tricumed

tricumed Medizintechnik GmbH Postfach 6109 24122 Kiel Germany

Urgent Safety Information

Possible increased flow volume of the implantable infusion pump Lenus pro® in connection with the substance Remodulin after several years of use

Article-No.	215 V 1000 200 WA
	215 V 1300 200 WA
	215 V 1300 200 WB
	215 V 2000 200 WA
	215 V 2000 400 WA
	215 V 3000 600 WA

Description of the problem

26.11.2013

In the course of the market observation of more than 150 implanted infusion pumps of the type Lenus pro it was found that for individual patients the progress of the Remodulin therapy an increased flowrate of more than 10 %, i.e. higher than the manufacturer's limit for deviations, was discovered.

The isolated observed incidents of increased flow volume concern infusion pumps which conveyed the drug Remodulin for longer periods of time (2 to 4 years). The only possible reason for the increased flow is an increase in the canal diameter within the chip capillary.

This would mean that the drug Remodulin would cauterise the glass surface within the canal. A very unlikely incident, but obviously one that cannot be completely ruled out: The glass capillaries are made of glass which is suitable for medical applications and absolutely inert.

The drug Remodulin is filled, stored and sold in glass bottles. To achieve clarity in the question to what extent the drug Remodulin really does increase the canal of the glass capillary, i.e. remove material from the glass capillary's surface, Tricumed Medizintechnik started examinations on an explanted infusion pump's chip capillary, which had conveyed Remodulin for about 4 years and finally showed an increase in the flowrate of more than 10 %. As a result of the examination it was found that the explanted pump's glass capillary showed slightly enlarged canal geometry.

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Introduced measures and clinical effects on the patient

- The company OMT GmbH & Co KG is the exclusive sales partner for this long-term implant. As a first corrective action together with the sales partner the recording and analysis of the refill data was introduced. This requires that the treating doctors provide the company Tricumed Medizintechnik GmbH with the refill data.
  All recorded data are collected in a data file and analysed. If a flowrate exceeds the introduced flowrate deviation limit (± 10%) then this information is directly given to the responsible doctor, The doctor then initiates, for example via drug concentration changes, a reduction of the drug dosage. This measure therefore leads to a shortened refill cycle at unchanged therapy.

- The second corrective action is introduced by the new development of a chip capillary with a more resistent glass. This correction of the glass chip requires a development and test expenditure of about 7 months and is expected to be concluded in June 2014.

- Risks for present therapy patients: The isolatedly occurred increase of the flowrate runs contiuously, slowly increasing over a period of time of several years, so there is no danger of an overdose for patients. We have no knowledge of a respective patient impairment A danger for the patient could be that the pumps is empty earlier than planned and the patient could experience an undersupply. To ensure a safe therapy the pump's drainage must be definitely be avoided. The corrective measures introduced ensure that the patients receive sufficient therapy.

- Risks in further use of the Lenus pro: As alternative therapy forms (for example extern catheters or port systems) show a considerably higher therapy risk in the form of increased infection rates and larger technical failure rates of external pumps, patient care can be safely continued subject to the introduced measures (avoidance of pump drainage).

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Distribution of the information described in this document

Please ensure for your facility that all users of the above mentioned products as well as other persons who need to be informed are aware of this urgent safety information. If you have passed on the above mentioned products to a third party, please pass on a copy of this information or inform the contact person mentioned underneath.

Please do keep this information at least until the measure will be completed.

The German Federal Institute for Drugs and Medical Devices ("Bundesinstitut für Arzneimittel und Medizinprodukte BfArM") has received a copy of this urgent safety information.

We regret the inconveniences which may possibly occur for you or your patients through this.

Contact person

Should you have any questions concerning the safety information described above, please contact the safety representative for medical products who is available under the following telephone number: **+49 431 70 990 34 (Mo – Fr. 06:00 – 15 :00)** or by fax under **+49 431 70 990 99**

Thank you very much for your assistance.

With best regards

Managing Director

Karl-Heinz Otto

Safety Representative for Medical Products

Marc Bülow

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