

**DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY!**

<b>Rapid Alert Notification of a Medicinal Product Falsification</b> <input type="checkbox"/> <b>ASSUMED</b> <input type="checkbox"/> <b>REASONABLY SUSPECTED</b> <input checked="" type="checkbox"/> <b>VERIFIED</b>	
Regierungspräsidium Darmstadt, 64278 Darmstadt	
1. To/Empfänger:	FAX
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	
<input checked="" type="checkbox"/>	
2. Classification (not mandatory)	3. <b>Falsification</b>
4. Product: <b>Pascorbin</b>	5. Marketing Authorisation Number: * <b>6727989.00.00 (authorization in Germany)</b> <b>For use in humans</b>
6. Brand/Trade Name: <b>Pascorbin</b>	7. INN or Generic Name: <b>not applicable</b>
8. Dosage Form: <b>solution for injection</b>	9. Strength: <b>150 mg ascorbic acid per ml</b>
10. Batch number (and bulk, if different): <b>0203</b> <b>(as indicated on the label of the falsified Pascorbin)</b>	11. Expiry Date: <b>03/2024</b> <b>(as indicated on the label of the falsified Pascorbin)</b>
12. Pack size and Presentation: <b>vials with 50 ml solution for injection</b> <b>(corresponding to 7.5 g ascorbic acid per 50 ml)</b>	13. Date Manufactured: * <b>Remains unclear because the present falsified product has not been manufactured by Pascoe pharmazeutische Präparate GmbH.</b>
14. Marketing Authorisation Holder: <b>Of the original medicinal product: Pascoe pharmazeutische Präparate GmbH, Schiffenberger Weg 55, 35394 Giessen, Germany</b>	
15. Manufacturer†: <b>Remains unclear because the present falsified product has not been manufactured by Pascoe pharmazeutische Präparate GmbH.</b> Contact Person:  Telephone:	16. Recalling Firm
17. Rapid Alert Notification Reference Number: <b>DE_HE_2022-416</b>	

18. Details:

On 2022-October-26 Pascoe pharmazeutische Präparate GmbH received an email from a physician from Turkey who asked for medical advice due to a serious adverse drug reaction that occurred after application of Pascorbin. Pictures of the used Pascorbin bottles were attached to the email. The pictures strongly indicate a product falsification of Pascorbin due to the following criteria:

- The combination of printed batch number (0203) and expiry date (03/2024) on the bottle label does not match to the production data of pharmazeutische Präparate GmbH. Pascoe has never produced this combination for Pascorbin.
- The floral pattern in the background of the label text does not match the appearance of the original label. In comparison to the original label, the floral pattern on the bottle from the Turkish reporter contains more floral ornaments that are arranged much more closely.
- The arrangement of the text on the bottle label is different. Words hyphenated on the original label (Natriumhydrogencarbo-nat and Injektionsfla-sche) have not been hyphenated on the label of the reporter. Partly, the distance between two words or punctuations is bigger compared to the original label. Furthermore, there are typing errors ("Nich" instead of "Nicht"; "unzugänglich" instead of "unzugänglich") and dashes are used twice instead of dots.
- Overall, the intensity of the font colour differs from the usual appearance of the original Pascorbin label.

So far, it is completely unclear which solution/ substance was contained in the infusion bottle and was infused to the affected patient.

Further details including the pictures are documented in the attached medical case assessment of Pascoe pharmazeutische Präparate GmbH.

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

To date, Pascoe pharmazeutische Präparate GmbH do not have an official marketing authorization for Pascorbin in Turkey. Therefore, the product is not distributed by Pascoe in Turkey.

According to the reporting physician from Turkey, the used Pascorbin was bought from a drug sales representative who said that his company would source Pascorbin from Germany (no further information available).

20. Action taken by Issuing Authority: FOR YOUR INFORMATION

21. Proposed Action: forwarding this notification to affected authorities

22.

23. Contact Person:

24.

25. Date: Nov. 16, 2022

26. Time: \*

\* 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 certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.

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## Medical assessment for pot. case no. TR-PASCOE-22093M1

On 2022-Oct-26, a female pediatrician from Turkey reported via email about a potential adverse drug reaction associated with **Pascorbin 7.5 g**:

In detail, she reported that a male colleague from her (also a physician) bought Pascorbin 7.5 g for himself in Turkey. About 20 minutes after the infusion, he developed **presyncope, low blood pressure, tachycardia, fever, chills and vomiting**.

The patient was treated (not further specified) and is recovering. At the date of reporting, he was feeling better but still not very well.

The following laboratory tests were done: hemoglobin low; leucocytes low; thrombocytes low; GOT (AST) increased, GPT (ALT) increased and GGT increased; bilirubin increased.

Further vital signs were: blood pressure 30 mmHg, heart rate >120, body temperature 40°C.

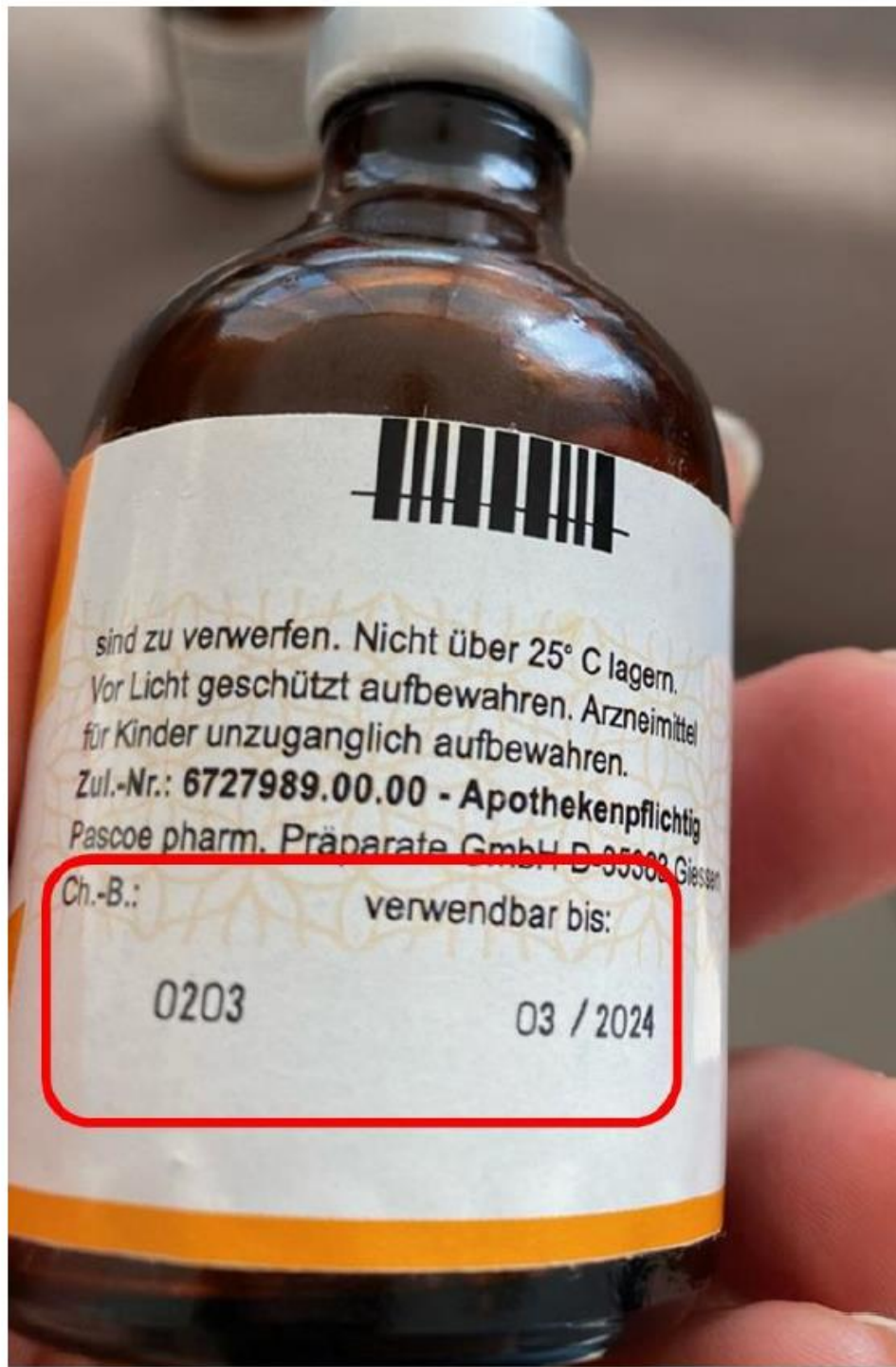
In addition, the pediatrician reported that there was no allergy, no rash, no scratchy throat, no angioedema. No concomitant medication or concomitant diseases were described.

Due to the case description, the case was classified as a **medically important condition (→ serious case)**. It remains unclear so far if the patient was hospitalized, but based on the described reactions, a medical treatment to avoid the further development of life-threatening conditions can obviously be assumed.

Importantly, pictures of the used Pascorbin bottles were provided by the reporter in her email. **Based on the pictures we have to assume a product counterfeit of Pascorbin 7.5 g** in this case due to the following criteria:



- The combination of printed batch number (0203) and expiry date (03/2024) on the bottle label does not match to our production data. We never produced this combination for Pascorbin.




- The floral pattern in the background of the text does not match the appearance of the original label. In comparison to the original label, the floral pattern on the bottle from the reporter contains more floral ornaments that are arranged much more closely.

Pictures from the reporter:



The original label of Pascorbin does look as follows:

**Wirkstoff: Ascorbinsäure**  
**150 mg pro ml Injektionslösung**  
**7,5 g Ascorbinsäure/50 ml**  
**Injektionslösung zur intravenösen Anwendung.**  
**Zus.: 1 Inj. fl. mit 50 ml Inj. lsg. enth.: Ascorbinsäure**  
**7,5 g (1 ml Inj. lsg. enth. 150 mg Ascorbinsäure).**  
**Sonst. Best. teile: Natriumhydrogencarbonat, Wasser**  
**für Injektionszwecke. Enthält Natriumhydrogencarbo-**  
**nat. Packungsbeilage beachten. 50 ml Injektionsfla-**  
**sche. **Hinw.:** Die konservierungsmittelfreie Inj. lsg.**  
**ist nur zur einmaligen Entnahme vorgesehen. Die**  
**Anwendung muss unmittelbar nach Anbruch der**  
**Injektionsflasche erfolgen. Nicht verbrauchte Reste**

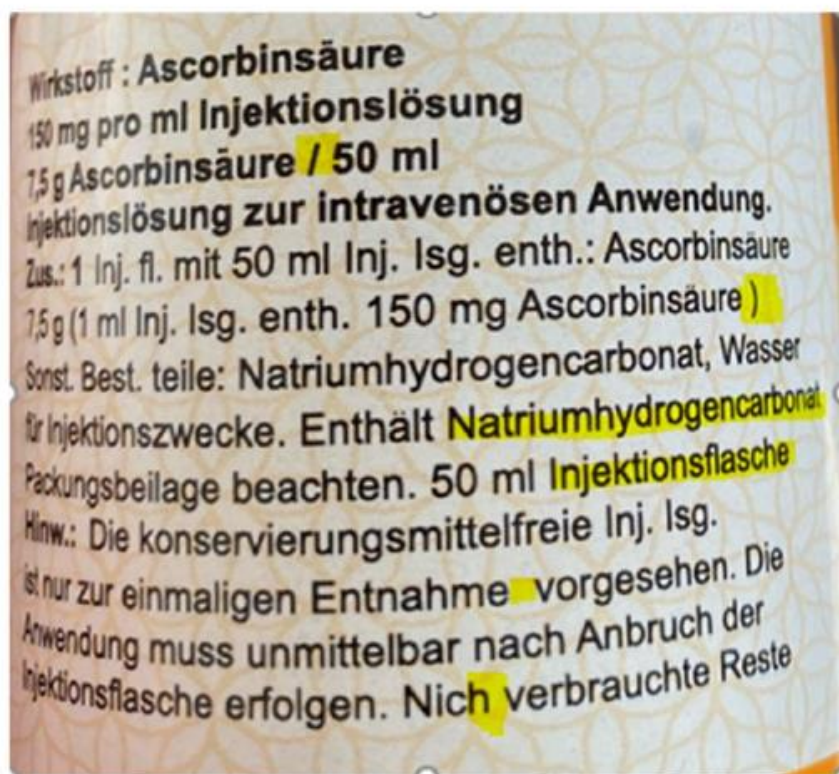


The original label features a clean design with an orange header containing the 'Pascoe' logo and 'Naturmedizin seit 1895'. Below this is a white section with the product name 'Pascorbin®' in bold black text. The bottom section is orange with a subtle, larger-scale floral pattern.



- The arrangement of the text on the bottle label is different. Words hyphenated on the original label (Natriumhydrogencarbo-nat and Injektionsflasche) have not been hyphenated on the label of the reporter. Partly, the distance between two words or punctuations is bigger compared to the original label. Furthermore, there are typing errors (“Nich” instead of “Nicht”; “unzugänglich” instead of “unzugänglich”) and dashes are used twice instead of dots.

Picture from the reporter:



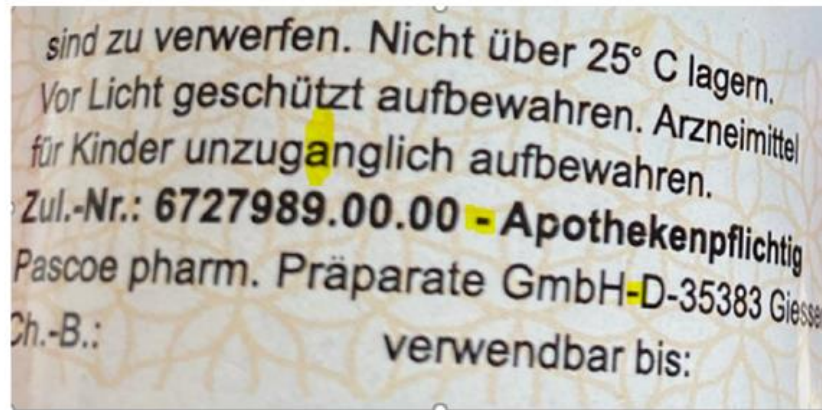
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Anwendung muss unmittelbar nach Anbruch der  
Injektionsflasche erfolgen. Nicht verbrauchte Reste





Picture from the reporter:



The original label of Pascorbin does look as follows:

sind zu verwerfen. Nicht über 25° C lagern.  
Vor Licht geschützt aufbewahren. Arzneimittel  
für Kinder unzugänglich aufbewahren.  
Zul.-Nr.: 6727989.00.00 · Apothekenpflichtig  
Pascoe pharm. Präparate GmbH·D-35383 Giessen  
Ch.-B.:                      verwendbar bis:

- Overall, the intensity of the font color differs from the usual appearance of the original Pascorbin label.

We do not have an official marketing authorization for Pascorbin 7.5 g in Turkey yet. An attempt is being made to gain more information about the possible source of the product counterfeit. The competent authority in Turkey will also be informed about this case.

**Due to the closed timely relationship of only 20 minutes between infusion and first onset of the described reactions, it can be assessed as probable (according to WHO-UMC) that the adverse reactions are due to the applied infusion.**

**However, the causal relationship is not assessable for our original product Pascorbin 7.5 g due to the fact that the used product is a counterfeit product. Because of this counterfeit, it is so far completely unclear which solution/substance was contained in the infusion bottle and was infused to the affected patient.**

According to the current SmPC of Pascorbin 7.5 g such or similar events like short-term circulatory disorders can occur. In the case of acute infections, reactions such as chills and a rise in temperature have been observed in very rare cases. Gastrointestinal disorders such as nausea/vomiting are also possible. So, presyncope, low blood

pressure, tachycardia, fever, chills and vomiting can in principle be assessed as listed and expected. However, so far there have only been rare cases of singular symptoms and hardly a combination presented here. Furthermore, the intensity of the symptoms is far from previously detected and therefore expected strength.

As mentioned above, since we do not know what exactly was inside the counterfeit Pascorbin bottle, it is not possible to attribute the side effects to our original Pascorbin 7.5 g.

**There is no change of the benefit-risk ratio for the original Pascorbin 7.5 g product.**

03.11. 2022, HMI