

AstraZeneca Pharmaceuticals LP
1800 Concord Pike PO Box 15437
Wilmington DE 19850-5437

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Dear Pharmacist,

AstraZeneca Pharmaceuticals LP is pleased to inform you that we have established a new relationship with Biovail Pharmaceuticals Inc. to market ZOLADEX[®] (goserelin acetate implant) 3.6 mg for endometriosis to OB/GYNs. Additionally, AstraZeneca offers the advantage of the SafeSystem[™] Syringe with a siliconized needle and an automatic safety shield, which helps prevent needlestick injuries to health care professionals. We believe health care providers can benefit from the flexibility of a drug such as ZOLADEX, which does not need to be mixed prior to administration.

Thus, we would like to reintroduce you to the endometriosis indication of ZOLADEX 3.6 mg.

ZOLADEX 3.6 mg is indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. Experience with ZOLADEX for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months.

Experience the benefits of ZOLADEX in the management of endometriosis:

- Significant reductions in the mean subjective symptom scores
- Provides sustained pain relief
- Reduces the size of endometrial lesions

Important Information Regarding the Management of Endometriosis With ZOLADEX.

In controlled clinical studies using the 3.6-mg formulation every 28 days for 6 months, ZOLADEX was shown to be as effective as danazol therapy in relieving clinical symptoms (dysmenorrhea, dyspareunia, and pelvic pain) and signs (pelvic tenderness, pelvic induration) of endometriosis and decreasing the size of endometrial lesions as determined by laparoscopy. In one study comparing ZOLADEX with danazol (800 mg/day), 63% of ZOLADEX-treated and 42% of danazol-treated patients had a greater than or equal to 50% reduction in the extent of endometrial lesions. In the second study comparing ZOLADEX with danazol (600 mg/day), 62% of ZOLADEX-treated and 51% of danazol-treated patients had a greater than or equal 50% reduction in the extent of endometrial lesions. The clinical significance of a decrease in endometriotic lesions is not known at this time; in addition, laparoscopic staging of endometriosis does not necessarily correlate with severity of symptoms.

In these two studies, ZOLADEX led to amenorrhea in 92% and 80%, respectively, of all treated women within 8 weeks after initial administration. Menses usually resumed within 8 weeks following completion of therapy.

Within 4 weeks following initial administration, clinical symptoms were significantly reduced, and at the end of treatment were, on average, reduced by approximately 84%.

During the first 2 months of ZOLADEX use, some women experience vaginal bleeding of variable duration and intensity; in all likelihood, this bleeding represents estrogen withdrawal bleeding and is expected to stop spontaneously.

There is insufficient evidence to determine whether pregnancy rates are enhanced or adversely affected by the use of ZOLADEX.

Important Clinical Considerations When Prescribing ZOLADEX® (goserelin acetate implant)

ZOLADEX is a synthetic decapeptide analogue of LHRH, which acts as a potent inhibitor of pituitary gonadotropin secretion when administered in the biodegradable formulation.

When used in females, this gonadotropin inhibition results from a down-regulation in the pituitary gland, which is similar to the suppression ZOLADEX instills in males.

Other Considerations:

ZOLADEX Product Information

Strength	3.6 mg
NDC #	0310-0950-36

Wholesalers: orders can be placed by EDI, by fax 302-886-1771, or by calling AstraZeneca Customer Service at 1-800-842-9920,

Important Safety Information about ZOLADEX

ZOLADEX is contraindicated in women who are pregnant or may become pregnant, breast feeding, or have undiagnosed abnormal vaginal bleeding.

Contraception is not ensured by taking ZOLADEX. Nonhormonal methods of contraception must be used during treatment with ZOLADEX and for at least 12 weeks after stopping treatment or the return of menses.

As with other GnRH agonists, ZOLADEX therapy results in a loss of bone mineral density (BMD). BMD changes may be partially reversible. Retreatment is not recommended. Patients who previously underwent GnRHa therapy may be at additional risk for BMD changes and should be closely monitored.

Most common adverse events with ZOLADEX are related to hypoestrogenism and include hot flashes, vaginitis, headache, emotional lability, change in libido, sweating, depression, and change in breast size.

[Please see full Prescribing Information for ZOLADEX.](#)

Sincerely,



Jonathan P. Walker,
Commercial Brand Leader

ZOLADEX is a registered trademark of AstraZeneca Pharmaceuticals LP. SafeSystem is a trademark of the AstraZeneca group of companies.

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