



Bristol Menopause
& Wellwoman Clinic

Off-License Prescribing



What is Off-License Prescribing?

Off-license prescribing is when the person prescribing the medicine wants to use it in a different way than that stated in its license. This could mean using the medicine for a different condition or a different group of patients, or it could mean a change in the dose or that the medicine is taken in a different way. Clinicians may prescribe certain medications if they believe it is the best option for the patient, particularly when alternatives are unavailable or unsuitable.

This does not mean that the medicine is unsafe. Rather, it means the manufacturer has not sought a license for its use in that specific condition, patient group, or formulation within the UK.

Prescribing medications off-license is common practice, particularly in specialised areas such as hormone therapy, where healthcare professionals use their expertise to tailor treatments for individual needs.

Why are Off-License Prescriptions Used?

Personalised care: Some patients may not respond well to standard licensed treatments and require tailored regimes.

Lack of Licensed Alternatives: When no approved medication is available for a particular condition, off-license use may be the best or only option.

Emerging Evidence: New research may show a medication can be effective in a way that hasn't yet been included in its license

Clinical Guidelines or Specialist Recommendations: Some professional guidelines support off-license use based on research or extensive clinical experience, even if the medication isn't officially licensed for that purpose.

Is It Safe to Use Medications Off-License?

Off-license prescribing is common and normally very safe. Your clinician will always discuss the risks and benefits with you to ensure you are making an informed choice.

When would medications be prescribed “off-license”

Testosterone for Women: Testosterone is licensed for use in men to treat low androgen levels. Research has shown that some women will benefit from testosterone therapy alongside their HRT to help with low libido. Testosterone gel, such as Testogel or Tostran, is often used off-license for women. Androfeme is licensed for women in Australia and is imported into the UK for private use under a special license.

Higher than licensed doses of oestradiol: May be used when there is poor transdermal absorption of oestradiol. We will always try to use alternative options before considering higher than licensed dose of medication.

Changes to progestogen regimes: We may recommend using a higher dose of progestogen to control bleeding, or when prescribing a high dose oestrogen to protect the lining of the womb. We may also recommend using micronised progestogens vaginally to help with progestogen associated side effects.

HRT for Premenstrual Dysphoric Disorder: HRT may benefit women with PMDD by suppressing ovulation and minimising hormonal fluctuations but is only currently licensed for menopausal symptoms.

All off-license prescribing at BMC adheres to national guidelines from the British Menopause Society and the National Association of Premenstrual Disorders.

Questions?

If you have been prescribed an off-license medication at BMC and have further questions, please contact us at hello@bristolmenopause.com



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www.bristolmenopause.com

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0117 452 5747

Low Barn, Sheepway, Portbury, Bristol, BS20 7TF