



Department of
Health

An Roinn Sláinte

Máinnystrie O Poustie

www.health-ni.gov.uk

For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
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Our Ref: PHC/23/2021
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MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

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

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

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



Mrs Cathy Harrison
Chief Pharmaceutical Officer