

### To whom it may concern

Aspirin Protect 100mg, 30 enteric coated tablets, Batch BT13J11, Expiry Date: 04.2025 (country make-up exclusively for Kosovo)

Falsified products have been identified in Kosovo, all marked with the same variable data, imitating the above-mentioned genuine Bayer Aspirin Protect 100 mg 30 Tablets packages, batch code BT13J11, Expiry date 04 2025. The packages were detected in the legal supply chain in a pharmacy.

Please find below a description of six differences between falsified and the original genuine product.

If any of the below-explained characteristics apply, it is a falsification.

Instructions to check whether the **outer packaging** is genuine:

1. Check the **Sticker** ("banderola") on the carton which is mandatory in Kosovo if its artwork and properties are deviating from the genuine one (as published by the authorities):



 Check if the separate parts of the Address of the Manufacturer (indicated on the longer small side of the carton) have a comma (",") at the end: Bayer Bitterfeld GmbH, OT Greppin, Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen, Gjermani/Nemacka

The genuine product has no commas in the address:

May 27, 2022

Bayer d.o.o. Bravničarjeva 13 1000 Ljubljana

Registrsko sodišče: Okrožno sodišče v Ljubljani Št. Registrskega vložka: 1/474/00

Board of Management: Werner Baumann, Chairman Sarena Lin Wolfgang Nickl Stefan Oelrich Rodrigo Santos Heiko Schipper

Chairman of the Supervisory Board: Norbert Winkeljohann

Registered Office: Leverkusen Local Court of Cologne HRB 48248 Original product



3. Check if the **Variable Data** printed on the smaller side of the carton are printed in white on black (The genuine product is printed in black on white – but consider also next no. 4!)

Falsified product



Original product



4. Check if the **Variable Data Font** printed on the smaller side of the carton are printed in black with serifs for the "11" in the batch code BT13J11

(The genuine product has no serifs such as "11".)
Falsified product
Original product





5. Check if the **Patient Information Leaflet** is just one page printed on both sides

(The genuine product contains a patient information leaflet with two pages connected on one side. Both pages are printed on both sides; in total 4 pages with Kosovo and Albanian text)





6. Check if the **Blister** is just marked with the batch code, such as "BT13J11"

(The genuine product indicates the track of the packaging line after the batch code e.g., "BT13J11 /2" while the number, such as "2" shown here, can vary.)

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## Falsified product



# Original product



If any of the above-explained characteristics apply, it is a falsification.

Please contact regional Bayer affiliate if further verification of product is needed on:

qa.slovenia@bayer.com

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Patient safety is Bayer's top priority. Drug counterfeiting is a serious problem worldwide and a criminal act, as it endangers the health and life of patients. Bayer has been actively fighting counterfeit medicines for a long time.

Further information can be found on the Internet at https://www.bayer.com/en/pharma/beware-of-counterfeits

Suspicious products can be reported here https://www.bayer.com/en/products/beware-of-counterfeits-contact

### Bayer assessment:

The counterfeit products which are subject of this letter have been identified within the legal supply chain but outside of Bayer's controlled supply chain.

Bayer in general cannot evaluate safety/efficacy for counterfeits outside of Bayer's controlled Supply Chain. Based on the available data, it is not possible to specify the potential risks of use of this product (no details regarding the composition of tablets regarding presence of contaminants, proportion of undetected/unknown active substance, other substances, etc.). In general, any falsification never has the same profile with respect to quality, efficacy and safety once compared with the authorized genuine product.

From the safety perspective, Bayer recommends **not** to use the counterfeit / falsification in the present case which is a product out of specifications. These products may contain an inappropriate dose of active substance (in lower or higher concentrations compared to the original product) or may even lack the declared active pharmaceutical ingredient, which will not achieve the adequate therapeutic effect for the approved indication(s) of the genuine product. Additionally, the counterfeits / falsifications may expose the users to unknown and harmful substances that may cause adverse effects and impair the user's health.