

**RAN-Formular (Rapid-Alert-Notification) zur Mitteilung über den RAS-Verteiler**

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

**Rapid Alert Notification of a Medicinal Product Falsification**

☐ **ASSUMED**      ☐ **REASONABLY SUSPECTED**      ☒ **VERIFIED**

Landesamt für soziale Dienste Schleswig-Holstein  
Abteilung Gesundheits- und Verbraucherschutz  
Dezernat 31 Arzneimittelüberwachung  
Gartenstraße 24  
24534 Neumünster  
Germany

1. To/Empfänger:		FAX
<input checked="" type="checkbox"/> Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)		0228-207-4636
<input type="checkbox"/> Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)		030-18444-30409
<input type="checkbox"/> Paul-Ehrlich-Institut/Bundesamt für Sera und Impfstoffe (PEI)		06103-77-1263
<input checked="" type="checkbox"/> Ministerium für Soziales, Gesundheit, Jugend, Familie und Senioren des Landes Schleswig-Holstein		
2. <i>Classification (not mandatory)</i>	3. Falsification (verified)	
4. Product: Ciclopoli gegen Nagelpilz ( <i>Ciclopoli against onychomycosis</i> )	5. Marketing Authorisation Number: * 63359.00.00 For use in humans	
6. Brand/Trade Name: Ciclopoli	7. INN or Generic Name: Ciclopirox	
8. Dosage Form: Medicated Nail Lacquer	9. Strength: 8% (80 mg / 1 g)	
10. Batch number (and bulk, if different): N/A (see 18.)	11. Expiry Date: N/A (see 18.)	
12. Pack size and Presentation: 1 x 6.6 ml	13. Date Manufactured: * N/A (see 18.)	
14. Marketing Authorisation Holder: Polichem S.A. 50, Val Fleuri 1526 Luxembourg LUXEMBOURG		
15. Manufacturer <sup>†</sup> and co-distributor in Germany: Almirall Hermal GmbH Scholtzstr. 3 21465 Reinbek GERMANY Contact Person: Dr. Marit Stieglitz Telephone: +49 40 72704 233	16. Recalling Firm	
17. Rapid Alert Notification Reference Number: not assigned		

<p>18. Details:</p> <p>The company got multiple complaints from customers that ordered the product from the webpage <a href="http://www.ciclopoli.net">www.ciclopoli.net</a>. A complaint sample was analysed. Multiple falsification characteristics were noticed, for example:</p> <ul style="list-style-type: none"> <li>- API Ciclopirox is not present.</li> <li>- Lacquer is not water soluble (original lacquer is water soluble).</li> <li>- Variable data is missing both on box and bottle.</li> <li>- As leaflet the German <i>Fachinformation</i> (summary of product characteristics) is in the box instead of the regular patient information.</li> <li>- Former packaging artworks are used showing the company logo "Taurus Pharma" that is not used anymore.</li> <li>- Further discrepancies were observed on the bottle label as well in shape of the cap and the bottle.</li> </ul> <p>The webpage <a href="http://www.ciclopoli.net">www.ciclopoli.net</a> seems to belong to the company 'Brand solutions Ltd.' and/or 'Brand solutions Trading', Bld. Aleksandar Pushkin 38, Office 6, Pavlovo 1618 Sofia, Bulgaria. Both Polichem S.A. and Almirall Hermal did not authorise any use of product information on the webpage. For 'brand solutions Trading' the address kv. BorovoBlk. 12, Entrance: B, Apt: 22, Sofia 1000, Bulgaria and the warehouse in Srebrostryi Industrial Area, Sofia, Bulgaria is also reported.</p> <p>Since variable data is missing on the falsified product and distribution is apparently outside the legal supply chain, a recall on pharmacy and wholesaler level is not reasonable.</p>		
<p>19. Information on distribution including exports (e. g. type of customer, e.g. hospitals):*</p> <p>The original product is distributed with the brand name <i>Ciclopoli</i> in the following countries: Germany, Switzerland, Israel, Russian Federation</p> <p>The original product is also distributed under different trade names in the following countries:</p> <p>Argentina, Australia, Austria, Belgium, Boliva, Bulgaria, Chile, Columbia, Cyprus, Czech Republic, Denmark, Ecuador, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Latvia, Lebanon, Lithuania, Mexico, New Zealand, Norway, Peru, Poland, Portugal, Romania, Russian Federation, Slovakia, South Korea, Spain, Sweden, Switzerland, Venezuela</p>		
<p>20. Action taken by Issuing Authority:</p> <p>Issuance of RAN</p>		
<p>21. Proposed Action:</p> <p>Information of the GMP and regulatory authorities in order to make aware of the falsification and to enable support of the law enforcement authorities.</p>		
<p>22. From (Issuing Authority):</p> <p>Landesamt für soziale Dienste Schleswig-Holstein mail to: post.arzneimittelueberwachung@lasd.landsh.de</p>		<p>23. Contact Person:</p> <p>Dr. Carsten Bode (Ext. 958) Kirsten Haarstrick (Ext. 916) Telephone: +49 4321 913-Ext.</p>
<p>24. Electronically signed in internal file</p>	<p>25. Date: 15<sup>th</sup> of January 2021</p>	<p>26. Time: *</p>

\* 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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