

NEXUS Germany GmbH . Irmastraße 1 . D-78166 Donaueschingen

To all NEXUS / HIS customers

Your message from

Your sign

Our sign

Date

16 February 2023

Urgent safety information

Software update regarding NEXUS / MEDICATION - Extend Partial Regulation

Sender:

NEXUS Germany GmbH Irmastraße 1
D-78166 Donaueschingen

Addressee:

All customers of NEXUS / HIS with Release 8.0 ServiceRelease 22-4
and Release 8.0 ServiceRelease 23-1, which have NEXUS / MEDICATION in use.

Identification of the medical devices concerned:

NEXUS / MEDICATION Version 22

Note: NEXUS / HIS as a system includes the medical product NEXUS / MEDICATION among others.

Description of the problem including the identified cause:

A dose change for an already existing prescription including a time shift backwards (into the future) using the option "Extend previous partial prescription" can lead to a prescribed medication not being administered.

The reason for this is the effect that the dosage display of the medication order ("Prescribe medication" module) can deviate from that in the modules of the medication guideline list ("Direct and administer medication" and "Ward curve" modules) or disappear completely on some days.

When does this malfunction occur?

A malfunction in the dose change only occurs with exactly the following prerequisite and operation. Only 1 case was reported to us in which this malfunction was detected.

Prerequisite:

The prescription type "Interval" or "Continuous" must be used.

There must be an order that has an end date in the future in the "Date/Time to" field.

Example from 14.02.2023:

Tramabeta prescription with dosing schedule 1-0-0-1 and end date 16.02.2023.

S	I	B	Bezeichnung	Wirkstoff	RAM	Dosierung	DFR	App.	Da...	El...	Frequenz / VA	Bemerkung	Merkt...
			Abilify Maintena 300mg Depot-Injekt...	Arripiprazol	3340951700	0-0-1 St		TR5	St		1x / Tag		
			ASPIRIN SINUCOMPLEX	Pseudoephedrin hydrochl...	3350626700	0-1-1 St		GRA	St		2x / Tag		
			Paracetamol Ampullen	para-Benzochinonum aq...	3346153900	1-1-1-1 St		AMP	St		4x / Tag		
			Paracetamol i.v. 0,15mg - Hikma Pharma...	Clonidin hydrochlorid, CL...	3339957111	0-0-1 tbi		AMP	tbi		1x / Tag		
			Tramabeta	Tramadol hydrochlorid, Tr...	3339957111	1-0-0-1 g		TRG	g		1x / Tag		

Gültigkeitszeitraum		Mengen und Zeiten	
Datum/Zeit von	Dauer (24h)	Frequenz	Datum/Zeit bis
14.02.2023 15:54	2	Tagl.	16.02.2023 15:55

Mengen und Zeiten			
08:00	12:00	18:00	21:00
0	0	1	0

Operation in Medication Order ("Prescribe Medication" module):

If, in the case of such a prescription, a dose is subsequently prescribed in the "Prescribe Medication" module, the dose is changed, a new dosage line is created at the same time.

If, before saving, the start time of the new dosage data record is also given a future date, a message window appears that offers the two options

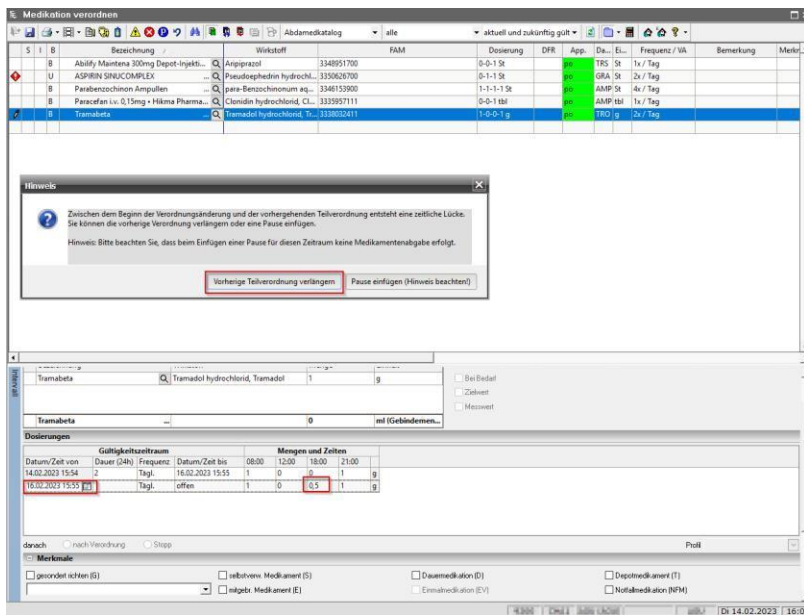
"Extend previous partial regulation" or "Insert pause (note!)" offers.

If the option "Extend previous partial regulation" is selected, the end date of the first partial regulation can be set.

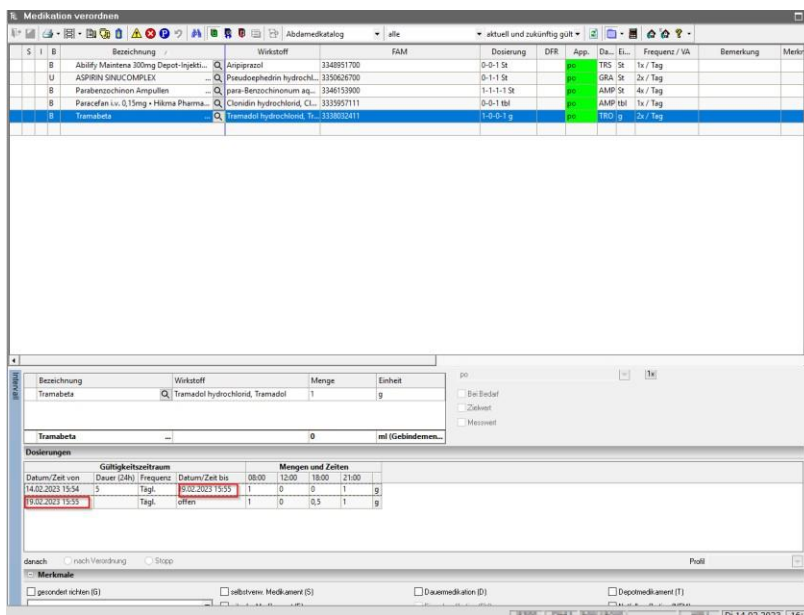
dosage data set (partial prescription) can be extended and stored.

Example: Value in the 18:00 column is increased from 0 to 0.5

and the commencement (date/time of) is to be changed from 16.02.2023 to 19.02.2023.



By selecting the option "Extend previous partial prescription", the end date of the first dosage record is also set to 19.02.2023. The change is then saved.



Effect in medication guideline list (modules "Direct and administer medication" and "Ward curve"):

In the following, for the added extension of the partial regulation, the notification of the Medication in the module "Medication alignment and administration" and in the module "Ward curve". Example: Tramabeta is not displayed in the period from 16/02/2023 15:55 to 19/02/2023 15:55.

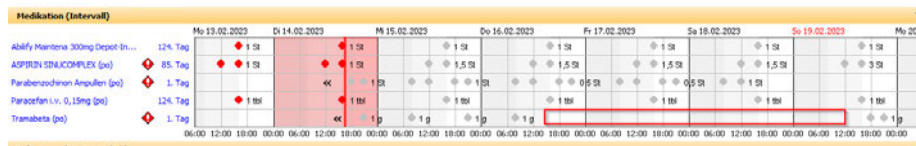
Medikation richten und verabreichen

18.02.2023

Aktuelle + Bedarf

alle

S	B	Bezeichnung	I	Bemerkung	Mer...	Bes	Dosierung	Einheit	Frequenz / VA	App.	Dam
Patient: Faust, Wilfried, M, 10.10.2000; 22 Jahre; 212863-002											
Verordnungszeit											
B		Abilify Maintena 300mg Depot-Injektions suspension - BB Farma s.r.l.	Q				0-0-1 St	St	1x / Tag		TRS
U		ASPIRIN SINJOCOMPLEX	Q				0-2-1-5 St	St	2x / Tag		GRA
B		Parabenzochinon Ampullen	Q				1-1-0,5-0,5 St	St	4x / Tag		AMP
B		Paracetamol 0,15mg - Hikma Pharma GmbH	Q				0-0-1 tbi	tbi	1x / Tag		AMP



What measures are to be taken by the addressee? Software update: correction of the malfunction

The fix is available in the form of a hotfix:

- For NEXUS / HIS Release 8.0 ServiceRelease 22-4: HF9.01.0132
- For NEXUS / HIS Release 8.0 ServiceRelease 23-1: HF9.04.0012

Disclosure of the information described herein:

Please ensure that all users of the above products and other persons to be informed are made aware of this **Urgent Safety Information**. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.

Please keep this information at least until the measure has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact person for further enquiries:

The staff of the NEXUS ServiceDesk will be happy to answer your questions (Tel: 0800 962 00 60 or servicedesk@nexus-ag.de).

With kind regards



NEXUS Deutschland GmbH Quality
Management