OD
 - **OR**
- Doxycycline 100mg OD
 - **OR**
- Erythromycin 500mg BD

AND / OR

- Co-cyprindiol OD
- Any other oral contraceptive pill

Spironolactone can also be started as a bridging treatment while awaiting outpatient dermatology review for isotretinoin.

SPIRONOLACTONE AND SPORT

Spironolactone is included on the World Anti-Doping Agency's (WADA) List of Prohibited Substances and Methods. The primary reason for this inclusion is its potential to act as a masking agent for other prohibited substances. This should be considered for any patients who participate in competitive sport.

SICK DAY RULES

Patients should be advised to stop medication if unwell with any of the following:

- Vomiting or diarrhoea (unless only minor)
- Fevers, sweats, rigors.

Spironolactone may be restarted when patient is feeling well (after 24-48 hours of eating and drinking normally).

References

1. Santer M, Lawrence M, Renz S, Eminton Z, Stuart B, Sach TH, Pyne S, Ridd MJ, Francis N, Soulsby I, Thomas K. Effectiveness of spironolactone for women with acne vulgaris (SAFA) in England and Wales: pragmatic, multicentre, phase 3, double blind, randomised controlled trial. *bmj*. 2023 May 16;381
2. National Institute for Health and Care Excellence. Acne vulgaris: management. 2021
3. Primary Care Dermatology Society (PCDS). **Acne Vulgaris - Clinical Guidance** [Internet]. PCDS; [cited 2024 Nov 25]. Available from: <https://www.pcds.org.uk/clinical-guidance/acne-vulgaris>
4. British Association of Dermatologists (BAD). **Acne referral guidance for primary care** [Internet]. London: BAD; 2024 [cited 2024 Nov 25]. Available from: <https://cdn.bad.org.uk/uploads/2024/02/22103437/Acne-referral-guidance-for-primary-care.pdf>
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6. Medicines.org.uk. Spironolactone 25 mg Tablets - Summary of Product Characteristics (SmPC) [Internet]. Datapharm; [cited 2024 Nov 25]. Available from: <https://www.medicines.org.uk/emc/product/12015/smpc#about-medicine>