

CUSTOMER NOTICE

14th July 2015

Subject: Atosiban IV - Launch & Packaging Change

Bowmed Ibisqus Limited will begin distribution of the following product, during July 2015, on behalf of the Marketing Authorisation (MA) Holder, Ibigen Srl:

- Atosiban 6.75mg/0.9ml Solution for injection (PL 31745/0033)
- Atosiban 37.5mg/5ml Concentrate for solution for infusion (PL 31745/0034)

In order to provide product in a timely manner to our NHS customers it has been necessary for Bowmed Ibisqus to gain Medicines and Healthcare Products Regulatory Agency (MHRA) approval for a batch specific variation for one batch of each product. The MHRA is allowing distribution of batch **B-301, Expiry February 2017** without the changes detailed below to the labelling and PIL.

The MHRA has requested changes to the approved European PIL and labelling and all subsequent batches will be manufactured to include the following additional or revised text.

- Labelling (37.5mg/5ml strength only)

- Addition of "Dilute before use" on the main face of the carton
- Change from "For IV use" to "For IV use after dilution" on the vial label

- PIL (both strengths)

- Removal of an introductory statement in the dosage information
- Amendment to the 'pregnancy' section to include: 'Pregnancy, breast-feeding and fertility'
- You should only be given this medicine if you are between 24 and 33 weeks of pregnancy. If this does not apply to you, please speak to your doctor. If you are still breast feeding a child from an earlier pregnancy, you should stop during your treatment with Atosiban, as breastfeeding may stimulate uterine contractions.'

In addition, please note that the batch number of B-301 has been applied by the manufacturer to both the Atosiban 6.75mg/0.9ml Solution for injection and the Atosiban 37.5mg/5ml Concentrate for solution for infusion. All future batches will have a batch number specific to each product concentration.

Should you need any further information or assistance in this matter please contact our medical information department on 01483 212151 or email via medinfo@bowmed.com