



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

### Caution in Use

### Distribute to Pharmacy/Wholesaler Level

Date: 02 September 2021

EL (21)A/21

Our Ref: MDR 197-08/21

Dear Healthcare Professional,

## Accord Healthcare Limited

### Rosuvastatin 5 mg film-coated tablets

**PL 20075/0402**

Batch Number	Expiry Date	Pack Size	First Distributed
P2003918	05/2022	28	18-10-2020
P2004589	05/2022	28	27-01-2021
P2006170	10/2022	28	17-03-2021
P2100919	12/2022	28	17-06-2021
P2100504	12/2022	28	28-06-2021
P2100505	12/2022	28	28-06-2021
P2102016	01/2023	28	01-08-2021
P2102004	12/2022	28	07-07-2021

### Rosuvastatin 10 mg film-coated tablets

**PL 20075/0403**

Batch Number	Expiry Date	Pack Size	First Distributed
P2004270	04/2022	28	08-11-2020
P2005749	08/2022	28	07-04-2021
P2005771	08/2022	28	01-04-2021
P2006215	11/2022	28	13-06-2021
P2100654	01/2023	28	17-05-2021
P2100655	01/2023	28	13-05-2021
P2101700	01/2023	28	07-07-2021
P2101824	02/2023	28	04-07-2021
P2101396	02/2023	28	07-07-2021

### Rosuvastatin 20 mg film-coated tablets

**PL 20075/0404**

Batch Number	Expiry Date	Pack Size	First Distributed
P2003123A	03/2022	28	27-05-2021
P2101390	12/2022	28	27-06-2021

### Rosuvastatin 40 mg film-coated tablets

**PL 20075/0405**

Batch Number	Expiry Date	Pack Size	First Distributed
P2101978	02/2023	28	04-07-2021

Active Pharmaceutical Ingredient: Rosuvastatin calcium



### **Brief description of the problem**

Accord Healthcare have informed us of an error with the patient information leaflets (PILs) that have been packaged in the above batches of products. These were an older version of the PIL which did not include the most up to date safety information.

The information missing from the PILs are as below:

#### Section 2 Other medicines and Rosuvastatin tablets:

Tell your doctor if you are taking any of the following:

Regorafenib (used to treat cancer), any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Warnings and precautions): atazanavir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.

#### Section 4 Possible side effects:

Stop taking Rosuvastatin tablets and talk to your doctor immediately

- If you experience muscle rupture
- If you have lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Rosuvastatin tablets may cause the following possible side effects:

Rare (may affect up to 1 in 1,000 people)

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, then stop taking Rosuvastatin tablets and seek medical help immediately
- Muscle damage in adults – as a precaution, stop taking Rosuvastatin tablets and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

### **Advice for healthcare professionals**

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the product and where possible, provide an updated PIL. The updated PIL is available via the MHRA website:

[Rosuvastatin 5 mg film-coated tablets-PIL](#)

[Rosuvastatin 10 mg film-coated tablets-PIL](#)

[Rosuvastatin 20 mg film-coated tablets-PIL](#)

[Rosuvastatin 40 mg film-coated tablets-PIL](#)

Accord Healthcare Limited have confirmed that all future batches will contain the updated PIL and that upon request they will send hard copies by post of the updated PIL to wholesalers and pharmacies, so that any remaining stock in the dispensary can be supplemented with the updated PIL information



**Further Information**

For more information or medical information queries, please contact: Accord Medical Information Department on 01271 385257, email- [medinfo@accord-healthcare.com](mailto:medinfo@accord-healthcare.com)

For stock control queries, please contact: Accord- Customer Services Team on 0800 373573

For updated PIL requests please contact Email: [contact@accord-healthcare.com](mailto:contact@accord-healthcare.com) Phone: 01271 385200

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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