ינואר 2024

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת איי.אל.מדי-מרקט בע"מ מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

ATOSIBAN PHARMIDEA
אטוסיבן פארמאידאה

חומר פעיל: ATOSIBAN (AS ACETATE) 7.5 MG / ML

צורת מינון: SOLUTION FOR INJECTION / CONCENTRATE FOR SOLUTION FOR INFUSION

עדכונים בעלון לרופא

<u>התוויה כפי שאושרה בתעודת הרישום:</u>

Atosiban is indicated to delay imminent pre-term birth in pregnant women with:
- regular uterine contractions of at least 30 seconds duration at a rate of 4 or more per 30 minutes
- a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of 50 % or more - age: 18 years and above - a gestational age from 24 until 33 completed weeks - a normal foetal heart rate.

ברצוננו להודיע שהעלון לרופא עודכן. בהודעה זו כלולים העדכונים המהותיים בלבד. החמרות מסומנות בצהוב, תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת בקו חוצה.

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1. NAME OF THE MEDICINAL PRODUCT

ATOSIBAN PHARMIDEA

~~Solution for injection or concentrate for solution for infusion.~~

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4. CLINICAL PARTICULARS

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4.2 Posology and method of administration

<u>Posology</u>

Treatment with Atosiban Pharmidea should be initiated and maintained by a physician experienced in the treatment of pre-term labour. Atosiban Pharmidea is administered intravenously in three successive stages: an initial bolus dose (6.75 mg), performed with Atosiban Pharmidea 6.75 mg/0.9ml solution for injection, immediately followed by a continuous high dose infusion (loading infusion 300 µg/min) of Atosiban Pharmidea 37.5 mg/5 ml concentrate for solution for infusion during three hours, followed by a lower dose of Atosiban Pharmidea 37.5 mg/5 ml concentrate for solution for infusion (subsequent infusion 100 µg/min) up to 45 hours. The duration of the treatment should not exceed 48 hours. The total dose given during a full course of Atosiban Pharmidea therapy should preferably not exceed 330<u>.75</u> mg of the active substance.

The following table shows the full posology of the bolus injection followed by the infusion:

Step	Regimen	~~Injection~~/infusion rate	Atosiban Pharmidea dose
1	0.9 ml intravenous bolus injections given over 1 minute	Not applicable ~~Over 1 minute~~	6.75 mg
2	3 hours intravenous loading infusion	24 ml/hour (300 µg/min)	54 mg
3	Up to 45 hours subsequent intravenous infusion	8 ml/hour (100 µg/min)	Up to 270 mg

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Method of administration

For instructions on preparation of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Atosiban Pharmidea ~~should~~ must not be used in the following conditions:

- Gestational age below 24 or over 33 completed weeks
- Premature rupture of the membranes >30 weeks of gestation
- Abnormal foetal heart rate
- Antepartum uterine haemorrhage requiring immediate delivery
- Eclampsia and severe pre-eclampsia requiring delivery
- Intrauterine foetal death
- Suspected intrauterine infection
- Placenta praevia
- Abruptio placenta
- Any other conditions of the mother or foetus, in which continuation of pregnancy is hazardous
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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4.6 Fertility, pregnancy and lactation

Atosiban should only be used when pre-term labour has been diagnosed between 24 and 33 completed weeks of gestation. If during pregnancy the woman is already breast-feeding an earlier child, then breast-feeding should be discontinued during treatment with Atosiban Pharmidea, since the release of oxytocin during breast-feeding may augment uterine contractility, and may counteract the effect of tocolytic therapy.

In atosiban clinical trials, no effects were observed on lactation. Small amounts of atosiban have been shown to pass from plasma into the breast milk of breastfeeding ~~lactating~~ women.

Embryo-foetal toxicity studies have not shown toxic effects of atosiban. No studies were performed that covered fertility and early embryonic development (see section 5.3).

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5.2 Pharmacokinetic properties

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There is no experience with atosiban treatment in patients with impaired function of the liver or kidneys. Renal impairment is not likely to warrant a dose adjustment, since only a small extent of atosiban is excreted in the urine. In patients with impaired hepatic function, atosiban should be used with caution (see sections 4.2 and 4.4).

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6. PHARMACEUTICAL PARTICULARS

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6.2 Incompatibilities

Atosiban PharmIdea 6.75 mg/0.9 ml solution for injection:

In the absence of compatibility studies, this medicinal product ~~should~~ must not be mixed with other medicinal products.

Atosiban PharmIdea 37.5 mg/5 ml concentrate for solution for infusion:

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6 .

6.3 Shelf life
The expiry date of the product is indicated on the packaging materials.
Once the vial has been opened, the product must be used immediately.
Atosiban PharmIdea 37.5mg/5ml concentrate for solution for infusion after dilution:
Chemical and physical in use stability has been demonstrated for 24 hours at 20-25°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C unless dilution has taken place in controlled and validated aseptic conditions.
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6.6 Instructions for use and handling
The vials should be inspected visually for particulate matter and discoloration prior to administration.

Preparation of the initial intravenous injection:
Withdraw 0.9 ml of a 0.9 ml labelled vial of Atosiban Pharmidea 6.75mg/0.9ml, solution for injection and administer slowly as an intravenous bolus dose over one minute, under adequate medical supervision in an obstetric unit.
The Atosiban Pharmidea 6.75mg/0.9ml, solution for injection vial should be used immediately.
In the absence of incompatibility studies, this medicinal product should not be mixed with other medicinal products (see section "Incompatibilities").
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