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Urgent safety information

Communication of update of wording in the Instructions For Use (IFU), "Taking Other Products".

Regarding

Movicol® (please refer to the list of products below)

Sender:
Norgine BV
Ronald O'Connell
150 Antonio Vivaldistraat
Amsterdam
1083 HP
Netherlands

+31 20 567 0900
roconnell@norgine.com

Addressee:

The targeted group for this Urgent Safety Information are Pharmacists.

Identification of the medical devices concerned:

The Urgent Safety Information Notification concerns the following products:

- MOVICOL® flüssig Orange, Konzentrat zur Herstellung einer Lösung zum Einnehmen
- MOVICOL® Junior Schoko, 6.9 g Pulver zur Herstellung einer Lösung zum Einnehmen
- MOVICOL® Junior aromafrei, 6.9 g Pulver zur Herstellung einer Lösung zum Einnehmen
- MOVICOL® Schoko, 13.9 g Pulver zur Herstellung einer Lösung zum Einnehmen
- MOVICOL® aromafrei, 13.7 g Pulver zur Herstellung einer Lösung zum Einnehmen
- MOVICOL®, 13,8 g Pulver zur Herstellung einer Lösung zum Einnehmen
- MOVICOL® V, 13,8 g Pulver zur Herstellung einer Lösung zum Einnehmen
- MOVICOL® trinkfertig, 25 mL Beutel, Lösung zum Einnehmen

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Description of the problem including the identified cause:

A report was received by the manufacturer of a possible drug-device interaction between MOVICOL and Novodigal (Digoxin) where a patient experienced an exacerbation of their underlying cardiac condition.

Novodigal was administered at the same time as MOVICOL. The possibility of Novodigal having been washed out by MOVICOL cannot be ruled out. MOVICOL (Macrogol 3350) acts by virtue of its physical action in the gut, which induces a laxative effect. Through its osmotic action Macrogol 3350 retains water in the gut, thereby increasing the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of defaecation. The decreased gastrointestinal transit time may lead to reduced absorption of other medications, resulting in sub-therapeutic systemic concentrations.

The wording in the current IFU states that "s*ome medicines, e.g. anti-epileptics, may not work as effectively during use with Movicol. Please inform your doctor or pharmacist if you are taking, or have recently taken, any medicines, including medicines obtained without a prescription*".

In consultation with BfArM, the IFU will be updated with the wording for the "wash-out" effect of other medicines by MOVICOL, including the rationale behind the cautionary statement to provide better context for the end user.

There is a possibility that the absorption and consequently the effectiveness of other medicines taken orally could be reduced if taken at the same time as MOVICOL. Therefore, as a precautionary measure, other medicines should not be taken orally for one hour before, during and for one hour after taking MOVICOL.

Please consult your doctor or pharmacist if you are taking, or have recently taken, any medicines, including medicines obtained without a prescription.

Action to be taken by Pharmacists:

The IFU section, "Taking other products" has been updated to provide the time period for which other orally taken medicines should not be taken in conjunction with MOVICOL.

Upon dispensing MOVICOL please state the following updated wording in the IFU to the patient:

There is a possibility that the absorption and consequently the effectiveness of other medicines taken orally could be reduced if taken at the same time as

MOVICOL. Therefore, as a precautionary measure, other medicines should not be taken orally for one hour before, during and for one hour after taking MOVICOL.

Please consult your doctor or pharmacist if you are taking, or have recently taken, any medicines, including medicines obtained without a prescription.
The IFU will be formally updated in new packs of MOVICOL from August 2022.

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:

Norgine GmbH
Dr. med. Stefan Ullrich
Interim Medical Director Germany
Im Westpark 14
D-35435 Wettenberg
Tel. +49 641 98497220
Mobile: +49 172 674 3831

Signature

[redacted]