BAUERFEIND

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Urgent Safety Information

Recall

concerning

VenoTrain micro, VenoTrain soft, VenoTrain ulcertec,

and VenoTrain cocoon compression stockings because of incorrect packaging labels

March 31, 2022

Sender:

Ines Exner
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Recipient:

Medical retailers and pharmacies that have ordered VenoTrain micro, VenoTrain soft, VenoTrain ulcertec, or VenoTrain cocoon medical compression stockings from Bauerfeind AG during the specified period.

Identification of affected medical products:

VenoTrain micro, VenoTrain soft, VenoTrain ulcertec, VenoTrain cocoon medical compression stockings: individual products that were packaged and delivered between February 17 and March 21, 2022. A list with the numbers of the affected products is enclosed.

Description of the issue including the identified cause:

Issue: On the packaging labels of some VenoTrain micro, VenoTrain soft, VenoTrain ulcertec, and VenoTrain cocoon compression stockings that were packaged and delivered between February 17 and March 21, 2022, the “Use by” symbol (hour glass) is missing, including a specification of the date, i.e. the expiration date.
Medical compression stockings are medical products with a limited shelf life. If the date specification is missing, medical retailers and pharmacists cannot tell up to which date the products can be given to patients without posing a risk. That is why the products without date specification have to be recalled.

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Correct label:

Faulty label:

Reason: A system error occurred during label reprint, preventing the expiration date being printed on the label. The error was immediately corrected after its detection, and labeling strictly checked using additional measures.

Risks for patients: The products themselves are not faulty; they are safe. Patients who have received affected products are not at risk. Medical compression stockings are intended for immediate use after they have been issued. The average wearing duration is six to twelve months.

What action does the recipient need to take?

All affected medical retailers and pharmacies will receive "Urgent Safety Information" from Bauerfeind AG and are asked to return the affected products. At the same time, the relevant sales staff will get in touch with the customers in question. Returns are handled in accordance with Bauerfeind AG's Returns Policy which allows a credit note or replacement. Additionally, medical retailers can order new goods straight away.
Schedule:

- From March 31 to April 14, 2022, all affected medical retailers and pharmacies will be notified: in writing via "Urgent Safety Information" as well as by the relevant sales staff.
- All products should be returned by April 30, 2022.
- On May 17, 2022, the BfArM (Federal Institute for Drugs and Medical Devices) will receive the closing report.

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