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**

Regierungspräsidium Karlsruhe
Referat 25 – Ärztliche und Pharmazeutische Angelegenheiten
Markgrafenstr. 46
76133 Karlsruhe

1. To / Empfänger:		FAX
☒	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-4636
☐	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030-18444-30409
☐	Paul-Ehrlich-Institut / Bundesamt für Sera und Impfstoffe - (PEI)	06103-77-1263
☒	Ministerium für Soziales und Integration Baden-Württemberg, Referat 53, Else-Josenhans-Str. 6, 70173 Stuttgart	0711-123-3816

2. *Classification (not mandatory)*

3. Falsification

4. Product:

Dapoxetine Tablets 60 mg Dapotime Tablets
Sildenafil Citrate Tablets 100 mg Cenforce-100
Vidalista 20 Tadalafil Tablets 20mg

5. Marketing Authorisation Number: *

For use in humans/animals (delete as required)

6. Brand/Trade Name: n/a

7. INN or Generic Name:

8. Dosage Form:

Tablets

9. Strength:

Dapotexin 60mg
Sildenafil 100mg
Tadalafil 20mg

10. Batch number (and bulk, if different):

B.No. 385-05 Dapoxetin
B.No. TC-1260088 Sildenafil
B.No. TV-620034 Vidalista

11. Expiry Date:

12. Pack size and Presentation:

13. Date Manufactured: *

14. Marketing Authorisation Holder: *

HAB Pharmaceuticals and Research Ltd. - Dapoextin
Centurion Remedies Ltd. - Sildenafil
G5 & G6 ... Estate…Vadodara - Vidalista

15. Manufacturer†:

India

Contact Person:

Telephone:

16. Recalling Firm

17. Rapid Alert Notification Reference Number: **DE_**

18. Details:

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

Suspicion of the distribution of drugs through illegal distribution channels

Supplier: Estere Lapina / Grandezza Ou“, Krisjana iela 118, LT-1013 Riga (Lettland)

20. Action taken by Issuing Authority: FOR YOUR INFORMATION

The goods were secured by the customs office

21. Proposed Action:

22. From (Issuing Authority):

Regierungspräsidium Karlsruhe

mail to: abteilung2@rpk.bwl.de

23. Contact Person:

Sabine Hofsäss

Telephone: +49 721 926 7641

24. Signed: Sabine Hofsäss

25. Date: 27.11.2020

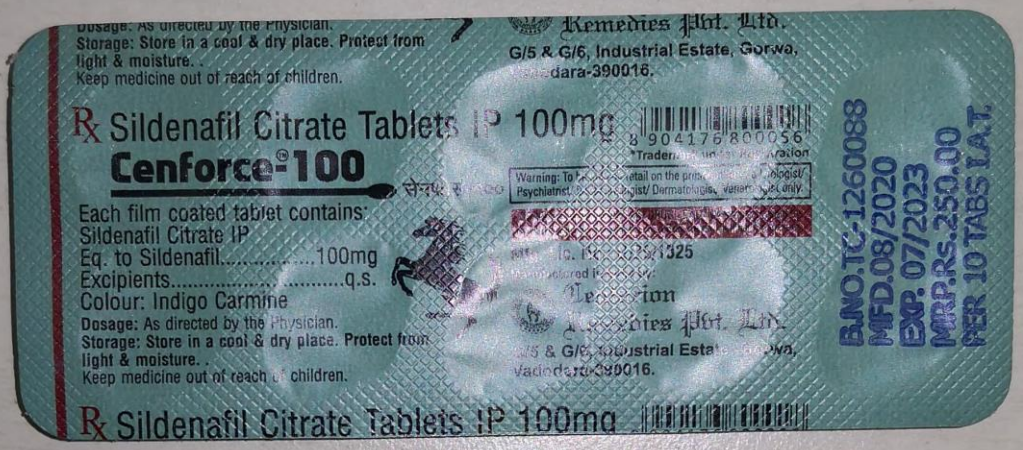
26. Time: *

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 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.

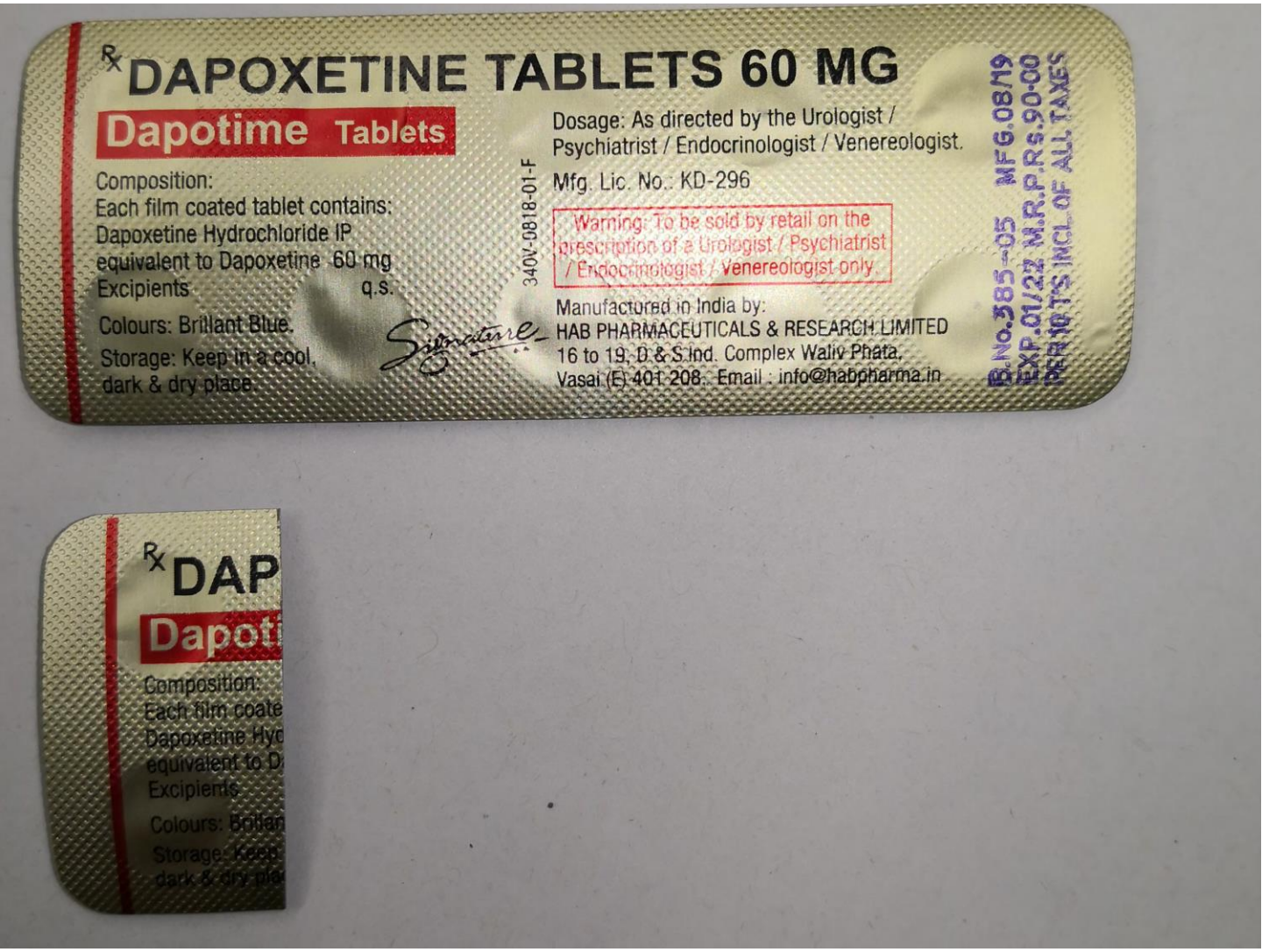
This is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone immediately and return it to us at the above address by mail. Thank you




Dosage: As directed by the Physician.
Storage: Store in a cool & dry place. Protect from light & moisture.
Keep medicine out of reach of children.
Rx Sildenafil Citrate Tablets IP 100mg
Cenforce-100
Each film coated tablet contains:
Sildenafil Citrate IP
Eq. to Sildenafil.....100mg
Excipients.....q.s.
Colour: Indigo Carmine
Dosage: As directed by the Physician.
Storage: Store in a cool & dry place. Protect from light & moisture.
Keep medicine out of reach of children.
Rx Sildenafil Citrate Tablets IP 100mg
Remedies Pvt. Ltd.
G/5 & G/6, Industrial Estate, Gorwa,
Vadodara-390016.
B.NO.TC-1260088
MFD.08/2020
EXP. 07/2023
MRP.Rs.250.00
PER 10 TABS I.A.T.




VIDALISTA 20
Tadalafil Tablets IP 20mg
Keep out of reach of children.
Mfg. Lic. No.:
B.NO.TC-1260034
MFD.08/2020
EXP. 07/2023
MRP.Rs.300.00


℞ DAPOXETINE TABLETS 60 MG
Dapotime Tablets
Composition:
Each film coated tablet contains:
Dapoxetine Hydrochloride IP
equivalent to Dapoxetine 60 mg
Excipients q.s.
Colours: Brillant Blue.
Storage: Keep in a cool,
dark & dry place.
340V-0818-01-F
Dosage: As directed by the Urologist /
Psychiatrist / Endocrinologist / Venereologist.
Mfg. Lic. No.: KD-296
Warning: To be sold by retail on the
prescription of a Urologist / Psychiatrist
/ Endocrinologist / Venereologist only.
Manufactured in India by:
HAB PHARMACEUTICALS & RESEARCH LIMITED
16 to 19, D & S Ind. Complex Waliv Phata,
Vasai (E) 401 208. Email : info@habpharma.in
B.No.385-05 MFG.08/19
EXP.01/22 M.R.P.Rs.90-00
PER 10 T'S INCL. OF ALL TAXES
℞ DAP
Dapoti
Composition:
Each film coate
Dapoxetine Hyd
equivalent to D
Excipients
Colours: Brillan
Storage: Keep
dark & dry pla



Excipients.....q.s.
Colour: Indigo Carmine
Dosage: As directed by the Physician.
Storage: Store in a cool & dry place. Protect from light & moisture.
Keep medicine out of reach of children.

℞ Sildenafil Citrate Tablets IP 100mg

Cenforce®100 सेनफोर्स-१००

Each film coated tablet contains:
Sildenafil Citrate IP
Eq. to Sildenafil.....100mg
Excipients.....q.s.
Colour: Indigo Carmine
Dosage: As directed by the Physician.
Storage: Store in a cool & dry place. Protect from light & moisture.
Keep medicine out of reach of children.

Manufactured in India by:
Centurion Remedies Pvt. Ltd.
G/5 & G/6, Industrial Estate, Gorwa,
Vadodara-390016.

8 904176 800056

Warning: To be sold by retail on the prescription of a Urologist/ Psychiatrist/ Endocrinologist/ Dermatologist/ Venerologist only.

*Trademark under Registration

Mfg. Lic. No.: G/25/1325
Manufactured in India by:
Centurion Remedies Pvt. Ltd.
G/5 & G/6, Industrial Estate, Gorwa,
Vadodara-390016.

B.NO.T-260783
MFD.03/2040
EXP.07/2023
MRP.Rs.250.00
PER 10 TABS I.A.T

		Consignor:	Estere Lapina / Grandezza Ou, Krisjana iela 118, LT-1013 Riga (Lettland).						
	Name	API	Amount (Tablets)	Manufcaturer	Batch	Consignor		Date of seizure by German customs	
Shipment 1	Dapoxetine Tablets 60 mg Dapotime Tablets	Dapotexin 60mg	12	HAB Pharmaceuticals and Research Ltd.	B.No. 385-05	Estere Lapina/Grandezza Ou		19/11/2020	
Shipment 2	Sildenafil Citrate Tablets 100 mg Cenforce-100	Sildenafil 100mg	74	Centurion Remedies Ltd.	B.No. TC-1260088	Estere Lapina/Grandezza Ou		19/11/2020	
Shipment 2	Vidalista 20 Tadalafil Tablets 20mg	Tadalafil 20mg	94	G5 & G6 ... Estate...Vadodara	B.No. TV-620034	Estere Lapina/Grandezza Ou		19/11/2020	
Shipment 3	Sildenafil Citrate Tablets 100 mg Cenforce-100	Sildenafil 100mg	128	CenturionRemedies Ltd.	B.No. TC-1260088	Estere Lapina/Grandezza Ou		19/11/2020	
Shipment 3	Vidalista 20 Tadalafil Tablets 20mg	Tadalafil 20mg	110	G5 & G6 ... Estate...Vadodara	B.No. TV-620034	Estere Lapina/Grandezza Ou		19/11/2020	
Shipment 4	Sildenafil Citrate Tablets 100 mg Cenforce-100	Sildenafil 100mg	60	CenturionRemedies Ltd.	B.No. TC-1260088	Estere Lapina/Grandezza Ou		19/11/2020	
Shipment 5	Sildenafil Citrate Tablets 100 mg Cenforce-100	Sildenafil 100mg	14	CenturionRemedies Ltd.	B.No. TC-1260088	Estere Lapina/Grandezza Ou		19/11/2020	