

**CÔNG TY TRÁCH NHIỆM HỮU HẠN
DKSH PHARMA VIỆT NAM**

**CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập – Tự do – Hạnh phúc**

Số: 01-Aug-2025
(V/v: Báo cáo thuốc giả Lexomil® 6mg
tại thị trường Việt Nam)

Bình Dương, ngày 28 tháng 8 năm 2025

Kính gửi: Sở Y Tế Tp. Hồ Chí Minh
Cục Quản Lý Dược
Trung Tâm Thông Tin Thuốc Quốc gia

CỤC QUẢN LÝ DƯỢC	
Đ	Số: 5304
É	Ngày: 05/9/2025
N	
Chuyển: <i>all</i>	

Công ty TNHH DKSH Pharma Việt Nam (sau đây gọi tắt là DKSH Pharma) xin gửi lời chào trân trọng đến Quý Cơ quan.

Hiện nay, DKSH Pharma Việt Nam là đơn vị nhập khẩu một số sản phẩm thuốc do Cheplapharm Arzneimittel GmbH (sau đây gọi tắt là CHEPLAPHARM) là chủ sở hữu, vào thị trường Việt Nam.

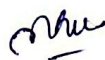
Vừa qua, CHEPLAPHARM nhận được thông tin là Phòng Cảnh sát Kinh tế - Đội 6, Phòng PC03, Công An Tp. Hồ Chí Minh tại Việt Nam đang thu giữ sản phẩm mang nhãn hiệu LEXOMIL® 6 mg dạng viên nén, số lô F3193F01, hạn dùng 12/2027 do CHEPLAPHARM là chủ sở hữu (theo số hồ sơ: 536/CSKT-D6).

Theo báo cáo điều tra từ CHEPLAPHARM, Sản phẩm thật LEXOMIL® 6mg, hoạt chất Bromazepan 6mg, dạng bào chế viên nén, qui cách đóng gói hộp 30 viên, số lô F3193F01, hạn dùng 12/2027, được sản xuất bởi và đóng gói tại Cenexi (Fontenay sous Bois 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois France) vào ngày 07/12/2022. Lô sản phẩm LEXOMIL® 6mg, số lô F3193F01 được xuất bán bởi CHEPLAPHARM, được phân phối tại thị trường Pháp, không được nhập khẩu vào Việt Nam bởi DKSH Pharma và cũng không được phân phối tại thị trường Việt Nam.

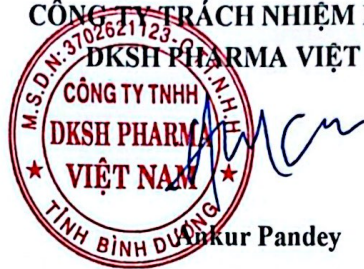
CHEPLAPHARM đã tiến hành so sánh, đối chiếu bao bì của mẫu sản phẩm thật và sản phẩm đang thu giữ, đồng thời xác nhận bằng văn bản rằng sản phẩm mang nhãn hiệu Lexomil® 6 mg, số lô F3193F01, hạn dùng 12/2027 đang thu giữ bởi Công an TP. Hồ Chí Minh là thuốc giả. (Xin vui lòng xem chi tiết báo cáo đính kèm).

Nhằm hỗ trợ CHEPLAPHARM trong việc báo cáo thuốc giả và để đảm bảo an toàn cho người sử dụng, DKSH Pharma xin trân trọng thông báo đến Quý Cơ Quan. Kính đề nghị Quý Cơ quan xem xét, đồng thời có hình thức thông tin rộng rãi đến cộng đồng nhằm ngăn chặn việc sử dụng thuốc giả.

Trân trọng kính chào./.



CÔNG TY TRÁCH NHIỆM HỮU HẠN
DKSH PHARMA VIỆT NAM



Dính kèm:

1. Thư yêu cầu báo cáo thuốc giả của CHEPLAPHARM gửi DKSH.
2. Báo cáo điều tra thuốc giả sản phẩm LEXOMIL® 6mg, số lô F3193F01 của CHEPLAPHARM.



CHEPLAPHARM Arzneimittel GmbH _ Ziegelhof 24 _ 17489 Greifswald _ Germany

DKSH SINGAPORE PTE. LTD.

24 Penjuru Road

#03-02

609128 Singapore

Greifswald, 08/20/2025

Submission of Falsification Report FAL-2025-031 to Vietnamese Authorities on Behalf of Cheplapharm

Dear Sir or Madam,

In connection with the current falsification case FAL-2025-031, we kindly request your support. Cheplapharm has prepared a comprehensive falsification report regarding this case. We ask you to submit this report directly to the Vietnamese authorities on behalf of Cheplapharm in a timely manner.

Given the importance of prompt and accurate reporting, we would appreciate receiving confirmation once the report has been submitted to the authorities.

Please do not hesitate to contact us should you require any further information or clarification.

We thank you in advance for your support and cooperation.

Yours sincerely,

Susanne Böhme

Signature Name: Susanne Böhme
Username: susanne.boehme@cheplapharm.com
Signing Time: Aug 20, 2025, 12:41:40:618 a.m. (UTC)
Signing Reason: I read and approve this document

box SIGN 19KJQXQ1-17V6586Z

Susanne Böhme
Qualified Person

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BANK DETAILS
Deutsche Bank _ IBAN: DE34 1307 0000 0227 3332 00 _ SWIFT-Code: DEUTDEBRXXX
All currencies

REGISTERING COURT
Stralsund _ HRB 5896



CHEPLAPHARM Arzneimittel GmbH _ Ziegelhof 24 _ 17489 Greifswald _ Germany

Greifswald, 20-Aug-25

TO WHOM IT MAY CONCERN

AUTHENTICITY REPORT

Confirmed Falsification of Lexomil® 6 mg tablets in Vietnam

CHEPLAPHARM Reference: FAL-2025-031

Dear Sir or Madam,

We, CHEPLAPHARM Arzneimittel GmbH (referred to as CHEPLAPHARM), hereby inform the competent authority of the interim investigation results concerning the confirmed falsification of Lexomil® 6 mg tablets in Vietnam.

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1. Reason for Investigation

On 31 July 2025, CHEPLAPHARM was contacted by the manufacturer Les Laboratoires Servier regarding a seizure conducted by the Ho Chi Minh City Police (Economic Police Department, Team 6, PC03 Department) in Vietnam on various products bearing the Servier logo (case reference number: 536/CSKT-D6). One of these products was Lexomil® 6 mg bar-shaped tablets in the French layout (150 units), with CHEPLAPHARM as the product owner. The concerned batch is F3193F01 with an expiry date of 12/2027. This report has been prepared to determine whether the Lexomil® 6 mg tablets seized by the police in Vietnam are genuine products of CHEPLAPHARM or if they are falsified.

2. Available Information for Investigation

For the technical investigations, CHEPLAPHARM received photos showing all sides of the secondary packaging, the top and one side of the primary packaging, and the tablets inside the Lexomil® 6 mg tablet container.

3. Lot Tracing for the Genuine Finished Product and Trending

Genuine LEXOMIL® 6 mg bar-shaped tablets, batch F3193F01 (exp. 12/2027), were manufactured and packaged at Cenexi (Fontenay sous Bois 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois France), on 07 December 2022. It was released by CHEPLAPHARM Arzneimittel GmbH and distributed to the French market by CHEPLAPHARM France. This batch was not distributed to Vietnam.

The batch number indicated on the primary packaging of the seized product is F3173, which corresponds to the primary packaged tablets of genuine Lexomil® 6 mg bar-shaped tablets, batch F3173F01. The expiry date of this batch is 09/2027. It was packaged and manufactured at Cenexi (Fontenay sous Bois 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois France), on 20 September 2022, released by CHEPLAPHARM Arzneimittel GmbH, and distributed to the French market by CHEPLAPHARM France. This batch was also not distributed to Vietnam.

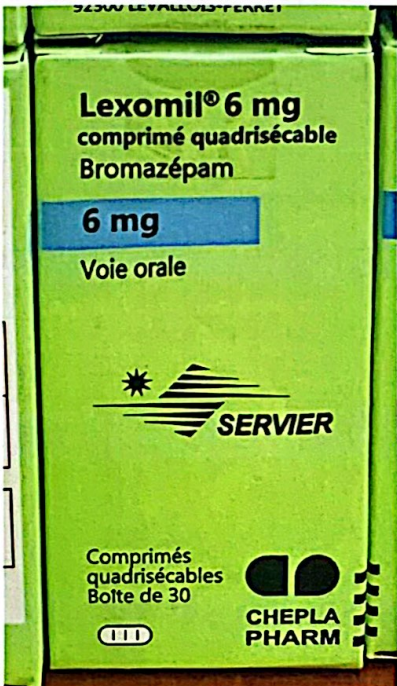
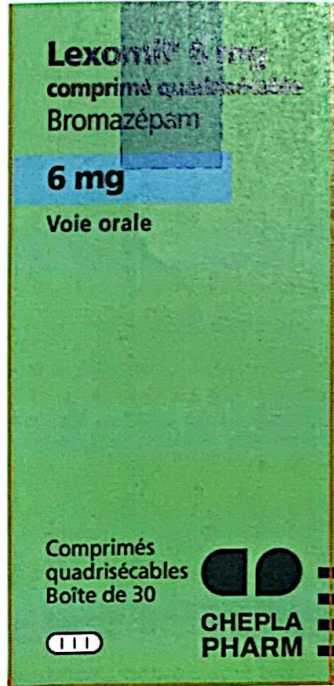
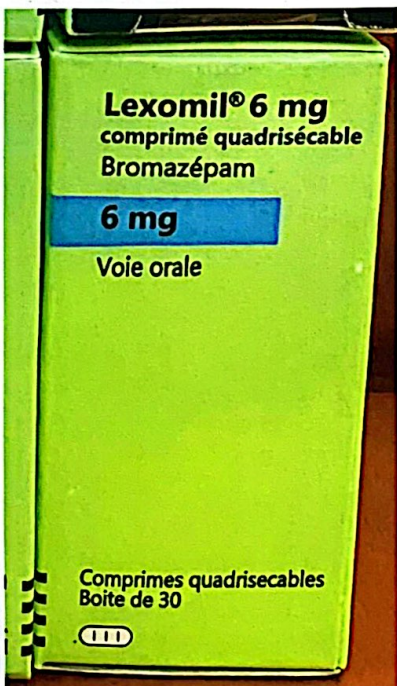
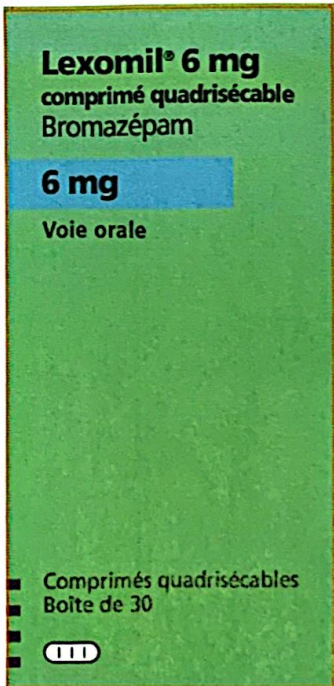
The trend by batch number showed that this is the only reported falsification with these batch numbers.

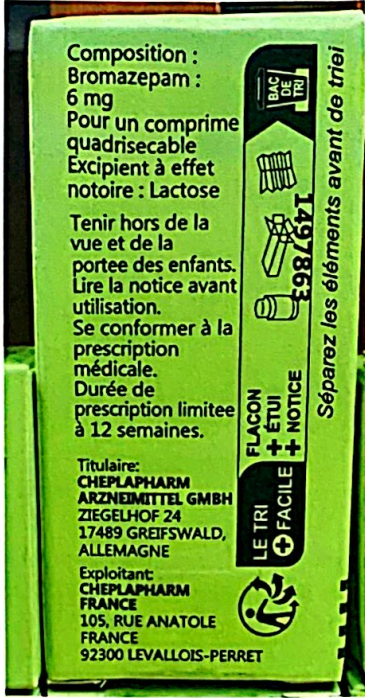
4. Packaging Material Investigation Summary

The Quality Assurance Department of CHEPLAPHARM examined the photos of the suspected falsification samples. These samples were compared to the approved artworks for the French market.

Falsification Sample	Genuine Product
Secondary Packaging	
 Lexomil® 6 mg comprimé quadrisécable Bromazépam 6 mg Voie orale Comprimés quadrisécables Boîte de 30 III	 Lexomil® 6 mg comprimé quadrisécable Bromazépam 6 mg Voie orale Comprimés quadrisécables Boîte de 30 III
 F3193F01 12.2027 RE545E91TTHXQA6 Lot/EXP/SN	 F3193F01 12.2027 P6KCUE21X078V17



Falsification Sample	Genuine Product
 Lexomil® 6 mg comprimé quadrisécable Bromazépam 6 mg Voie orale  SERVIER Comprimés quadrisécables Boîte de 30  CHEPLA PHARM	 Lexomil® 6 mg comprimé quadrisécable Bromazépam 6 mg Voie orale Comprimés quadrisécables Boîte de 30  CHEPLA PHARM
 Lexomil® 6 mg comprimé quadrisécable Bromazépam 6 mg Voie orale Comprimés quadrisécables Boîte de 30  CHEPLA PHARM	 Lexomil® 6 mg comprimé quadrisécable Bromazépam 6 mg Voie orale Comprimés quadrisécables Boîte de 30  CHEPLA PHARM

Falsification Sample	Genuine Product
 Médicament autorisé n° 3400931742845 Liste I RESPECTER LES DOSES PRÉSCRITES Uniquement sur ordonnance LEXOMIL + GROSSESSE = DANGER Ne pas utiliser chez l'adolescente ou la femme en âge de procréer, et sans contraception efficace, ou chez la femme enceinte, sauf en l'absence d'alternative thérapeutique. Attention, danger : ne pas conduire Pour la reprise de la conduite, demandez l'avis d'un médecin PC 03400931742845	 Médicament autorisé n° 3400931742845 Liste I RESPECTER LES DOSES PRÉSCRITES Uniquement sur ordonnance LEXOMIL + GROSSESSE = DANGER Ne pas utiliser chez l'adolescente ou la femme en âge de procréer, et sans contraception efficace, ou chez la femme enceinte, sauf en l'absence d'alternative thérapeutique Attention, danger : ne pas conduire Pour la reprise de la conduite, demandez l'avis d'un médecin PC 03400931742845
 Composition : Bromazépam : 6 mg Pour un comprimé quadriséculaire Excipient à effet notoire : Lactose Tenir hors de la vue et de la portée des enfants. Lire la notice avant utilisation. Se conformer à la prescription médicale. Durée de prescription limitée à 12 semaines. Titulaire: CHEPLAPHARM ARZNEIMITTEL GMBH ZIEGELHOF 24 17489 GREIFSWALD, ALLEMAGNE Exploitant: CHEPLAPHARM FRANCE 105, RUE ANATOLE FRANCE 92300 LEVALLOIS-PERRET LE TRI FLACON + ÉTUI + NOTICE + FACILE + Séparez les éléments avant de trier	 Composition : Bromazépam : 6 mg Pour un comprimé quadriséculaire Excipient à effet notoire : Lactose Tenir hors de la vue et de la portée des enfants. Lire la notice avant utilisation. Se conformer à la prescription médicale. Durée de prescription limitée à 12 semaines. Titulaire: CHEPLAPHARM ARZNEIMITTEL GMBH ZIEGELHOF 24 17489 GREIFSWALD, ALLEMAGNE Exploitant: CHEPLAPHARM FRANCE 105, RUE ANATOLE FRANCE 92300 LEVALLOIS-PERRET LE TRI FLACON + ÉTUI + NOTICE + FACILE + Séparez les éléments avant de trier
Primary Packaging	

Falsification Sample	Genuine Product
 12 2027 F3173 EXP/Lot 90002551/10 FR-CP 28056425 SERVIER Lexomil® 6mg comprimés quadriséables	
	
Dosage Form	
	

The following differences and results were found:

The comparison with the artwork of the secondary packaging revealed discrepancies in several cases regarding the additional logo of Les Laboratoires Servier and the font used. Additionally, the absence of accents is noted on all sides of the secondary packaging material. The comparison of the top of the packaging revealed three words where the accents are missing: *Comprimés*, *quadriséables*, and *Boîte*. The bottom side of the packaging shows differences in the position and font used. On the front side, the main difference is the presence of the Les Laboratoires Servier logo. On the right side of the packaging, the accents are missing for the words: *Comprimés*, *quadriséables*, and *Boîte*. On the left side, the colour, thickness, and positioning of the frame differ. In the lower frame regarding the impairment of driving ability, the font used differs entirely from the original. On the backside of the

packaging, the most prominent discrepancies are again the absence of the accents, missing for the words: *Bromazépam*, *comprimé*, *quadrisécable*, *portée*, and *limitée*. Additionally, a number is printed on the disposal instructions that does not exist in the original artworks.

The product code, batch number, and expiry date of the secondary packaging align with the retention sample. The serial number has been verified; it is valid, and the item is still in status "available." However, the printing of the Data-Matrix code, the arrangement, and the font of the variable data differ from the retention sample.

The small excerpt of the primary packaging shows discrepancies in font style and positioning, and again the additional logo of Les Laboratoires Servier. Furthermore, the expiry date printed on the primary packaging of the falsified sample, "12/2027," is incorrect, and both the bottom and the top of the primary packaging are designed differently. In contrast to the falsified sample, the bottom of the primary packaging of the retention sample is green, the top closes flush, and has an inner spiral. Additionally, the batch number printed on the primary packaging does not match the batch number on the secondary packaging.

The tablets show no abnormalities based on the photos. However, without a chemical analysis, no statement can be made about their authenticity.



5. Chemical Analysis of Suspected Falsified Sample

Chemical analysis is not possible since the physical samples have not been provided.

6. Patient risk assessment

The appearance of the secondary packaging on the provided pictures lead to a verification for falsified packaging material. Since no chemical analysis results are available for the active ingredient content or potentially critical ingredients in the potentially falsified tablets, a final assessment is not possible. Thus, a risk to patient safety cannot be ruled out, so the counterfeit is classified as RAS II.

7. Conclusion

CHEPLAPHARM was not able to perform a complete investigation, because only pictures of the suspected falsified samples were available. The packaging material investigation on the provided pictures has revealed clear verification for falsified packaging material.

CHEPLAPHARM will close the record FAL-2025-031 as confirmed falsification.

With kind regards

CHEPLAPHARM Arzneimittel GmbH

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 Signing Time: Aug 20, 2025, 12:59:04.270 p.m. (UTC)
 Signing Reason: I read and approve this document
 boxSIGN 1V7J696Z-4WRKJ95J

Dr. Thomas Emmrich
 Deputy EEA-QPPV

Susanne Böhme
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 Signing Reason: I read and approve this document
 boxSIGN 19KJQJQ1-4WRKJ95J

Susanne Böhme
 Qualified Person