

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

## About Endometriosis:<sup>1,2</sup>

- 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 derivates are used. New treatment options that are currently under investigation are selective progestogen receptor modulators (SPRMs), aromatase inhibitors (AI), cyclooxygenase (COX)-2 inhibitors, angiogenesis disruptors and immune modulators.<sup>3</sup>
- Stringent guidelines recommend to use Dienogest as 1<sup>st</sup> line treatment option for the management of endometriosis<sup>4</sup>



## Dienogest-A unique hybrid progestin<sup>5</sup>

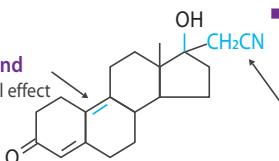
- Dienogest's special chemical structure is responsible for its unique pharmacological profile

### 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 e.g Cytochrome P450- prevents drug interactions
- No relevant interaction with corticosteroid binding protein – no glucocorticoid side effect
- Prevents accumulation in the blood

## Proven Result<sup>6-9</sup>

- 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. 2. R.Watanayasinghorenchai, S.Rattanarsi, 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 Women's 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 Noninterventional Study. *Adv Ther*. 2020 May;37(5):2526-2537; 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, Liying Dong, et. al. Dienogest 2 mg Daily in the Treatment of Adolescent 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

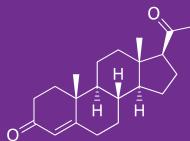
## 1<sup>st</sup> Dienogest brand available in Bangladesh



6 Years of use  
in Bangladesh Market  
316,852 users<sup>5</sup>



Approved  
in  
104 Countries<sup>5</sup>



Only low-dose oral progestin with pronounced endometrial effect<sup>4</sup>



Excellent efficacy on pain  
associated with  
endometriosis<sup>7</sup>



**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 term<sup>6</sup>**



**Proven by comprehensive  
clinical development  
program backed by Real  
World Evidence<sup>5</sup>**



**Significant lesion reduction**  
Addresses the underlying pathology of endometriosis and significantly reduces lesions as measured by r-AFS score via laparoscopy<sup>8</sup>

**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 Wattayanayangcharoenchai, 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 Lagana, 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): 2073-2089.5.Klaas Heinemann, Bruno Imrith, Lena Marions, et al. Safety of Dienogest and Other Hormonal Treatments for Endometriosis in Real-World Clinical Practice (VPOS): A Large Noninterventional Study. *Adv Ther*. 2020 May;37(5):2528-2537. 6. 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); 7. Andreas D Ebert, Liying 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 February 9; 8. *On file on file*. 9. Nel P Johnson, Lone Hammelhøj, et al. World Endometriosis Society consensus on the classification of endometriosis. December 2016 *Human Reproduction*, 10. Adolfo E Schindler, Dienogest in long-term treatment of endometriosis. *Int J Womens Health*. 2011; 3: 175–184.



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