

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 <input checked="" type="checkbox"/> ASSUMED <input type="checkbox"/> REASONABLY SUSPECTED <input type="checkbox"/> VERIFIED	
Staatliches Gewerbeaufsichtsamt Braunschweig, Dezernat 21, Ludwig-Winter-Strasse 2, 38120 Braunschweig	
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"/> Niedersächsisches Ministerium für Soziales, Gesundheit und Gleichstellung Postfach 141, 30001 Hannover Referat 402 - Arzneimittelwesen	
2. Classification (not mandatory)	3. Falsification Assumed falsification due to open seal
4. Product: See annex 1	5. Marketing Authorisation Number: * see annex 1 For use in humans/animals (delete as required)
6. Brand/Trade Name: see annex 1	7. INN or Generic Name: ./.
8. Dosage Form: see annex 1	9. Strength: see annex 1
10. Batch number (and bulk, if different): see annex 1	11. Expiry Date: see annex 1
12. Pack size and Presentation: see annex 1	13. Date Manufactured: * ./.
14. Marketing Authorisation Holder: see annex 1	
15. Manufacturer [†] : Contact Person: Telephone:	16. Recalling Firm
17. Rapid Alert Notification Reference Number: DE_	
18. Details: packages were sold with opened seals	

<p>19. Information on distribution including exports (e. g. type of customer, e.g. hospitals): The wholesaler Prokuri Pharma GmbH, Altdorfer Straße 29, 72663 Großbettlingen in Germany bought medicinal products from various wholesalers with open seal. The wholesaler Med-X-Press GmbH, Pracherstieg 1, 38644 Goslar, Germany is the service provider for Prokuri Pharma GmbH. Med-X-Press is responsible for the receiving of the medicinal products, the storage and the packaging for distribution of the products. These products according to annex 1 are in the status of blocked goods in the storage area of Med-X-Press. In regards to further investigation we noticed much more medicinal products which were sold (vial Med-X-Press GmbH) with open seal in the past (see attached list of incoming goods). The list of outgoing goods is not complete yet and will be send as soon as possible.</p>		
<p>20. Action taken by Issuing Authority: Information of the competent authorities by RAN</p>		
<p>21. Proposed Action:</p>		
<p>22.</p>		<p>23.</p>
<p>24. Signed: Petra Honl</p>	<p>25. Date: 20.11.2019</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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Medicinal Product	Amount	Batch No	Expiry Date	Marketing Authorisation Holder	Marketing Authorisation Number
JANUMET 50 MG/850 MG film coated tablets 56 ST	1	S013456	31.10.2020	MSD SHARP & DOHME GMBH, 85530 Haar or Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN Haarlem Niederlande	EU/1/08/455/003
MAXALT LINGUA 10 MG 18 tablets	44	1031527	30.06.2022	MSD SHARP & DOHME GMBH, 85530 Haar	43365.01.00
MAXALT LINGUA 10 MG 18 tablets.	4	1031240	30.06.2022	MSD SHARP & DOHME GMBH, 85530 Haar	43365.01.00
DuoTrav 3x2.5ml Eye drops	1	19F04JD	31.05.2021	Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland	EU/1/06/338/002

Übersicht Wareneingänge / List of incoming goods-1

Datum	Name, Ort	Artikel	Charge	Verfall	Menge
14.11.2019	Alliance Healthcare, Harsum	Duotrav 40 MY G/ML+5 MG/ML Augentr 3x2,5 ML	19F04JD	05/2021	1
11.11.2019	Sanacorp, Langenhagen	Maxalt Lingua 10 MG	1031527	06/2022	31
11.11.2019	Sanacorp, Langenhagen	Maxalt Lingua 10 MG	1031240	06/2022	4
11.11.2019	Alliance Healthcare, Harsum	Maxalt Lingua 10 MG	1031527	06/2022	2
08.11.2019	Phoenix Pharmahandel, Göttingen	Maxalt Lingua 10 MG	1031527	06/2022	7
08.11.2019	Alliance Healthcare, Harsum	Maxalt Lingua 10 MG	1031527	06/2022	4
29.10.2019	Alliance Healthcare, Harsum	Onglyza 2,5 MG FTBL 98 ST	X861A	02/2022	1
10.10.2019	Kwizda Pharmahandel, Linz (AT)	Viramune SUS 50 MG/SML 240 ML	AA6193D	01/2022	1
26.09.2019	Alliance Healthcare, Harsum	Briviact 50 MG 56 ST	262788	04/2022	1
16.09.2019	KH Pharma, Soest	Januvia 100 MG FTBL 98 ST	5012656	03/2022	1
16.09.2019	KH Pharma, Soest	Janumet 50MG/850 MG FTBL 56 ST	5013456	10/2020	1
16.09.2019	KH Pharma, Soest	Forxiga 10 MG FTBL 28 ST	X458E	12/2021	1
09.09.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R021138	07/2021	1
09.09.2019	Sanacorp, Langenhagen	Maxalt Lingua 10 MG	1030863	01/2022	1
10.09.2019	Medicor Pharmaceuticals, DE Lelystad (NLD)	Isentress FTBL 400 MG 60 ST	S011578	07/2021	1
02.09.2019	Phoenix Pharmahandel, Göttingen	Forxiga 10 MG FTBL 28 ST	X458E	12/2021	1
29.07.2019	Herba Chemosan, Klagenfurt (AT)	Clobex 500 MCG/G SH 125 ML	9114228	05/2022	2
23.07.2019	Cross Healthcare, Throsk (GB)	Metopirone 250 MG Capsule 50 (NL)	MM048AU	01/2021	1
16.07.2019	Mammut-Apotheke, Ahlen	Tasigna 200 MG 14x28 ST	SJE29Y	12/2020	1
04.07.2019	Sanacorp, Langenhagen	Levetiracetam Desitin 1000 MG Granulat 200 ST	0018004167	09/2023	1
27.06.2019	Phoenix Pharmahandel, Göttingen	Triumet 50 MG/600MG/300MG 30 ST	AU6R	10/2021	1
25.06.2019	Sanacorp, Langenhagen	Travatam 40 MYG/ML Augentr 3x2,5 ML	19A24FD	12/2020	1
24.06.2019	Phoenix Pharmahandel, Göttingen	Janumet 50MG/1000 MG FTBL 196 ST	S012770	10/2020	1
24.06.2019	Sanacorp, Langenhagen	Maxalt Lingua 10 MG	1030392	01/2022	1
14.06.2019	Alliance Healthcare, Harsum	Janumet 50 MG/1000 MG FTBL 56 ST	S008994	09/2020	2
14.06.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R034002	11/2021	2
12.06.2019	Jacoby GmbH, Braunau am Inn (AT)	Femoston Conti 1 MG/5 MG FTBL 28 ST (AT)	358269	01/2022	1
11.06.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034006	10/2021	2
11.06.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034002	11/2021	2
11.06.2019	Sanacorp, Langenhagen	Tagrisso 80 MG FTBL 30 ST	FGRZ	08/2021	1
11.06.2019	Sanacorp, Langenhagen	Janumet 50 MG/850 MG FTBL 56 ST	S004001	06/2020	1
07.06.2019	Alliance Healthcare, Harsum	Janumet 50 MG/1000 MG FTBL 56 ST	S008994	09/2020	1
07.06.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034002	11/2021	8
07.06.2019	Phoenix Pharmahandel, Göttingen	Janumet 50 MG/1000 MG FTBL 56 ST	S010506	09/2020	3
05.06.2019	Sanacorp, Langenhagen	Pentacarinat 300 Vials 5 ST	810294	08/2023	1
05.06.2019	Alliance Healthcare, Harsum	Briviact 100 MG 56 ST	25056Q	01/2022	1

Übersicht Wareneingänge / List of incoming goods - 2

Datum	Name, Ort	Artikel	Charge	Verfall	Menge
05.06.2019	Apotheke zur Kaiserkrone, Wien (AT)	Viramune SUS 50 MG/5ML 240 ML	AA34734P	03/2021	1
04.06.2019	Sanacorp, Langenhagen	Janumet 50 MG/850 MG FTBL 56 ST	5004001	06/2020	1
04.06.2019	Sanacorp, Langenhagen	Janumet 50 MG/1000 MG FTBL 196 ST	5011894	10/2020	3
31.05.2019	Abis-Pharma, Wasingen	Forxiga 5 MG FTBL 28 ST	X223A	07/2021	1
31.05.2019	Abis-Pharma, Wasingen	Forxiga 10 MG FTBL 28 ST	X299A	09/2021	1
20.05.2019	Sanacorp, Langenhagen	Thyrozol 5 MG 50 ST	250936	02/2022	2
16.05.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034006	10/2021	1
07.05.2019	Alliance Healthcare, Harsum	Briviact 50 MG 14 ST	253125	01/2022	1
06.05.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034006	10/2021	3
06.05.2019	Phoenix Pharmahandel, Göttingen	Xigduo 5 MG/1000 MG FTBL 196 ST	X286A	12/2021	1
06.05.2019	Phoenix Pharmahandel, Göttingen	Janumet 50 MG/1000 MG FTBL 196 ST	5009516	12/2020	3
06.05.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R031750	10/2021	1
26.04.2019	Phardis B.V., Alkmaar (NLD)	Acixtra 1,5 MG/0,3 ML 7 ST	00388	02/2021	2
24.04.2019	Ilapo GmbH & CO KG, München	Egaten 250 MG 4 TBL (F)	02130017B	04/2020	1
08.04.2019	Phoenix Pharmahandel, Göttingen	Janumet 50 MG/1000 MG FTBL 56 ST	5003114	08/2020	1
08.04.2019	Kwizda Pharmahandel, Linz (AT)	Clobex 500 MCG/G SH 125 ML	9114210	01/2022	1
05.04.2019	Phoenix Pharmahandel, Göttingen	Xigduo 5 MG/1000 MG FTBL 196 ST	X283A	10/2021	2
03.04.2019	Sanacorp, Langenhagen	Janumet 50 MG/850 MG FTBL 56 ST	5000536	06/2020	1
02.04.2019	Sanacorp, Langenhagen	Venclyxto 100 MG 112 ST	1099444	02/2020	2
01.04.2019	Sanacorp, Langenhagen	Venclyxto 50 MG 7 ST	1105209	02/2020	3
01.04.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R031750	10/2021	3
22.03.2019	Alliance Healthcare, Harsum	Gilenya 0,5 MG Hartkapseln 98 ST	SKP95	08/2020	1
20.03.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R028315	09/2021	1
20.03.2019	MEX Medical Export SAS, Hillon (FRA)	Gilenya 0,5 MG Hartkapseln 98 ST	SKP95	08/2020	1
20.03.2019	MEX Medical Export SAS, Hillon (FRA)	Vastarel CPR 20 MG BT 60 (FR)	624444	05/2020	3
20.03.2019	MEX Medical Export SAS, Hillon (FRA)	Glucophage CPR 850 MG BT 90 (FR)	E202207	10/2023	1
20.03.2019	Phoenix Pharmahandel, Göttingen	Torasemid ABZ 10 MG TBL 100 ST	U26195B	07/2021	1
20.03.2019	Phoenix Pharmahandel, Göttingen	Gilenya 0,5 MG Hartkapseln 98 ST	SKP95	08/2020	6
18.03.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R028315	09/2021	1
12.03.2019	Alliance Healthcare, Harsum	Forxiga 10 MG FTBL 98 ST	X95A	09/2021	2
08.03.2019	Herba Chemosan, Klagenfurt (AT)	Hulio 40MG/0,8 ML ILO I. Fertigspr. 2 ST	1608397	06/2020	1
08.03.2019	Herba Chemosan, Klagenfurt (AT)	Toujeo ULSG FPEN 300 E/ML 3ST	8F118A	11/2020	8
01.03.2019	Phoenix Pharmahandel, Göttingen	Janumet 50 MG/1000 MG FTBL 196 ST	5001753	09/2020	69
01.03.2019	Phoenix Pharmahandel, Göttingen	Janumet 50 MG/1000 MG FTBL 56 ST	5002414	08/2020	1
27.02.2019	KH Pharma, Soest	Xigduo 5 MG/1000 MG FTBL 196 ST	X198	09/2021	1
15.02.2019	Alliance Healthcare, Bremen	Jakawi 15MG 56 ST	SKR24	08/2021	1
14.02.2019	Phoenix Pharmahandel, Göttingen	Xigduo 5 MG/1000 MG FTBL 196 ST	X102A	10/2021	1
13.02.2019	Alliance Healthcare, Bremen	Genvoxya 150/150/200/10MG FTA 3x30 ST	17GV142D	12/2019	1
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Übersicht Wareneingang / List of incoming goods-3

Datum	Name, Ort	Artikel	Charge	Verfall	Menge
07.08.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R034002	11/2021	1
05.08.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R034002	11/2021	1
01.08.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034002	11/2021	5
31.07.2019	Sanacorp, Langenhagen	Januvia 100 MG FTBL 28 ST	R034002	11/2021	1
15.07.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034002	11/2021	5
08.07.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034002	11/2021	10
24.05.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034006	10/2021	2
24.05.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R034006	10/2021	1
09.05.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R034006	10/2021	1
06.05.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R034006	10/2021	4
06.05.2019	Phoenix Pharmahandel, Göttingen	Januvia 50 MG/1000 MG FTBL 196 ST	S008764	12/2020	9
03.05.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R034006	10/2021	1
29.04.2019	Alliance Healthcare, Bremen	Januvia 100 MG FTBL 28 ST	R031750	10/2021	1
18.04.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R031750	10/2021	1
16.04.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R031750	10/2021	1
08.04.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R031750	10/2021	1
04.04.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R031750	10/2021	1
27.03.2019	Alliance Healthcare, Harsum	Januvia 100 MG FTBL 28 ST	R031750	10/2021	1
25.03.2019	Sanacorp, Langenhagen	Januvia 100 MG FTBL 28 ST	R031750	10/2021	1
25.03.2019	Sanacorp, Langenhagen	Januvia 50 MG/850 MG FTBL 56 ST	S000536	06/2020	1
20.02.2019	Alliance Healthcare, Bremen	Januvia 100 MG FTBL 28 ST	R028315	09/2021	1
12.02.2019	Alliance Healthcare, Bremen	Januvia 100 MG FTBL 28 ST	R023433	07/2021	1
11.02.2019	Alliance Healthcare, Bremen	Januvia 100 MG FTBL 28 ST	R023433	07/2021	1
04.03.2019	Phoenix Pharmahandel, Göttingen	Januvia 100 MG FTBL 28 ST	R028315	09/2021	1
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Übersicht Warenübergang - List of outgoing goods

Datum	Name, Ort	Lieferschein-Nr.	Artikel	Charge	Verfall	Menge
03.04.2019	Medcor Pharmaceuticals, Liphinstad (NOR)	2224	Gilmary 0,5 MG Hartgörseln 98 ST	56995	09/2020	8
26.04.2019	Citrusion AG, Zug (CHF)	2295	Egines 250 MG 4 TBL	021100178	04/2020	1
07.05.2019	Sigma Pharmaceuticals PLC, Hertfordshire (UK)	2322	Fontiga 10 MG 98 ST	X116A	09/2021	1
07.05.2019	CST Pharma Ltd, Walsall (UK)	2321	3igduo 5 MG/1000 MG FTBL 196 ST	X243A	10/2021	2
08.05.2019	Kosel Pharma, Slough (UK)	2330	Janumet 50 MG / 1000 MG FTBL 196 ST	5001764	12/2020	5
08.05.2019	Kosel Pharma, Slough (UK)	2330	Janumet 50 MG / 1000 MG FTBL 196 ST	5001510	12/2020	3
08.05.2019	Sigma Pharmaceuticals PLC, Hertfordshire (UK)	2426	Femaja 5 MG 28 ST	X223A	07/2022	1
12.06.2019	Agothero zur Kaserkron, Wien (AUT)	ER 178	Vitamine S15 50MG/50ML 240 ML	AA4M71AP	03/2021	1
12.06.2019	Sanacorp, Lainghages (DE)	ER 177	Pentacarmat 300 50x6 5 ST	BU29M	08/2023	1
17.06.2019	Day Lewis Medical Limited, Surrey (UK)	2416	Ferrosol Conto 1 MG/5MG FTBL 28 ST	194269	01/2022	1
17.06.2019	Medcor Pharmaceuticals, Liphinstad (NOR)	2415	Tafproso 80 MG FTBL 305T	Fce2	08/2021	1
04.07.2019	Medcor Pharmaceuticals, Liphinstad (NOR)	2590	Trinet YOMG/50MG/500MG 30 ST	AUG64	10/2021	1
08.07.2019	Pharma Ltd, Walsall (UK)	2515	Levetiracetam Dertlin 1000 MG 200 ST	0314004167	09/2023	1
12.07.2019	Day Lewis Medical Limited, Surrey (UK)	2578	Trocton 10 MG/5ML Augent 3x2,5 ML	1962465	12/2020	1
25.07.2019	inoby GMI Pharma GmbH, Brunsau am Inn (AUT)	2572	Pycomse 10 MG FTA 28 ST	122532	10/2022	1
30.07.2019	Heba Chemsan, Klagenfurt (AUT)	ER 199	Chobex 500 MCG/50 125 ML	9114228	05/2022	2
31.07.2019	Orifarm Trading GmbH & Co. KG, Lovelkufen (DE)	2596	Janumet 50 MG / 1000 MG FTBL 196 ST	5012770	10/2020	1
26.08.2019	CST Pharma Ltd, Walsall (UK)	2642	Xigduo 5 MG/1000 MG	X286A	12/2021	1
26.08.2019	CST Pharma Ltd, Walsall (UK)	2642	Maralt Lengon 10 MG	1630392	01/2022	1
19.09.2019	C. Krieger & Co., Koblentz (DE)	2718	Janumet 100 MG FTBL 28 ST	8021130	07/2021	1
19.09.2019	C. Krieger & Co., Koblentz (DE)	2718	Janumet 100 MG FTBL 28 ST	8024006	10/2021	2
01.10.2019	Sigma Pharmaceuticals PLC, Hertfordshire (UK)	2743	Femaja 10 MG 28 ST	X458E	12/2021	2
01.10.2019	Sigma Pharmaceuticals PLC, Hertfordshire (UK)	2743	Janumet 98 ST	5012656	05/2022	1
04.10.2019	CST Pharma Ltd, Walsall (UK)	2747	Maralt Lengon 10 MG	1030863	01/2022	1
14.10.2019	Keanda Pharmahandel, Linz (AUT)	ER 210	Vitamine-S15 50MG/50ML 240 ML	AA61920	03/2022	1
11.11.2019	Alliance Healthcare, Neusum (DE)	ER 215	Onglyza 2,5 MG FTBL 98 ST	X861A	02/2022	1