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EPAR summary for the public

Fablyn

lasofoxifene

This is a summary of the European public assessment report (EPAR) for Fablyn. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Fablyn.

What is Fablyn?

Fablyn is a medicine that contains the active substance lasofoxifene. It is available as tablets (500 micrograms).

What is Fablyn used for?

Fablyn is used for the treatment of osteoporosis (a disease that makes bones fragile) in postmenopausal women (women who have been through the menopause). It is used in women who are at risk of fracture (broken bones). Fablyn has been shown to reduce fractures in the spine and elsewhere in the body, but not in the hip.

When deciding whether to prescribe Fablyn or other treatments, doctors should consider whether the patient has any symptoms of the menopause, and the possible effects of treatment on the womb, the breast, and the heart and blood vessels.

The medicine can only be obtained with a prescription.

How is Fablyn used?

The recommended dose of Fablyn is one tablet once a day. It can be taken at any time of day. Patients may also receive calcium and vitamin D supplements if they do not get enough from their diet. Fablyn is intended for long-term use.

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Fablyn should be used with caution in women with severe liver or kidney problems.

How does Fablyn work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and more likely to break (fracture). Osteoporosis is more common in women after the menopause, when the levels of the female hormone oestrogen fall: oestrogen slows down bone breakdown and makes the bones less likely to fracture.

The active substance in Fablyn, lasofoxifene, is a selective oestrogen receptor modulator (SERM). Lasofoxifene acts as an 'agonist' of the oestrogen receptor (a substance that stimulates the receptor for oestrogen) in some tissues in the body. Lasofoxifene has the same effect as oestrogen in the bone.

How has Fablyn been studied?

The effects of Fablyn were first tested in experimental models before being studied in humans.

Two doses of Fablyn (250 and 500 micrograms once a day) have been compared with placebo (a dummy treatment) in one main study involving almost 9,000 postmenopausal women with osteoporosis aged 60 to 80 years. The main measure of effectiveness was the number of women who had a new fracture in the spine as seen on X-rays. The study also looked at existing spine fractures that got worse, new fractures in other parts of the body and the density of bones throughout the body.

What benefit has Fablyn shown during the studies?

Fablyn was more effective than placebo at reducing the number of new fractures. Over five years, 6% of the women taking Fablyn 500 micrograms had a new spine fracture (155 out of 2,748), compared with 9% of those taking placebo (255 out of 2,744). Also, results with the 250-microgram dose were pointing to 500 micrograms being more effective. Fewer women taking the higher dose had a fracture outside the spine and there were greater increases in bone density. Fablyn did not reduce the number of hip fractures to a level that would be relevant for patients.

What is the risk associated with Fablyn?

The most common side effect with Fablyn (seen in more than 1 patient in 10) is muscle cramps. For the full list of all side effects reported with Fablyn, see the package leaflet.

Fablyn must not be used in people who are hypersensitive (allergic) to lasofoxifene or any of the other ingredients. It must not be used in patients who have had problems with venous thromboembolism including deep vein thrombosis (DVT), pulmonary embolism (a blood clot in the lungs) and retinal vein thrombosis (a blood clot at the back of the eye). It must not be used in women with unexplained bleeding from the womb. Fablyn is only for use in women who have been through the menopause, so it must not be used in women who could become pregnant, or women who are pregnant or breast-feeding.

Why has Fablyn been approved?

The CHMP decided that Fablyn's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of Fablyn?

The company that makes Fablyn will make sure that an educational programme is available in all Member States for all healthcare workers who will prescribe Fablyn or order pelvic ultrasound scans for women taking the medicine. The programme will include information about the risk of venous thromboembolism, changes in the womb that may occur when taking the medicine, and the need to investigate unexplained bleeding from the womb.

Other information about Fablyn

The European Commission granted a marketing authorisation valid throughout the European Union for Fablyn on 24 February 2009.

The full EPAR for Fablyn can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Fablyn, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2012.