

Relugolix/estradiol/norethisterone (norethindrone) acetate: Adis Evaluation

Clinical Considerations

- First once-daily oral treatment
- Combination of a GnRH receptor antagonist (relugolix) plus add-back therapy in one pill
- Substantially improves heavy menstrual bleeding and other uterine fibroids-associated symptoms
- Generally well tolerated; minimal impact on bone loss

Plain Language Summary

Background and rationale

- Uterine fibroids may cause debilitating symptoms (such as heavy menstrual bleeding, pelvic pain and passing of blood clots). Hysterectomy, the only definitive treatment for this condition, is associated with some disadvantages (e.g. loss of future childbearing). Less invasive procedures and medical treatments are now available to treat the symptoms.
- Recently, a fixed-dose tablet comprising relugolix, estradiol and norethisterone acetate (Ryego®; Myfembree®) has been approved to treat symptoms of uterine fibroids.

Clinical findings

- In clinical trials, relugolix combination therapy substantially reduced menstrual bleeding and improved several other symptoms in women with uterine fibroids-associated heavy menstrual bleeding.
- The combination was generally well tolerated and had a minimal impact on bone loss, a known adverse effect of such therapies.

Conclusion

With its convenient once-daily administration, relugolix/estradiol/norethisterone acetate is a useful addition to current medical treatment options for premenopausal women with symptomatic uterine fibroids.

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