GROUPE PANPHARMA

ROTEXMEDICA

Gesundheit für alle!

ROTEXMEDICA GMBH · ARZNEIMITTELWERK
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TELEFON-DURCHWAHL: - 04154 862-0
UNSER ZEICHEN os./sch.
DATUM 07.03.2008

Unerwünschte Arzneimittelwirkungen bei Heparin-Rotexmedica Injektionslösung (Wirkstoff Heparin-Natrium)

Sehr geehrte Frau Apothekerin, sehr geehrter Herr Apotheker,
sehr geehrte Frau Doktor, sehr geehrter Herr Doktor,

In Ergänzung zu unserem Schreiben vom 05.03.2008 wird in Abstimmung mit dem Landesamt für soziale Dienste des Landes Schleswig-Holstein der Rückruf des oben genannten Produkts um weitere Chargen erweitert. Auf Grund der eingesetzten Rohstoffchargen kann nicht ausgeschlossen werden, dass die daraus hergestellten Fertigarzneimittel die im vorangegangenen Schreiben erwähnten unerwünschten Arzneimittelwirkungen (anaphylaktische Reaktionen mit Blutdruckabfall, zum Teil mit Koagelbildung im Blutschlauchsystem) auslösen können.
Zusätzlich zu den Chargen 70448, 70587 und 70699 (Rückruf erfolgte bereits am 05.03.2008) rufen wir hiermit aus Gründen äußerster Vorsicht folgende Chargen in allen Packungsgrößen zurück:

70030, 70056, 70067, 70097, 70099, 70100, 70136, 70137, 70276, 70279, 70449, 70512

Wir bitten um Rücksendung betroffener Packungen zur Verrechnung an Rotexmedica GmbH Arzneimittelwerk, Bunsenstraße 4 in 22946 Trittau.

Für Rückfragen stehen wir unter der Telefonnummer 04154 862-0 zur Verfügung.

Mit freundlichen Grüßen
ROTEXMEDICA GMBH Arzneimittelwerk

Patrick Lever
Geschäftsführung

Dr. Michael Nguyen
Stufenplanbeauftragter

20.000 03/07

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

Meldende Stelle

Landesamt für soziale Dienste Schleswig-Holstein, Abt. Gesundheitsschutz
State Social Services Agency of Land Schleswig-Holstein, Department of Healthcare
Adolf-Westphal-Straße 4
D-24143 Kiel

1. To / Empfänger:		FAX
☒	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-3515
☐	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	01888/412-2303
☐	Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI)	06103/77-1234
☒	Oberste Landesgesundheitsbehörde (Ministerium für Soziales, Gesundheit, Familie, Jugend und Senioren of Land Schleswig-Holstein)	0431/988-5416

2. Product Recall Class of Defect: I (circle one)	3. Counterfeit / Fraud (specify)* ---
4. Product: Heparin-Rotexmedica® solution for injection	5. Marketing Authorisation Number: * For use in humans/animals (delete as required) **6391377.00.00**
6. Brand/Trade Name: Heparin-Rotexmedica®	7. INN or Generic Name: Heparin-Natrium
8. Dosage Form: solution for injection	9. Strength: 5.000 I.E./ml
10. Batch/Lot Number: 70067, 70099, 70100, 70449, 70512	11. Expiry Date: 05/2010, 05/2011, 05/2011, 04/2012, 06/2012
12. Pack size and Presentation: all sizes	13. Date Manufactured: * 11.07.07, 14.06.07, 14.06.07, 25.05.07, 11.07.07
14. Marketing Authorisation Holder: * Rotexmedica GmbH Arzneimittelwerk, Bunsenstraße 4, D-22946 Trittau	

15. Manufacturer†:	16. Recalling Firm (if different):
Rotexmedica GmbH Arzneimittelwerk Bunsenstraße 4 D-22946 Trittau Contact Person: Dr. Michael Nguyen Telephone: +49 (0)4154-862161	Rotexmedica GmbH Arzneimittelwerk Bunsenstraße 4 D-22946 Trittau Contact Person: Dr. Michael Nguyen Telephone: +49 (0)4154-862161

17. Recall Number Assigned (if available) ---

18. Details of Defect/Reason for Recall:

In addition to our Rapid Alert Notification dated 05.03.2008 and our follow-up report dated 07.03.2008 we inform you that five further medicinal product batches (70067, 70099, 70100, 70449, 70512) of Rotexmedica GmbH have been identified to also contain the API batch 447012302M, manufactured by Changzhou Quianhong Bio Pharma Co. Ltd., China.

The connection to the quality of API heparin-natrium is still unclear.

For reasons of precaution these batches have also to be recalled.

19. Information on distribution including exports (type of customer, e.g. hospitals): *

70067: Feparvi, Panpharma;
70099, 70100: Feparvi;
70449: Germany;
70512: Germany.

20. Action taken by Issuing Authority:

Order of recall

21. Proposed Action:

The German authorities are requested to investigate the source of the API heparin at the marketing authorization holders.

Hospital pharmacies should withdraw the respective batches from their hospitals.

22. From (Issuing Authority):	23. Contact Person:
Landesamt für soziale Dienste Schleswig-Holstein, Abt. Gesundheitsschutz State Social Services Agency of Land Schleswig-Holstein, Department of Healthcare Adolf-Westphal-Straße 4 D-24143 Kiel	Silke Frick-Salzwedel Telephone: +49 (0)431 988-5656

24. Signed:	25. Date: 10.03.2008	26. Time: * 18.10 h

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has released the batch in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

Meldende Stelle

Landesamt für soziale Dienste Schleswig-Holstein, Abt. Gesundheitsschutz
State Social Services Agency of Land Schleswig-Holstein, Department of Healthcare
Adolf-Westphal-Straße 4
D-24143 Kiel

1. To / Empfänger:		FAX
☒	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-3515
☐	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	01888/412-2303
☐	Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI)	06103/77-1234
☒	Oberste Landesgesundheitsbehörde (Ministerium für Soziales, Gesundheit, Familie, Jugend und Senioren of Land Schleswig-Holstein)	0431/988-5416

2. Product Recall Class of Defect: I (circle one)	3. Counterfeit / Fraud (specify)* ---
4. Product: Heparin-Rotexmedica® solution for injection	5. Marketing Authorisation Number: * For use in humans/animals (delete as required) ---
6. Brand/Trade Name: Heparin-Rotexmedica®	7. INN or Generic Name: Heparin-Natrium
8. Dosage Form: solution for injection	9. Strength: 5.000 I.E./ml
10. Batch/Lot Number: 70701 80140	11. Expiry Date: 11/2011 01/2011 (Pakistan), 01/2013 (Vietnam)
12. Pack size and Presentation: all sizes	13. Date Manufactured: * 19.12.2007, 19.02.2008
14. Marketing Authorisation Holder: * Rotexmedica GmbH Arzneimittelwerk, Bunsenstraße 4, D-22946 Trittau	

15. Manufacturer†:	16. Recalling Firm (if different):
Rotexmedica GmbH Arzneimittelwerk Bunsenstraße 4 D-22946 Trittau Contact Person: Dr. Michael Nguyen Telephone: +49 (0)4154-862161	Rotexmedica GmbH Arzneimittelwerk Bunsenstraße 4 D-22946 Trittau Contact Person: Dr. Michael Nguyen Telephone: +49 (0)4154-862161

17. Recall Number Assigned (if available) ---

18. Details of Defect/Reason for Recall:

In addition to our Rapid Alert Notifications dated 05.03.2008 and 10.03.2008 we inform you that two further medicinal product batches (**70701, 80140**) of Rotexmedica GmbH contain *another* API batch of Yantai Dongcheng Biochemicals Co., Ltd., China, which is named **DHS070705**. Rotexmedica GmbH, who additionally to State Social Services Agency Schleswig-Holstein has performed laboratory tests, has noticed that this API batch DHS 070705 has shown the same 1H-NMR-result as API batch DHS 070603. DHS 070603 was used for manufacturing the concerned medicinal product batches 70699 and 70587 as we have informed you already in our first Rapid Alert Notification dated 05.03.2008. The 1H-NMR-result of both API batches is strongly different from the currently published FDA-standard.

A causal link between the adverse events respectively the notified clotting problems during dialysis and the stated deviation in 1H-NMR has not been established at the moment.

For reasons of precaution Rotexmedica GmbH has decided to recall the above mentioned medicinal product batches.

19. Information on distribution including exports (type of customer, e.g. hospitals): *

Only export !
Rotexmedica GmbH has already contacted the following firms:
70701: Laboratorios Feparvi Ltda., Calle 70 No. 4-50, Santafe de Bogota, Columbia
80140: Haji Medicine Co., B/327, Iqbal Road, Rawalpindi, Pakistan (Imports, Distributions)
80140: CPC NO.1, KM 6 GIAI PHONG STREET, DONG DA-HANOI, Vietnam (Central Pharmaceutical Company)

20. Action taken by Issuing Authority:

Investigations, e.g. laboratory testing, to find the reason for the adverse events.

21. Proposed Action:

The German Authorities should inspect whether there are other companies in Germany which have received the also suspected **API batch DHS070705** from Yantai Dongcheng Biochemicals Co., Ltd., China.

22. From (Issuing Authority): Landesamt für soziale Dienste Schleswig-Holstein, Abt. Gesundheitsschutz State Social Services Agency of Land Schleswig-Holstein, Department of Healthcare Adolf-Westphal-Straße 4 D-24143 Kiel		23. Contact Person: Silke Frick-Salzwedel Telephone: +49 (0)431 988-5656
24. Signed:	25. Date: 14.03.2008	26. Time: * 9.00 h

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has released the batch in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.