



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 17 August 2022

EL (22)A/35

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 |
|--------------|-------------|-----------|-------------------|
| P2102389 | 03/2023 | 28 | 24-06-2022 |

Rosuvastatin 10 mg film-coated tablets

PL 20075/0403

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| P2103803 | 04/2023 | 28 | 28-06-2022 |

Rosuvastatin 20 mg film-coated tablets

PL 20075/0404

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| P2104132 | 05/2023 | 28 | 28-06-2022 |

Active Pharmaceutical Ingredient: Rosuvastatin calcium

Brief description of the problem

Further to a previous defect notification, [[EL \(21\)/A21](#)] Accord Healthcare have informed us of an error with the patient information leaflets (PILs) that have been packaged in the above additional batches of products. These were an older version of the PIL which did not include the most up to date safety information.

Accord Healthcare have confirmed that this issue impacts 29086 packs across the three different batches mentioned. The MHRA have confirmed with Accord Healthcare that all other packs of the above batches on hold at the manufacturer will not be distributed.

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](#)

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

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

For updated PIL requests please contact Email: contact@accord-healthcare.com Phone: 01271 385200



Medicines & Healthcare products
Regulatory Agency

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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