

*A new generation **SERM** with increased bone effectiveness in high risk patients and a good endometrial and breast safety profile*

Conbriza® (bazedoxifene) approved by the Spanish Agency for Medicines and Healthcare Products (AEMPS) for treatment of postmenopausal osteoporosis

- *Over two out of every ten Spanish women suffer from osteoporosis and one out of every two women over 50 may suffer a bone fracture ⁽¹⁾, while 20% of hip fracture patients present a poor prognosis*
- *New generation SERMs ⁽²⁾ are presented as an initial treatment option in recent menopausal women by consistently acting where needed, adapting to the estrogenic receptor and modulating it.*
- *Bazedoxifene's greater effectiveness in reducing fractures and an absence of significant side effects encourage therapeutic compliance of osteoporosis sufferers, whose abandonment rate stands at around 50%*

Madrid, 30 September 2010.- Eleven years after the development of the last therapeutic option in the SERM class, this morning the biomedical companies Pfizer and Almirall presented Conbriza® (bazedoxifene), a new generation selective estrogen receptor modulator (SERM) indicated for the treatment of postmenopausal osteoporosis in women at increased risk of fracture.

The new generation of SERMs represented by bazedoxifene⁽²⁾ offers a fresh therapeutic option for women at increased risk of fracture after menopause, demonstrating its efficacy by increasing bone mineral density, reducing the risk of vertebral fractures and also reducing non-vertebral fractures in high risk patients ^(3, 4). Additionally, its good endometrial and breast safety profile and lack of significant side effects encourage patient therapeutic compliance.

According to **doctor Santiago Palacios**, director of the Palacios Centre for Women's Health and Medicine, "SERMs are a good therapeutic option for women with recent osteoporosis as they act as estrogen agonists or antagonists depending on the type of cells and tissues". In this sense, "bazedoxifene reflects the value of the new SERMs by showing greater estrogenic power in the bone and greater antiestrogenic power in the endometrium".

Carmen Valdés, National Coordinator of the Osteoporosis Group of the Spanish Society of Primary Care Physicians (SEMERGEN), states, “ *Not only do SERMs show effectiveness in preventing fractures, they also provide extraskeletal benefits to protect against unbalances arising from the menopause*”.

Both doctors agree that prevention of fractures is the principal objective of all osteoporosis treatment. **Carmen Valdés** adds the importance of indicating to all patients appropriate treatment to “*avoid new fractures that lead women into a state of dependency that affects the quality of their lives as well as a high consumption of financial and human resources*”. At the moment osteoporosis in Spain is the cause of around 90,000 hip fractures and 500,000 vertebral fractures every year⁵.

Doctor Palacios states, “ *bazedoxifene has enabled another step forward to be made in osteoporosis treatment by offering a high safety profile for the patient*”. He goes on to indicate the excellent “*breast health perspective of bazedoxifene*” shown by studies.

Efficacy and safety of bazedoxifene

Bazedoxifene (Conbriza[®]) has obtained approval in Spain from the Spanish Agency for Medicines and Healthcare Products (AEMPS) based on efficacy and safety data shown in two multi-centre, randomised, phase III, double blind, placebo and raloxifene controlled clinical studies in which around 10,000 postmenopausal women took part.

The first study performed after two years ⁽³⁾ demonstrated bazedoxifene’s capacity to prevent bone mass loss with an increase of spinal column bone mineral density compared to placebo in the 24 months of treatment.

The second study at three years ⁽⁴⁾ showed a 42% reduction of the risk of fractures compared to placebo. A *post hoc* analysis performed on around 1,800 patients with a high risk of fractures who took bazedoxifene indicated a 50% reduction of non-vertebral fractures compared to placebo and a 44% reduction compared to raloxifene.

A study follow-up at 5 years ^(6,7 and 8) ratified the efficacy of bazedoxifene in the prevention of fractures, reducing the prevalence of further vertebral fractures by 35% and non-vertebral fractures by 37%. It also demonstrated its good tolerability and a good long-term endometrial and breast safety profile, with no significant side effects

Women, menopause and osteoporosis

Bearing in mind that osteoporosis is a silent disease, “*the primary care doctor plays a fundamental role in early detection of this pathology through analysis and assessment of associated risk factors: age, early menopause, treatment with corticoids, history of fracture due to fragility in first degree relatives, personal history of early fractures, smoking and alcohol consumption, etc.*”, maintains **doctor Valdés**. Avoiding falls in postmenopausal women by adopting precautionary measures and including healthy lifestyle habits are other measures that have proven to be effective in delaying the appearance of the disease and the risk of fractures, adds the doctor.

The patient’s clinical history and monitoring of bone mineral density evolution are essential measures as “*if bone loss progresses rapidly, speeding up the appearance of a fracture,*

*immediate treatment should be established to avoid further fractures that draw the woman into a state of dependency ”, advises **doctor Valdés.***

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