

Dienogest-A unique hybrid progestin for long-term compliance in endometriosis

About Endometriosis:^{1,2}

- Endometriosis affects roughly 10% (190 million) of reproductive age women and girls globally.
- It is a chronic disease associated with severe, life-impacting pain during periods, sexual intercourse, bowel movements and/or urination, chronic pelvic pain, abdominal bloating, nausea, fatigue and sometimes depression, anxiety, and infertility.
- There is currently no known cure for endometriosis and treatment is usually aimed at controlling symptoms.
- Access to early diagnosis and effective treatment of endometriosis is important, however, diagnosing endometriosis can be challenging, with an average delay to diagnosis of seven years.

Innovation in Endometriosis Treatment

- Different pharmacologic treatment options are currently available. The most widely exerted medical therapy for endometriosis involves progestins (Dienogest) and oral contraceptives. Also, gonadotropin-releasing hormone (GnRH) agonists, GnRH- antagonists and androgen derivatives are used. New treatment options that are currently under investigation are selective progesterone receptor modulators (SPRMs), aromatase inhibitors (AI), cyclooxygenase (COX)-2 inhibitors, angiogenesis disruptors and immune modulators.³
- Stringent guidelines recommend to use Dienogest as 1st line treatment option for the management of endometriosis⁴



Dienogest-A unique hybrid progestin⁵

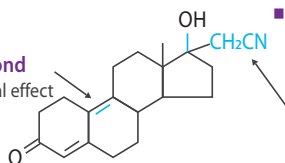
- Dienogest's special chemical structure is responsible for its unique pharmacological profile

Properties of 19-nortestosterone derivatives

- Strong progestational effect on endometrium
- Relatively short plasma half life of 9-11 hours
- High oral bioavailability >90%

Additional double bond

- Strong pregestational effect



Properties of progesterone derivatives

- Good tolerability & Anti-androgenic effects
- Relatively moderate inhibition of gonadotropin secretion (exerts no hypoestrogenic effect)
- Mainly peripheral action

Cyanomethyl instead of an ethinyl group in the 17a position

- Low interaction with hepatic proteins eg Cytochrome P450- prevents drug interactions
- No relevant interaction with corticosteroid binding protein – no glucocorticoid side effect
- Prevents accumulation in the blood

Proven Result ⁶⁻⁹

- Reduces pain of endometriosis significantly
- Dienogest 2 mg/day orally demonstrated equivalent efficacy to depot Leuprolide Acetate at a standard dose in relieving the pain associated with endometriosis while offering advantages in safety and tolerability
- Evidence based treatment option in adolescent endometriosis patients
- Reduces chocolate cysts rapidly to approximately 70% of initial size after 12 months of treatment
- Effective for the prevention of endometriosis pain recurrence
- Proven safe in continuous use for as long as 7 years

Ref: 1. Salvatore Caruso, Marco Iraci, Stefano Cianci, et. al. Effects of long-term treatment with Dienogest on the quality of life and sexual function of women affected by endometriosis-associated pelvic pain. Journal of Pain Research, Volume 12, 2019 - Issue 2. R Wattanayingcharoenchai, S Rattanasi, C Charakorn, et. al. Postoperative hormonal treatment for prevention of endometrioma recurrence after ovarian cystectomy: a systematic review and network meta-analysis. BJOG. 2021 Jan; 128(1): 25-35; 3. Fabio Barra, Antonio Simone Laganà, Carolina Scala, et. al. Pretreatment with dienogest in women with endometriosis undergoing IVF after a previous failed cycle. Reproductive BioMedicine Online. Volume 41, Issue 5, November 2020, Pages 859-868; 4. Paul L. McCormack. Dienogest: A Review of its Use in the Treatment of Endometriosis. Drugs 2010; 70 (16): 2073-2088; 5. Adolf E Schindler. Dienogest in long-term treatment of endometriosis. Int J Womens Health. 2011; 3: 175-184; 6. Klaas Heinemann, Bruno Imthurn, Lena Marions, et. al. Safety of Dienogest and Other Hormonal Treatments for Endometriosis in Real-World Clinical Practice (VIPOS): A Large Noninterventive Study. Adv Ther. 2020 May;37(5):2528-2537; 7. Thomas Römer. Long-term treatment of endometriosis with dienogest: retrospective analysis of efficacy and safety in clinical practice. October 2018 Archives of Gynecology and Obstetrics 298(4); 8. Andreas D Ebert, Lying Dong, et. al. Dienogest 2 mg Daily in the Treatment of Adolescents with Clinically Suspected Endometriosis: The ViSanne Study to Assess Safety in ADOLescents. J Pediatr Adolesc Gynecol. Epub 2017 Feb 9; 9. Neil P Johnson, Lone Hummelshøj, et. al. World Endometriosis Society consensus on the classification of endometriosis. December 2016 Human Reproduction.

Guideline recommended first-line therapy of endometriosis



Targeted oral progestin for long-term
compliance in Endometriosis

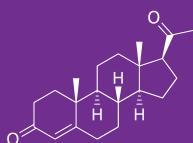
1st Dienogest brand available in Bangladesh



6 Years of use
in Bangladesh Market
316,852 users⁵



Approved
in
104 Countries⁵



Only low-dose oral
progestin with **pronounced**
endometrial effect⁴



Excellent efficacy on pain
associated with
endometriosis⁷



Suitable for long-term use with favorable
safety-bioavailability profile in endometriosis.
No clinically significant effect on BMD.
Pain relief is sustained over the long term⁶



Proven by comprehensive
clinical development
program backed by Real
World Evidence⁵



Significant lesion reduction
Addresses the underlying pathology of endometriosis and significantly
reduces lesions as measured by r-AFS score via laparoscopy⁸

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full prescribing
information

