



## Dienogest

### What is it?

Dienogest is a synthetic form of the naturally occurring hormone progesterone that the ovaries produce. It is not currently available on the NHS Lothian formulary.

### How does it work?

Dienogest may relieve the symptoms of endometriosis by stopping ovulation, which will lower the oestrogen levels and hence suppress the growth of endometriotic deposits. Endometriosis is also associated with inflammation, and Dienogest is thought to reduce inflammation. The combination of the anti-proliferative, anti-inflammatory, and anti-angiogenic effects of Dienogest may reduce endometriosis-associated pain.

In patients who have undergone surgery to treat endometriosis, Dienogest prescribed post-surgery may prevent the recurrence of endometriosis, both in the context of endometriosis symptom recurrence and endometrioma (ovarian cyst affected by endometriosis) recurrence.

### How is it given?

Dienogest (2mg) is an oral tablet which should be taken daily, preferably at the same time. It can be started anytime during the menstrual cycle. When a pack is finished, the next one should be started without a break. Tablets should also be taken on days of menstrual bleeding.

All forms of hormonal contraception (tablet/hormonal coil/patch/ring) should be stopped before starting Dienogest and during its use.

### Can I become pregnant when taking Dienogest?

Although Dienogest will stop ovulation in most users and reduce the chances of becoming pregnant, it is not a contraceptive and barrier contraception, e.g. condoms or non-hormonal methods, are recommended.

If you become pregnant, you are at a slightly increased risk of having an ectopic pregnancy.

## Are there any side effects?

The most common side effects include headache, breast discomfort, depressed mood, and acne, each occurring in < 1 in 10 users and of mild to moderate intensity.

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## Special considerations when taking Dienogest

### Bleeding patterns

Changes in bleeding patterns for the first three months can be seen in 20-30% of users. Users should be counselled and reassured about this effect.

- Initial bleeding can be consistent and typically lasts for 8–10 days. Starting Dienogest at the onset of menses may also decrease initial bleeding.
- Bleeding that occurs during long-term treatment is typically spotting. Suppose the ultrasound suggests the womb's lining has become thin (as expected); in that case, treatment can include a break of 5–7 days of Dienogest to allow the lining within the womb to grow or a short course of 1 mg oral or transdermal oestradiol (5–7 days).

Based on available data, the menstrual cycle returns to normal within two months after stopping treatment with Dienogest.

### Serious uterine bleeding

Menstrual blood loss may be aggravated using Dienogest in patients with adenomyosis or fibroids. If bleeding is heavy and continuous over time, this may lead to anaemia (severe in some cases). In such patients, discontinuation of Dienogest should be considered.

### Bone Mineral Density

The use of 2 mg Dienogest in adolescents (12 to <18 years) over a treatment period of 12 months was associated with a decrease in bone mineral density (BMD) of 1.2% in the lumbar spine from baseline to the end of treatment.

This slight reduction has to be balanced against recovery of bone mineral density once treatment is stopped alongside the significant reductions in endometriosis-associated pain observed with treatment.

Loss of BMD is of particular concern during adolescence and early adulthood, a critical period of bone build-up. It is unknown if decreased BMD in this population will reduce peak bone mass and increase the risk for fracture in later life.

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### When can I not take Dienogest?

Dienogest should not be used in the presence of any of the conditions listed below, OR if any of the conditions appear during the use of Dienogest, treatment must be discontinued immediately.

- Active venous thromboembolic disorder (blood clots in the veins)
- Arterial and cardiovascular disease, past or present (e.g. myocardial infarction- heart attacks, cerebrovascular accident -stroke, ischemic heart disease)
- Diabetes mellitus with vascular (artery/vein) involvement
- Presence or history of severe hepatic (liver) disease as long as liver function values (assessed as a blood test) have not returned to normal
- Presence or history of liver tumours (benign or malignant)
- Known or suspected sex hormone-dependent malignancies (cancers that are caused by hormones produced by the ovaries)
- Undiagnosed vaginal bleeding (bleeding that has not been investigated to establish the cause)
- Hypersensitivity to the active substance (allergy to Dienogest).