

Endometriosis.
You can't see it, but
we know how it feels.



Visanne
dienogest 2mg



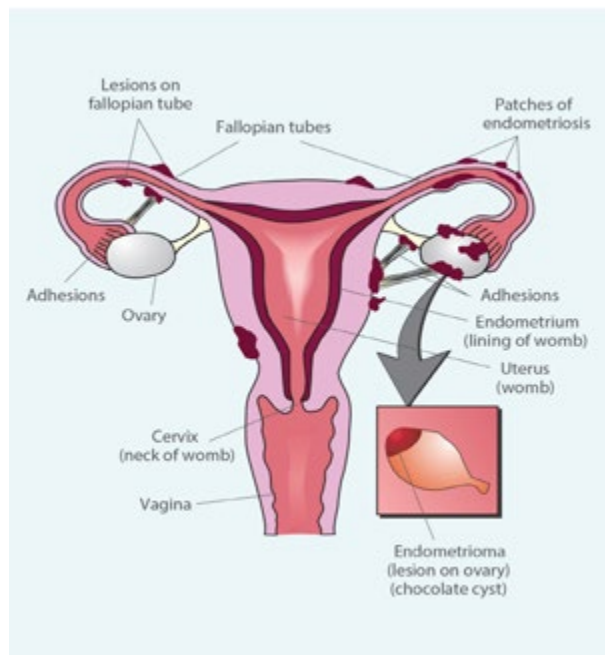
Index

- 3 Welcome to Visanne®
- 4 What is endometriosis?
- 5 Causes and risk factors for endometriosis
- 6 Common symptoms
- 7 What is Visanne®? What does Visanne® contain?
- 8 How does Visanne® work?
- 10 How effective is Visanne®?
- 12 Visanne® - before surgery
- 14 Visanne® - after surgery
- 16 For how long can Visanne® be used?
- 17 Who should NOT take Visanne®?
- 18 Side-effects of Visanne®
- 19 Visanne®'s impact on menstrual bleeding
- 20 How will Visanne® affect fertility?
- 21 Can Visanne® be used during pregnancy?
- 22 How does Visanne® compare versus Oral Contraceptives?
- 24 Can anti-inflammatory medications be taken with Visanne®?
- 25 How is endometriosis viewed by the medical aids?
- 26 Will the medical aid reimburse the costs associated with Visanne®?
- 26 What is a Prescribed Minimum Benefit?
- 27 What is an ICD-10 code and what does it mean?
- 28 What are the ICD-10 codes for endometriosis?
- 29 What is a Designated Services Provider?
- 30 What can you as a patient take responsibility for?
- 32 Help from the Council of Medical Schemes
- 33 Where to go for more endometriosis support
- 34 Visanne® dosage and directions for use
- 35 What is the Speak Up About Endometriosis Campaign?

Welcome to Visanne®!

Your healthcare professional has prescribed Visanne® for you. Facts empower women to make informed decisions about treatment options.

This booklet provides information about endometriosis and a summary of up-to-date evidence regarding the use of Visanne® as a medical treatment for endometriosis. It also provides an overview of the use of Visanne® as a treatment for endometriosis.¹ This information should not be interpreted as dictating an exclusive course of treatment to be followed.



What is endometriosis?

Endometriosis is a chronic, recurrent condition that is prevalent among women of reproductive age. In the absence of treatment, endometriosis is usually a progressive condition.¹

Endometriosis occurs when the endothelial cells that form the lining of the uterus grow elsewhere in the body to produce endometrium-like tissue. The most commonly affected areas are regions in the pelvic cavity e.g.

- the ovaries
- pouch of Douglas
- peritoneum
- uterosacral ligaments

These endometriotic lesions lead to a chronic, inflammatory reaction, accompanied by pain and the formation of scar tissue and adhesions. Endometriosis can also interfere with functioning of the bowel or bladder depending on the site of the endometriotic lesions.¹

Ovarian endometriomas are common in endometriosis.² It is a formation of a cyst within the ovary with ectopic (out-of-place) endometrial tissue lining. It is caused by endometriosis, and formed when a tiny patch of endometrial tissue bleeds, sloughs off, becomes transplanted, and grows and enlarges inside the ovaries. As the blood builds up over months and years, it turns brown as it contains degraded blood products and is thus often referred to as chocolate cysts of the ovary.³

References: 1. Mueck AO. Dienogest: an oral progestogen for the treatment of endometriosis. *Expert Rev Obstet Gynecol* 2011; 6(1):5–15. 2. Riviello C, Cozzolino M, Pavone D. Regression of a Large Endometrioma after Treatment with Dienogest. *J Fertil In Vitro IVF World Reprod Med Genet Stem Cell Biol* 2016; 4(1):1–2. 3. Fertilitypedia. Endometrioma. Available from: <https://fertilitypedia.org/edu/diagnoses/endometrioma#>. (Accessed date 20 September 2018).

What causes or puts one at risk for endometriosis?

There is no consensus on the cause/s of endometriosis² but various factors may play a role in the establishment and development of endometriosis.³

Family history: women with endometriosis and first degree relatives (e.g. mother, sister) of affected women are at a 3-9 times higher risk of developing endometriosis.³

Early age at the first menstrual period and long, heavy menstrual periods: these factors - and never having given birth - are associated with endometriosis.³

The immune system: It is possible that a problem with the immune system may make the body unable to recognize and destroy endometrial tissue that's growing outside the uterus.¹ Studies do not provide information on the sequence of endometriosis, and the various associated immunological diseases - so it is not known whether immune dysfunction is a cause or a consequence of endometriosis.³

Retrograde or reflux menstruation: The theory behind this concept is that menstrual blood containing endometrial cells flows back through the fallopian tubes and into the pelvic cavity instead of out of the body. Displaced endometrial cells stick to the pelvic walls and surfaces of pelvic organs and grow and continue to thicken and bleed over the course of each menstrual cycle.²

References: 1. Giudice LC, Kao LC. Endometriosis. *Lancet* 2004; 364:1789–1799. 2. Leyland N, Casper R, Laberge P, et al. SOGC Clinical Practice Guideline. Endometriosis: Diagnosis and Management. *J Obstet Gynecol Can* 2010; 32 (7 Suppl 2): S1–S32. 3. Parazzini F, Esposito G, Tozzi L, et al. Epidemiology of endometriosis and its comorbidities. *Eur J Obstet Gynecol Reprod Biol* 2017; 209: 3–7.

What are the most common symptoms associated with endometriosis?

Symptoms vary but women who experience the following symptoms have a high risk of endometriosis - especially if more than one of these symptoms are experienced: ¹

- stomach and/or pelvic pain unrelated to the menstrual cycle
- menstrual-related symptoms e.g. pain during menstrual periods and heavy or prolonged menstrual bleeding
- symptoms related to sexual intercourse e.g. persistent or recurrent genital pain that occurs just before, during or after intercourse and bleeding from the vagina after sexual intercourse
- ovarian cysts
- subfertility (difficulty falling pregnant) or infertility



While it is recognised that the symptoms identified as being associated with endometriosis are not entirely specific to the condition, there is good evidence to suggest that women reporting multiple symptoms should prompt further appropriate investigation to exclude or confirm a diagnosis of endometriosis.¹

Reference: 1. Ballard K, Seaman H, de Vries C, Wright J. Can symptomatology help in the diagnosis of endometriosis? Findings from a national case– control study—Part 1. *BJOG* 2008; 115:1382–1391.

What is Visanne®?

Visanne® (dienogest) is an oral progestogen that is approved for the treatment of endometriosis at a once daily dose. Visanne® is currently the only oral progestogen that has been specifically investigated for the treatment of endometriosis by dedicated clinical trial programs, including long-term studies.¹

Reference: 1. Mueck AO. Dienogest: an oral progestogen for the treatment of endometriosis. *Expert Rev Obstet Gynecol* 2011; 6(1): 5–15. **2.** Visanne® Professional Information, South Africa March 2022.

What does Visanne® contain?

The active substance is dienogest and each tablet contains 2 mg of dienogest.¹

The other non-medicinal ingredients are crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, potato starch, povidone and talc.¹

Reference: 1. Visanne® Professional Information, March 2022.

How does Visanne® work?

Treatment for endometriosis aims to alleviate pain and other symptoms, reduce endometriotic lesions, restore fertility and improve the woman's quality of life.¹ Visanne® offers unique benefits relevant to the treatment of endometriosis.²



Endometriosis appears to be estrogen dependent and so by reducing the production of estrogen one can reduce the progression of the disease.¹

Visanne® acts on endometriosis by abolishing the growth effects of estrogen on both the in-place and out-of-place endometrium.³ With Visanne®, the estrogen level is not decreased to zero but is reduced to an optimal level to treat endometriosis, avoiding adverse effects due to complete estrogen deprivation or deficiency, such as bone mineral density loss, hot flushes, loss of libido and other menopausal symptoms.¹

Visanne® also has potent endometrial effects via actions that include anti-inflammatory effects on endometriotic cells, as well as anti-proliferative and anti-angiogenic actions.¹

- The anti-inflammatory effect means that Visanne® acts to reduce certain signs of inflammation, such as swelling, tenderness and pain in the endometrial and surrounding tissues.
- Angiogenesis (the development of new blood vessels) is central to the development of endometriosis. The anti-angiogenic action means that Visanne® reduces the number of blood vessels thereby decreasing the blood supply to the lesions followed by atrophy (waste away) of the endometriotic lesions.
- The anti-proliferative effect means that Visanne® has a direct impact by inhibiting the growth of the lesions.

References: 1. Mueck AO. Dienogest: An oral progestogen for the treatment of endometriosis. *Expert Review Obstet Gynecol* 2011; 6(1):5–15. 2. Strowitzki T, Faustmann T, Gerlinger C, *et al*. Safety and tolerability of dienogest in endometriosis: pooled analysis from the European clinical study program. *Int J Women's Health* 2015; 7:393–401. 3. **Reference: 1.** Visanne® Professional Information, March 2022.

How effective is Visanne®?

Visanne® is a well-tolerated therapy with a favourable safety profile that is suitable for short-term and long-term use.¹ Visanne® is effective in reducing endometriosis-related pain symptoms such as dysmenorrhea (painful periods), premenstrual pelvic pain, dyspareunia (painful sexual intercourse) and chronic pelvic pain. Its efficacy is superior to placebo and equivalent to gonadotropin releasing hormone (GnRH) agonists, but with a better tolerability profile. As pain relief is one of the main goals of therapy in patients with endometriosis, it should be considered an indicator of treatment success.² In clinical studies patient satisfaction with Visanne® at the end of treatment was high, with 88.9% of women responding that they were "certainly willing" or "would prefer" to use Visanne® again.⁴

The impact of endometriosis on a woman's quality of life is substantial and wide ranging. Quality of life assessments in the Visanne® studies indicate that improvements in both physical and mental indices were attained within 12-week and 24-week treatment durations, and that these benefits were sustained.³



References: 1. Strowitzki T, Faustmann T, Gerlinger C, *et al.* Safety and tolerability of dienogest in endometriosis: pooled analysis from the European clinical study program. *Int J Women's Health* 2015; 7:393–401. 2. Bizzarri N, Remorgida V, Maggiore U, *et al.* Dienogest in the treatment of endometriosis. *Exp Opin Pharmacother* 2014; 15(13):1889–1902. 3. Schindler AE. Dienogest in long-term treatment of endometriosis. *Int J Women's Health* 2011; 3: 175–184. 4. Venkatesh S. Dienogest - The Millennium Molecule!! *J Gynecol* 2017; 2(2): 000141

Can Visanne be prescribed first-line, without surgery?

Yes, guidelines from the World Endometriosis Society have recommended Visanne® as an empirical treatment option for women without laparoscopic confirmation of endometriosis.¹

Empirical treatment refers to medical treatment that is given on the basis of the doctor's observation and experience.²

Based on broad experience, it can be predicted that Visanne® is well tolerated as long-term therapy in patients with endometriosis.³

References: 1. Strowitzki T, Faustmann T, Gerlinger C, *et al.* Safety and tolerability of dienogest in endometriosis: pooled analysis from the European clinical study program. *Int J Women's Health* 2015; 7:393–401. 2. <https://medical-dictionary.thefreedictionary.com/empirical+treatment> accessed 10/11/21. 3. Mueck AO. Dienogest: An oral progestogen for the treatment of endometriosis. *Expert Review Obstet Gynecol* 2011; 6(1):5–15.

Can Visanne® be prescribed after surgery for endometriosis?

Yes. Visanne® is also a suitable therapy following endometriosis surgery.¹

The decision to move to surgery in women with pain and suspected endometriosis should be based on clinical evaluation, imaging, and effectiveness of medical treatment. The Canadian Endometriosis Guidelines, amongst others, recommend that surgical management in women with endometriosis-related pain should be reserved for those in whom medical treatment has failed.²



Reference: 1. Strowitzki T, Faustmann T, Gerlinger C, *et al.* Safety and tolerability of dienogest in endometriosis: pooled analysis from the European clinical study program. *Int J Women's Health* 2015; 7:393–401. 2. Leyland N, Casper R, Laberge P, *et al.* SOGC Clinical Practice Guideline. Endometriosis: Diagnosis and Management. *J Obstet Gynecol Can* 2010; 32 (7 Suppl 2): S1–S32.

Why would it make sense to prescribe Visanne® after surgery for endometriosis?

Despite its proven efficacy, recurrence after surgery remains a formidable challenge¹:

- The average 2-year recurrence rate is calculated to be 21.5%;
- About 40–45% of patients have a relapse of endometriosis 5 years after the primary surgery;
- Reoperation occurs in over 50% of patients with endometriosis, with about 27% of them requiring three or more surgeries; and
- it seems that the recurrence rate for pain or dysmenorrhea is higher than that for clinical recurrence;
- repeated surgery is positively associated with increased morbidity and health care costs, and, in ovarian endometriosis, with damage to ovarian reserve.

Because endometriosis is a chronic, relapsing disorder, clinicians should develop a long-term plan of management with each patient that is dependent on symptoms, goals for fertility and quality of life.² Therefore, it is considered necessary to prevent recurrence by medication, such as Visanne®, until the patient wishes to become pregnant, avoid surgery if possible and continue long-term management until menopause.³

In fact, at least two expert panels recommend that post-operative treatment should be instituted in order to minimize the risk of recurrence and to extend the pain-free period after conservative surgery for patients with severe endometriosis.¹

To reduce the recurrence of endometrioma and therefore the necessity for reoperation over a prolonged period, treatment with Visanne® is effective.³ A study comparing two groups of patients who had ovarian endometrioma and who underwent laparoscopic stripping, showed that patients who wanted to become pregnant or did not wish to receive medication after the operation, had a 69% recurrence rate versus a 4% recurrence rate in those patients who did not wish to become pregnant and were given Visanne® after the surgery.³



References: 1. Guo S-W. Recurrence of endometriosis and its control. *Hum Reprod Update* 2009; 15(4): 441–461. 2. Leyland N, Casper R, Laberge P, et al. SOGC Clinical Practice Guideline. Endometriosis: Diagnosis and Management. *J Obstet Gynecol Can* 2010. 32 (7 Suppl 2): S1–S32. 3. Ota Y, Andou M, Yanai S, et al. Long-term administration of dienogest reduces recurrence after excision of endometrioma. *J Endometriosis Pelvic Pain Disorders* 2015; 7(2): 63–67.

For how long can Visanne® be used?

There is currently no cure for endometriosis and it should be viewed as a chronic disease that requires a life-long management plan with the goal of maximizing the use of medical treatment and avoiding repeated surgical procedures.¹

Treatment has three main goals:

- i. to reduce pain;
- ii. to increase the pregnancy rate for women who desire to have children; and
- iii. to delay recurrence for as long as possible.²

Only a few registered therapy options are available for the treatment of endometriosis, and most of these are not suitable for long-term treatment due to their side-effect profile.³ Convincing safety and tolerability data, in combination with proven efficacy, represent key characteristics when choosing an optimal therapy for long-term use in endometriosis.⁴

Clinical experience of Visanne® demonstrates that it significantly reduces endometriotic lesions and provides effective pain relief, combined with a favourable safety and tolerability profile that allows long-term use.¹

References: 1. Schindler AE. Dienogest in long-term treatment of endometriosis. *Int J Women's Health* 2011; 3: 175–184. 2. Guo S- W. Recurrence of endometriosis and its control. *Hum Reprod Update* 2009; 15(4): 441–461. 3. Mueck AO. Dienogest: an oral progestogen for the treatment of endometriosis. *Expert Review Obstet Gynecol* 2011; 6(1): 5–15. 4. Strowitzki T, Faustmann T, Gerlinger C, et al. Safety and tolerability of dienogest in endometriosis: pooled analysis from the European clinical study program. *Int J Women's Health* 2015; 7: 393–401.

Who should NOT take Visanne®?

Do not take Visanne® if you:¹

- have or have had a history of blood clots (e.g. in the legs or lungs), heart attack, stroke, or heart disease;
- have a history of or active venous embolic disorder
- have circulation problems due to diabetes (diabetes mellitus with vascular involvement);
- have abnormal liver test results caused by liver disease or liver problems;
- have or have had benign or malignant liver tumours;
- have a history of known or suspected estrogen- and/or progesterone-dependent tumours such as breast or uterine cancer;
- have undiagnosed abnormal vaginal bleeding;
- are allergic to dienogest or any ingredients of the medication.

Reference: 1. Visanne® Professional Information, March 2022.

What side effects are possible with Visanne®?

Side effects in clinical studies are generally mild to moderate in intensity and are associated with low discontinuation rates. In addition, the side effects associated with Visanne® decrease in both incidence and intensity over time.

The most frequently reported side effects (≥ 3%) with Visanne® are reflected in the table below.¹

ADR (MedDRA preferred term)	No (%) patients
Total population	332 (100.0%)
Headache	30 (9.0%)
Breast discomfort	18 (5.4%)
Depressed mood	17 (5.1%)
Acne	17 (5.1%)
Nausea	14 (4.2%)
Weight increased	12 (3.6%)
Abdominal pain	12 (3.6%)
Asthenic conditions	10 (3.0%)
Flatulence	10 (3.0%)
Ovarian cyst	10 (3.0%)

Note: Mean treatment duration: 39.8 weeks. Abbreviations: ADR, adverse drug reaction; MedDRA, Medical Dictionary for Regulatory Activities.

In a 2015 study, no individual side effect was responsible for increased premature discontinuation in more than 1% in the Visanne® group.¹

Should you experience any side-effects while taking Visanne®, this must be reported to a healthcare professional.

Reference: 1. Strowitzki T, Faustmann T, Gerlinger C, et al. Safety and tolerability of dienogest in endometriosis: pooled analysis from the European clinical study program. *Int J Women's Health* 2015; 7: 393–401.

Will Visanne® have an impact on menstrual bleeding?

Changes in bleeding pattern are a well-recognised characteristic of many progestogens.¹

Studies show that an initial increase in the number of bleeding/spotting days and a desynchronized / irregular bleeding pattern with Visanne® treatment is followed by a progressive reduction in bleeding/spotting days during continued treatment, accompanied by increases in amenorrhea (absence of menstrual bleeding) rates.² In a clinical study after 9-12 months of Visanne® use, bleeding was regularised in 22%, but 28% reported amenorrhoea (absence of a menstrual period), oligomenorrhoea (infrequent or very light) menstruation in 24% and polymenorrhoea (frequent recurrence of the menstrual cycle) in 2.7%.³

In studies, the number of discontinuations due to heavy or irregular bleeding while on treatment with Visanne® was low (i.e. 2 of 332 women), indicating that Visanne® is well tolerated by women in light of its efficacy for pain relief.²

References: 1. Mueck AO. Dienogest: an oral progestogen for the treatment of endometriosis. *Expert Review Obstet Gynecol* 2011; 6(1): 5–15. 2. Strowitzki T, Faustmann T, Gerlinger C, et al. Safety and tolerability of dienogest in endometriosis: pooled analysis from the European clinical study program. *Int J Women's Health* 2015; 7: 393–401. 3. Venkatesh S. Dienogest-The Millennium Molecule!! *J Gynecol* 2017; 2(2): 000141.

How will Visanne® affect fertility?

The risk of endometriosis appears to rise with a greater lifetime number of ovulatory cycles. Moreover, the role of ovulation in the genesis of ovarian endometriosis has been confirmed demonstrating that endometriomas develop from follicles immediately after ovulation.²

Studies confirm that Visanne® possesses potent ovulation-inhibiting effects. Visanne® causes complete inhibition of ovulation at a daily dose of 2 mg and therefore should not be used if pregnancy is desired.¹

Women with endometriosis may desire pregnancy once sufficient endometriosis-related pain relief is achieved. The ovarian activity resumes rapidly (range 1–43 days) after stopping treatment with Visanne®. Successful pregnancy has been reported in women with endometriosis following the cessation of Visanne® treatment.¹

References: 1. Venkatesh S. Dienogest-The Millennium Molecule!! *J Gynecol* 2017; 2(2): 000141.
2. Vercellini P, Eskenazi B, Consonni D, *et al.* Oral contraceptives and risk of endometriosis: a systematic review and meta-analysis. *Hum Reprod Update* 2011; 17: 159–170.

Can Visanne® be used during pregnancy?

As with other progestogens, there are limited data on the use of Visanne® in pregnant women. The available data do not indicate harmful effects for Visanne® with respect to reproductive toxicity and reveal no special risks on pregnancy. However, Visanne® should not be administered to pregnant women because there is no need to treat endometriosis during pregnancy.¹



Reference: 1. Schindler AE. Dienogest in long-term treatment of endometriosis. *Int J Women's Health* 2011; 3: 175–184.

How does Visanne® compare to the oral contraceptive pill for the treatment of endometriosis?

Combined estrogen-progestogen oral contraceptive pills have been used for decades as the first-line treatment for endometriosis despite an absence of controlled data regarding their effectiveness.¹

Surprisingly, only one randomized, placebo-controlled clinical trial has ever been published to investigate the effectiveness of oral contraceptive pills for pelvic pain and dysmenorrhea in patients with endometriosis.¹

There are other, relatively old, non-controlled studies of oral contraceptive pills in the treatment of pelvic pain and dysmenorrhea in women with documented endometriosis, and these show that about 50% of patients have partial or no improvement in symptoms. Of interest, an international study of women's perception of pain and bleeding in endometriosis, enrolled 441 women between the ages of 15 and 49 years in eight countries, including Canada and the United States. The women were interviewed using an online questionnaire. The responses about oral contraceptive pills use by patients with diagnosed endometriosis demonstrated that about 70% of women had used multiple oral contraceptive pills for relief of endometriosis pain and over 40% had been prescribed between 3 and 10 different oral contraceptive pills for endometriosis. These data suggest that there was recurrence of pelvic pain while taking an oral contraceptive pill and that the patients were switched to a different oral contraceptive pill in the hope of alleviating the pain.¹

This further supports the concept that oral contraceptive pill use is not completely effective in the treatment of endometriosis. Furthermore, switching from one oral contraceptive pill to another because of ineffectiveness of pain relief may lead to a delay in the diagnosis of endometriosis.¹

Finally, it has been argued that starting hormonal contraceptives in young girls because of primary dysmenorrhoea (painful periods) could be indicative of the diagnosis of deep endometriosis in later life. It is clearly a paradox that by recommending treatment in symptomatic (young) women one might induce the above mentioned delay in diagnosing the disease.²

Based on controlled trial data, it appears that women with suspected or confirmed endometriosis may do better with oral progestogen-only treatment, such as Visanne®, as the first-line treatment because progestogens have demonstrated benefits in reducing pain and suppressing the anatomic extent of endometriotic lesions.¹

References: 1. Casper R. Progestin-only pills may be a better first-line treatment for endometriosis than combined estrogen- progestin contraceptive pills. *Fertil Steril* 2017; 107(3): 533–536.
2. Dunselman G, Vermeulen N, Becker C, *et al.* ESHRE guideline: management of women with endometriosis. *Hum Reprod* 2014; 29(3): 400–412.

Can anti-inflammatory medication be taken with Visanne®?

Nonsteroidal anti-inflammatory drugs are frequently used by women with endometriosis in an attempt to achieve pain relief, although clinical trial evidence to support the efficacy of these agents in endometriosis is lacking.¹

A major limitation to the long-term use of nonsteroidal anti-inflammatory drugs (NSAIDs) is their significant side effects, including the risk of gastric ulceration and an anti-ovulatory effect when taken at mid-cycle.¹

Management of pain associated with endometriosis with targeted medical therapies, including Visanne®, may require at least one cycle to initiate pain relief. In this situation, it is appropriate to provide pain medication in the form of NSAIDs or even opioids to make the patient more comfortable until the primary medical management becomes effective.²

Reference: 1. Schindler AE. Dienogest in long-term treatment of endometriosis. *Int J Women's Health* 2011; 3: 175–184. **2.** Leyland N, Casper R, Laberge P, et al. SOGC Clinical Practice Guideline. Endometriosis: Diagnosis and Management. *J Obstet Gynecol Can* 2010; 32 (7 Suppl 2): S1–S32.

How is endometriosis viewed by the medical aids?

Endometriosis is a prescribed minimum benefit (PMB) condition under Diagnostic Treatment Pair (DTP) code 434M (Non-inflammatory disorders and benign neoplasms of ovary, fallopian tubes and uterus). Endometriosis in other areas is not included in the current PMB regulations. This implies that the medical scheme should fund the costs associated with the diagnosis and treatment of endometriosis.¹

The DTP covers the cost of medical and surgical management of endometriosis, with explicit mention of the following surgical procedures:¹

- Salpingectomy (surgical removal of the fallopian tube);
- Oophorectomy (surgical removal of one or both ovaries); and
- Hysterectomy (surgical removal of all or part of the womb).

Laparoscopy can be used to diagnose, to identify the stage of endometriosis, and to remove the abnormally deposited tissue. Laparoscopy should be funded as PMB level of care. Some medical schemes have Designated Service Provider (DSP) arrangements and protocols in place, which should be verified and discussed with the medical scheme prior to either diagnostic procedures or treatment being started.¹

Reference: 1. Maramba E. Endometriosis. *CMScript* 2016; 8: 1–4

Will the medical aid reimburse the costs associated with Visanne®?

Because endometriosis is a prescribed minimum benefit (PMB) condition the medical scheme should fund the costs associated with the diagnosis and treatment of endometriosis, including treatment with Visanne®.¹

Please note that only endometriosis of the uterus, ovary and fallopian tubes are PMB conditions. See page 28 for more information.

Reference: 1. Maramba E. Endometriosis. *CMScript* 2016; 8: 1–4

What is a Prescribed Minimum Benefit (PMB)?

Prescribed Minimum Benefits (PMBs) are a set of defined benefits to ensure that all medical aid members have access to certain minimum health services, regardless of the benefit option they have selected (including hospital plans). They were introduced into the Medical Schemes Act to ensure that members of medical aids would not run out of benefits for certain conditions and find themselves forced to go to State hospitals for treatment. These PMBs cover a wide range of ± 270 conditions, such as endometriosis, menopausal management, and many others, including medical emergencies. However, take note that certain limitations could apply, such as the use of a Designated Service Provider (DSP) and specified treatment standards.¹

Reference: 1. Council For Medical Schemes. Definition: What are PMBs? Available from: http://www.medicalschemes.com/medical_schemes_pmb/index.htm. [Accessed 30 August 2018].

What is an ICD-10 code and what does it mean?

ICD-10 stands for International Classification of Diseases and Related Health Problems (10th revision). It is a coding system developed by the World Health Organisation (WHO), that translates the written description of medical and health information into standard codes, e.g. N80.9 is an ICD-10 code for endometriosis. ICD-10 codes are used to inform medical schemes about what conditions their members were treated for so that claims can be settled correctly.¹

When you join a medical scheme, you choose and pay for a particular benefit option. This benefit option contains a basket of services that often has limits on the health services that will be paid for. Because ICD-10 codes provide accurate information on the condition you have been diagnosed with, these codes help the medical scheme to determine what benefits you are entitled to and how these benefits could be paid.¹

This becomes very important if you have a PMB condition, such as endometriosis, as these can only be identified by the correct ICD-10 codes. Therefore, if the incorrect ICD-10 codes are recorded on your invoices, referral letters, medicine prescription etc. your PMB-related services (e.g. diagnosis and treatment) might be paid from the wrong benefit (such as from your medical savings account), or it might not be paid at all if your day-to-day or hospital benefit limits have been exhausted.¹

Reference: 1. Council For Medical Schemes. ICD-10 Codes. Available from: http://www.medicalschemes.com/medical_schemes_pmb/ICD-10_codes.htm. [Accessed 30 August 2018].

What are the ICD-10 codes* for Endometriosis?

DTP 434M: The Female Reproductive System.

Endometriosis is a prescribed minimum benefit (PMB) condition under the PMB / DTP code 434M (non-inflammatory disorders and benign neoplasms of ovary, fallopian tubes and uterus).¹

N80 Endometriosis¹

	PMB Conditions
N80.0	Endometriosis of uterus
N80.1	Endometriosis of ovary
N80.2	Endometriosis of fallopian tube
N80.3	Endometriosis of pelvic peritoneum
N80.4	Endometriosis of rectovaginal septum and vagina
N80.5	Endometriosis of intestine
N80.6	Endometriosis of cutaneous scar
N80.8	Other endometriosis
N80.9	Endometriosis, unspecified

*This list is not an official and legally mandated document and should be used only as a general guideline for the correct use of ICD-10 codes for assistance with accurate and proper reimbursement. The responsibility for the interpretation and use of the guideline for the relevant condition lies with the reader. For a comprehensive list of conditions, please refer to your ICD-10 manual. Please note that this document is subject to regular updates.

Please note that only endometriosis of the uterus, ovary and fallopian tubes are PMB conditions. The relevant ICD-10 codes are in the highlighted areas above.

Reference: 1. Maramba E. Endometriosis. CMScript 2016; 8: 1–4. 2. Council For Medical Schemes. ICD-10 Codes. Available from: http://www.medicalschemes.com/medical_schemes_pmb/ICD-10_codes.htm. [Accessed 30 August 2018]. 2. Council For Medical Schemes. ICD-10 Codes. Available from: http://www.medicalschemes.com/medical_schemes_pmb/ICD-10_codes.htm. [Accessed 30 August 2018].

What is a Designated Service Provider (DSP)?

A Designated Service Provider (DSP) is a healthcare provider (doctor, pharmacist, hospital, etc.) that is a medical scheme's first choice when its members need diagnosis, treatment or care for a PMB condition.¹

If you choose not to use the DSP selected by your scheme, you may have to pay a portion of the bill as a co-payment. This could either be a percentage co-payment or the difference between the DSP's tariff and that charged by the provider you went to.¹

Medical schemes have to ensure that it is easy for beneficiaries to get to the DSPs. If there is no DSP within reasonable distance of your work or home, then you can visit any provider and the scheme is obliged to pay.¹

When you suffer an emergency condition, or are involved in an accident, you may go to the nearest healthcare facility for treatment, even if it is not a DSP. Your scheme will have to cover the costs.¹

Schemes also have to ensure that the DSPs of their choice can deliver the services needed and without members having to wait unreasonably long.

Where a DSP is unable to accommodate or treat a member, the medical scheme remains liable for all the costs of treating the PMB condition at a non-DSP.¹

Reference: 1. Council For Medical Schemes. Designated Service Providers. Available from: http://www.medicalschemes.com/CMS_Website_medical_schemes_pmb/designated_service_providers.htm. [Accessed 30 August 2018].

What can you as a Patient take Responsibility for?

1. Remember that you as a patient made the decision about the medical aid selected and the option within the medical aid e.g. hospital plan only.¹
2. Educate yourself about your medical scheme's rules, the listed medication and treatments (formularies) for endometriosis, as well as if and who the Designated Service Providers are.¹
3. Doctors do not usually have a direct contractual relationship with medical schemes. They merely issue their accounts and if the medical scheme does not pay, for whatever reason, the doctor turns to the patient for the amount due. This does not mean that PMBs are not important to healthcare providers nor that they don't have a role to play in its successful functioning.¹
4. Reimbursement claims require the use of ICD-10 codes. Make sure the correct ICD-10 code appears on all your invoices, referral letters, prescriptions etc. See the list of ICD-10 codes on page 28 e.g. Endometriosis ICD-10 Codes: N80.9.¹
5. If you use the correct ICD-10 code your account will be paid, as PMBs enjoy guaranteed medical aid cover. If you have been given a treatment, or choose a treatment, that is not on your medical aid's formulary you might have to pay in towards the treatment (a co-payment) but you are entitled to some financial cover.¹
6. Follow-up and check that your account is submitted within four months and paid within 30 days after the claim was received (accounts older than four months are not paid by medical schemes).¹



Reference: 1. Council For Medical Schemes. Responsibilities. Available from: http://www.medicalschemes.com/medical_schemes_pmb/responsibility.htm. [Accessed 30 August 2018].

Help From the Council of Medical Schemes.

Prescribed Minimum Benefits (PMBs) can be a rather complicated subject and your medical scheme might not be able to answer all your questions.

Do not despair.
The Council for Medical Schemes (CMS) was established to work with medical schemes in South Africa. In this role, its first priority is to protect the rights of consumers and to ensure that they are treated fairly.¹

Contact the Council for Medical Schemes in any of the following ways:

Reception: 0861 123 267

General Enquiries: 012 432 0500

Complaints:

Fax: 086 673 2466

E-mail: complaints@medicalschemes.co.za

Address: Block A, Eco Glades 2 Office Park,
420 Witch-Hazel Avenue, Eco Park, Centurion

Reference: 1. Council For Medical Schemes. Help from the CMS. Available from: <https://www.medicalschemes.co.za/contact-us/> [Accessed 10 June 2015].

Where to go for more endometriosis support?

There are endometriosis support groups in South Africa:

- **Endo-SA (Endometriosis Society of South Africa)**
- **Endometriosis Warriors South Africa**
- **South African Endometriosis Support**
- **Foundation for Endometriosis Awareness, Advocacy & Support**



SPEAK UP
ABOUT ENDOMETRIOSIS

Visanne® dosage and direction for use.



- Take the first tablet from the first pack on day 1 of the menses¹
- One tablet daily without any break, taken preferably at the same time each day¹
- Tablets must be taken continuously every day without regard for bleeding¹
- Once a complete pack of tablets has been taken, begin the new pack on the next day without any interruption¹
- If you miss a dose or if you vomit or have diarrhea within 3 to 4 hours of taking a tablet, take a tablet as soon as possible and continue with your regular schedule. If it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule. Do not take a double dose to make up for a missed one. If you are not sure what to do after missing a dose, contact your doctor or pharmacist for advice¹

Reference: 1. Visanne® Visanne® Professional Information, March 2022.

What is the Speak Up About Endometriosis Campaign?



With an estimated 1 in 10 women in the world affected by the painful consequences of endometriosis, it is shameful how little awareness there is about the life altering realities of endometriosis.¹

This often leaves those afflicted with endometriosis feeling isolated and helpless.¹

Delay in diagnosing endometriosis is the most commonly reported theme. It has been reported that some women delay seeking help for their symptoms because they believe all women have painful periods and that when women do reveal their symptoms to a family member, friend, teacher, colleague or in some cases healthcare professionals, their experiences are typically normalised as being what all women must endure.¹

Let's use our voices, real and virtual, to raise awareness about endometriosis. By "Speaking Up About Endometriosis" we can give women living with the condition a better life, their sexuality, their education, their careers, their fertility, their love of life, get them up off the couch and packing away their hot water bottles. There is effective treatment and management of endometriosis available.

Break the silence! Speak Up About Endometriosis!

Reference: 1. Young K, Fisher J, Kirkman M. Women's experiences of endometriosis: a systematic review and synthesis of qualitative research. *J Fam Plann Reprod Health Care* 2014; 0:1–10.



SPEAK UP

ABOUT ENDOMETRIOSIS

Visanne[®]
dienogest 2mg

[S3] Visanne[®] Tablets. Each tablet contains 2 mg dienogest. RSA Reg. No.: 44/21.8.2/0159. Mauritius: Reg. No.: PB/12884/05/2017. Namibia: [NS2] Reg. No.: 13/21.8.2/0230. Zimbabwe: (PP) Reg. No.: 2017/21.8/5493. Malawi: Reg. No.: PMPB/PL16/16. Botswana: (S2) Reg. No.: BOT2404375. Zambia: (POM) Reg. No.: ZAMRA-HM-22-85.

For full prescribing information, refer to the Professional Information approved by the medicines regulatory authority.

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Collaboration Hub, 1st Floor, Waterfall Circle, 9 Country Estate Drive, Waterfall City, 2090, South Africa.
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