



FOR CONSUMER MEDIA

Science For A Better Life

Endometriosis treatment now widely available for Australian women

Endometriosis affects up to one-in-ten Australian women every year

Bayer Australia Ltd has introduced Visanne® (dienogest), a prescription medicine for the treatment of women with endometriosis.¹

Visanne is now widely available for prescription for women with endometriosis, in consultation with their doctor, to help alleviate the signs and symptoms of endometriosis, a condition that affects up to one-in-ten Australian women every year.²

Dr Susan Evans, an Australian gynaecologist and Director of the not-for-profit Pelvic Pain Foundation of Australia said “Endometriosis is an important condition affecting 5-10% of young women, often forming in their teens and twenties. Unfortunately, the condition may go undiagnosed for many years, and can cause problems with persistent pelvic pain or infertility.

“While it’s normal for women to have some period pain, this should not be distressing. Normal period pain should be easily managed. When pain can’t be managed in this way, it’s important for girls and women to see a doctor – and for an effective management plan for their pain to be made. Reducing the number of periods, or making periods lighter and less painful, is often part of the overall management plan.

“Each woman deserves an individual approach looking at her needs and personal choices. Our difficulty is that current treatment options may not suit everyone, so the availability of more treatment options is welcome.

“It is important that young women have the opportunity to fully develop their educational, employment, relationship and personal potential without the limitations of endometriosis and pelvic pain.”

Endometriosis is defined as the presence of tissue like the lining of the womb (the endometrium) outside the womb, which induces a chronic, inflammatory reaction.³ Symptoms may include pain during intercourse (dyspareunia), painful periods (dysmenorrhoea), premenstrual pain, pelvic pain and bowel-or-bladder associated symptoms.^{4,5} An estimated 25-50% of women with infertility have endometriosis and 30-50% of women with endometriosis have infertility.⁵

Visanne was initially registered with the Therapeutic Goods Administration (TGA) in 2010¹ but not officially launched following feedback from doctors about the need for longer-term data that would reflect real-life usage of the treatment.

Following the publication of long-term clinical data⁶, and at the same time the interest shown in the product by women affected by endometriosis, Bayer expedited the process to bring Visanne to Australia as quickly as possible.

Lesley and Syl Freedman set up a petition on change.org as well as a patient support group EndoActive Australia & NZ to show how many women wanted Bayer to bring Visanne to Australia and to provide a support network for the women who are affected by endometriosis.

“We are absolutely thrilled that thousands of women and girls in Australia suffering chronic pain from endometriosis will now have access to this important new treatment option.

“These brave women and girls deserve relief from the pain and symptoms of endometriosis and the chance to lead active, productive, happy lives.

“On behalf of them we wish to thank the 74,617 people who signed our petition on change.org and Dr Twomey and Bayer for responding with compassion to our appeal for help.”

The long-term data investigated the efficacy and safety of Visanne as a long-term treatment for endometriosis (for 65 weeks) and included further follow-up after treatment discontinuation.⁶

The results confirmed that women with endometriosis treated with Visanne over 65 weeks of treatment experience a decrease in pelvic pain. This continues for up to 24 weeks after treatment is stopped.⁶ Visanne has also been shown to reduce the number of endometrial lesions in the pelvis.⁷

Visanne is taken as a once daily 2mg tablet.¹

Bayer has been working with the medical community to ensure that it has the latest information and education on treating and managing endometriosis and so that doctors can identify which patients would most benefit from Visanne.

ENDS

PBS information: The product is not listed on the PBS for the treatment of endometriosis.

**BEFORE PRESCRIBING PLEASE REVIEW FULL PRODUCT INFORMATION
AVAILABLE ON REQUEST FROM BAYER**

http://www.bayer.com.au/scripts/pages/en/bayerrsquos_products/index.php?aktion=details&id=625&l1=&l2=

For further information:

3rd March 2015

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TGA approved indications

Visanne (dienogest) is approved for the treatment of endometriosis.

Date of TGA approval: 11 June 2010.

Consumer Medicine Information (CMI)

For further information about Visanne please speak with a healthcare professional and access the full Consumer Medicine Information (CMI) available at:

http://www.bayer.com.au/scripts/pages/en/bayerrsquos_products/index.php?aktion=details&id=625&l1=&l2=

Important safety information

The most frequently reported undesirable effects during treatment that were considered at least possibly related to Visanne were headache (9.0%), breast discomfort (5.4%), depressed mood (5.1%), and acne (5.1%).¹

About Bayer Australia Ltd www.bayer.com.au

Bayer is an international, research-based company specialising in health care, nutrition and high-tech materials. It has operated in Australia since 1925 and has a long term commitment to the health of all Australians, the agricultural industry and the welfare of animals, large and small. Bayer Australia Ltd currently employs over 1,100 people across the country and is dedicated to servicing the needs of rural Australia and the local community. Bayer is deeply committed to research and development and has a strong tradition of innovation with over 5,000 products and services. The company's focus on people, partnerships and innovation underpins all aspects of its operations, consistent with its mission, "Bayer: Science For A Better Life".

Minimum Product Information for Visanne

Visanne[®]: dienogest 2 mg. **Indications:** Treatment of endometriosis. **Dosage and Administration:** 1 tablet daily. **Contraindications:** Known or suspected pregnancy; lactation; active venous thromboembolic disorder; arterial and cardiovascular disease, present or in history (e.g. myocardial infarction, cerebrovascular accident, ischaemic heart disease); diabetes mellitus with vascular involvement; present or history of severe hepatic disease as long as liver function values have not returned to normal; present or history of liver tumours (benign or malignant); known or suspected sex hormone-dependent malignancies; undiagnosed vaginal bleeding; hypersensitivity to the active substance or to any of the excipients. **Precautions:** Circulatory disorders and increased risk of arterial or venous thrombotic events e.g. age, hypertension, smoking, family history of venous/arterial thromboembolism, prolonged immobilisation); changes in bleeding pattern; chloasma; increased risk of osteoporosis; depression; Others: refer to full product information. **Interactions:** CYP3A4 inducers: phenytoin; barbiturates; primidone; carbamazepine; topiramate; rifampicin; griseofulvin; St John's Wort; CYP3A4 inhibitors: azole antifungals; verapamil; macrolides; diltiazem; grapefruit juice; Others: refer to full product information. **Adverse Effects:** headache, breast discomfort, depressed mood, acne, irregular vaginal bleeding. Others: refer to full product information. **Date of most recent amendment:** 26 November 2014. PLEASE REVIEW PRODUCT INFORMATION BEFORE PRESCRIBING. Full product information is available on request from Bayer Australia Ltd or can be accessed from www.ebs.tga.gov.au. Bayer Australia Ltd, ABN 22 000 138 714, 875 Pacific Highway, Pymble, NSW 2073. [®]Registered trademark of the Bayer group, Germany.

¹ Visanne PI September 2014.

² Crosignani P *et al.* Advances in the management of endometriosis: an update for clinicians. *Hum Reprod Update* 2006; 12(2): 179–189.

³ Meuleman C *et al.* High prevalence of endometriosis in infertile women with normal ovulation and normospermic partners. *Fertility and Sterility* 92 (1) July 2009.

⁴ Sinaii N, Plumb K. *et al* 2008. Differences in characteristics among 1000 women with endometriosis based on extent of disease. *Fertility & Sterility* 89(3):538-545.

⁵ Hickey M, Ballard K and Farquhar. 2014 Endometriosis. *BMJ* 348;g1752.

⁶ Petraglia F, Hornung D, *et al*, 2012. Reduced pelvic pain in women with endometriosis: efficacy of long-term dienogest treatment. *Arch Gynecol Obstet* 285:167-17.

⁷ Köhler, Günter, *et al.* "A dose-ranging study to determine the efficacy and safety of 1, 2, and 4mg of dienogest daily for endometriosis." *International Journal of Gynecology & Obstetrics* 108.1 (2010): 21-25.