30 May 2013
EMA/CHMP/314586/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Atosiban SUN

atosiban

On 30 May 2013 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Atosiban SUN intended for the delay imminent pre-term birth in pregnant adult women.

The applicant for this medicinal product is Sun Pharmaceutical Industries Europe BV. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Atosiban SUN is atosiban, an Other gynecologicals (G02CX01). In human pre-term labour, atosiban at the recommended dosage antagonises uterine contractions and induces uterine quiescence. The onset of uterus relaxation following atosiban is rapid, uterine contractions being significantly reduced within 10 minutes to achieve stable uterine quiescence

Atosiban SUN is a generic of Tractocile, which has been authorised in the EU since 20 January 2000. Studies have demonstrated the satisfactory quality of Atosiban SUN. Atosiban SUN is administered intravenously and is 100% bioavailable; therefore, a bioequivalence study versus the reference product Tractocile was not required. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Atosiban SUN will be implemented as part of the marketing authorisation.

The approved indication is: to delay imminent pre-term birth in pregnant adult women with:

- regular uterine contractions of at least 30 seconds duration at a rate of ≥ 4 per 30 minutes
- a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of ≥ 50%
- a gestational age from 24 until 33 completed weeks
- a normal foetal heart rate

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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It is proposed that the treatment with Atosiban SUN should be initiated and maintained by a physician experienced in the treatment of pre-term labour.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Atosiban SUN and therefore recommends the granting of the marketing authorisation.