Chief Medical Officer Directorate
Pharmacy and Medicines Division

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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

3 December 2020

Dear Healthcare Professional,

DRUG ALERT CLASS 3 NO 57 2020 MEDICINES RECALL ACTION WITHIN 5 DAYS LUPIN HEALTHCARE (UK) LTD SIMVADOR 10, 20 AND 40 MG TABLETS

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy and Wholesaler Level

Date: 03/12/2020 EL (20)A/57 Our Ref: MDR 150-11/20

Dear Healthcare Professional,

Lupin Healthcare (UK) Limited

Simvador 10mg Tablets **PL 35507/0012**
Simvador 20mg Tablets **PL 35507/0013**
Simvador 40mg Tablets **PL 35507/0014**

Product	Batch Number	Expiry Date	Pack Size	First Distributed
Simvador 10mg Tablets	G902211	Jan-22	28's	07/01/2020
Simvador 20mg Tablets	G902283	Jan-22	28's	29/10/2019
Simvador 40mg Tablets	G803251	Feb-21	28's	27/07/2018
Simvador 40mg Tablets	G803252	Feb-21	28's	27/07/2018
Simvador 40mg Tablets	G803253	Feb-21	28's	27/07/2018
Simvador 40mg Tablets	G803254	Feb-21	28's	27/07/2018
Simvador 40mg Tablets	G802355	Feb-21	28's	27/07/2018
Simvador 40mg Tablets	G902245	Jan-22	28's	14/11/2019
Simvador 40mg Tablets	G902242	Jan-22	28's	19/11/2019
Simvador 40mg Tablets	G902243	Jan-22	28's	30/12/2019
Simvador 40mg Tablets	G902241	Jan-22	28's	29/01/2020

Active Pharmaceutical Ingredient: simvastatin

Brief description of the problem
Lupin Healthcare (UK) Limited has informed us that the affected batches above (also distributed by Discovery Pharmaceuticals/Dexcel Pharma Limited) have been packaged with a version of patient information leaflet (PIL) that does not include the most up to date safety information.

There are no concerns with the quality, safety and efficacy of the product. However, these affected batches are being recalled due to concerns around the omission of the safety information. The information missing from the PILs are as below:

Section 2 What you need to know before you take Simvador:
Do not take Simvador if you:

- If you are taking one or more than one of the following drugs at the same time:
  - ***Cobicistat***
  - ***Lomitapide (used to treat a serious and rare genetic cholesterol condition)***

Section 2 Warnings and Precautions:
Tell your doctor:

- ***If you are Asian, because a different dose may be applicable to you***

Section 2 Other medicines and Simvador:
Do not take Simvastatin and tell your doctor if you are taking:

- ***Elbasvir or grazoprevir (medicines for Hepatitis C virus infection)***
- ***medicines with the active ingredient cobicistat***
- ***amiodarone (used to treat an irregular heartbeat)***
- ***lomitapide (used to treat a serious and rare genetic cholesterol condition)***
- ***daptomycin (a drug used to treat complicated skin and skin structure infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin. Your doctor may decide that you stop taking simvastatin for a while***

Section 3 How to take Simvador
If you stop taking Simvador, talk to your doctor or pharmacist because your cholesterol may rise again. If you have any further questions on the use of this product, as your doctor or pharmacist

Section 4 Possible side effects
The following rare serious side effects were reported:

- ***Hypersensitivity (allergic) reactions including:***
- ***Swelling of the face, tongue and throat which may cause difficulty in breathing (angioedema)***
- ***Severe muscle pain usually in the shoulders and hips***
- ***Rash with weakness of limbs and neck muscles***
- ***Pain or inflammation of the joints***
- ***Inflammation of the blood vessels (vasculitis)***
- ***Unusual bruising, skin eruptions and swelling (dermatomyositis), hives, skin sensitivity to the sun, fever, flushing***
- ***Shortness of breath (dyspnoea) and feeling unwell***
- ***Lupus-like disease picture (including rash, joint disorders and effects on blood cells)***

The following very rare serious side effect was reported:

- ***A serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis)***

The following side effects have also been reported rarely:

- ***Trouble sleeping (very rare)***

The following side effects have also been reported but the frequency cannot be estimate from available information (frequency unknown)

- Inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or ***fever***

Advice for healthcare professionals

Stop supplying the above batches immediately. Quarantine all stock and return it to your supplier using your supplier's approved process.

As a general reminder, patients who experience side effects from taking any medicines should be encouraged to report a suspected problem or incident via the Yellow Card scheme and seek medical advice accordingly.

Further Information

For stock control enquiries please contact +44 (0) 1565 751 378 Option 2 or information@lupin.com

For more information or medical information enquiries please contact +44 (0) 1565 751 378 Option 1 or Pharmacovigilance Department at EU-PV@lupin.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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