

# GYNAECOLOGY & OBSTETRICS UPDATE

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## SELECTIVE OESTROGEN RECEPTORS MODULATORS (SERMs)

I have received many questions about the new HRT Raloxifene HCL!. It is one of the pharmaco-therapeutic group SERMs or Selective Oestrogen Receptor Modulators which include other preparations eg. Tamoxifen. **SERMs are not HRT** but they have selective agonist or antagonist activities on tissues responsive to oestrogen. Raloxifene HCL, for example, acts as agonist on bone and partially on cholesterol metabolism but not in the hypothalamus or in the uterine or breast tissue.

### Therapeutic indications

- *The ONLY indication of Raloxifene HCL is the prevention of non-traumatic vertebral fracture in postmenopausal women at increased risk of osteoporosis. There are NO data on extra-vertebral fractures.*
- *Raloxifene HCL is NOT effective in reducing vasodilatation (hot flushes) or other symptoms of the menopause associated with oestrogen deficiency. Furthermore hot flushes were modestly increased in the first 6 months of treatment in comparison to placebo (24.3% & 18.2% respectively).*
- Therefore, Raloxifene HCL should **NOT** be considered as a therapeutic option to control menopausal symptoms. It should only be considered for prevention of vertebral fractures in patients at high risk of osteoporosis.

### Pharmacological properties

In comparison to HRT, and indeed to other therapeutic options, for **osteoporosis prevention** the following effects of Raloxifene HCL should be considered:

- Effects on menopausal symptoms: symptoms may be increased.
- Effects on cardiovascular system: Both HRT and Raloxifene HCL are associated with similar increase of risk of thrombo-embolic events.
- Effects on lipid metabolism: Total cholesterol and LDL cholesterol are decreased. *In contrast to oestrogen HDL cholesterol did not change significantly and no data are available to demonstrate any benefit on cardiovascular disease.*
- Effects on endometrium: Compared to placebo, Raloxifene was not associated with spotting or bleeding or endometrial hyperplasia (which may occur with unopposed oestrogen).
- Effects on breast tissue: Raloxifene does not stimulate breast tissue. It was associated with significantly fewer breast symptoms (swelling, tenderness, pain) than with oestrogens. However Raloxifene should not be used in patients with endometrial or breast cancer.

### References

- New England Journal of Medicine (1997); 337:1641-7
- Raloxifene HCL: Summary of product characteristics