



Spironolactone Information Sheet

Spironolactone has been used off-license in women with acne for over 30 years due to its anti-androgenic properties and is included in American Guidelines for acne. However, although widely used by some dermatologists in the UK, there is little convincing trial evidence of its benefit.

What dose of spironolactone is prescribed for adult female acne?

SAFA participants are prescribed spironolactone (or placebo) 50mg once daily for 6 weeks, increased to 100mg once daily for a further 18 weeks if tolerated. Effectiveness of treatment is judged after 12 weeks. The reason for dose escalation is to avoid side effects from spironolactone, which can cause gastro-intestinal disturbances, dizziness, gynaecomastia and menstrual disturbances, particularly at higher doses.

Is potassium and renal monitoring required?

American guidelines¹ and large UK-based observational datasets suggest that, providing a baseline renal function test is normal then no further monitoring is required. All participants in the SAFA trial have renal function tests, including potassium, carried out at baseline, so do not need further blood testing.

Is spironolactone teratogenic?

Spironolactone should be avoided in pregnancy but risk of harm to the foetus is thought to be less high than for other oral acne treatments,^{1,2} such as tetracycline antibiotics, co-cyprindiol and oral isotretinoin. Pregnancy risk relates to feminisation of the male foetus in the last trimester. Pregnancy tests are carried out at baseline in the SAFA trial and participants of child-bearing potential at risk of pregnancy are advised they must use effective contraception.

Why isn't spironolactone used for men with acne?

A small study found that a many young men with acne who were treated with spironolactone experienced breast enlargement and the trial was stopped early.

Why are we doing the SAFA trial?

Non-adherence to topical treatments for acne is common and patients commonly receive prolonged courses of oral antibiotics. Rising rates of antibiotic resistance suggest an urgent need for evidence to support alternatives. Although the combined oral contraceptive pill is effective it is not licensed for this use in the UK and is contra-indicated for some or not tolerated by others. Co-cyprindiol is also effective in female acne and is licensed for this but safety concerns mean it is not recommended for long-term use, which can be frustrating for women keen to avoid recurrence. The National Institute for Health Research (Department of Health) commissioned this trial to determine whether spironolactone would be a suitable alternative treatment for women with persistent moderate or severe acne.

References

1. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol 2016;74(5):945-73 e33.
2. British National Formulary. <http://www.bnf.org>