Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 12 February 2020 EL (20)A/06 Our Ref: MDR 143-01/20

Dear Healthcare Professional,

Accord Healthcare Ltd

Atrolak XL 50mg Prolonged-release tablets PL 20075/0213

Batch Number	Expiry Date	Pack Size	First Distributed
322729	05/2021	60	19/12/19
Y06455	10/2021	60	03/09/19

Atrolak XL 150mg Prolonged-release tablets PL 20075/0446

Batch Number	Expiry Date	Pack Size	First Distributed
Y04771	10/2021	60	06/11/19
Y04788	10/2021	60	27/09/19
Y02374	05/2021	60	07/08/19

Atrolak XL 200mg Prolonged-release tablets PL 20075/0214

Batch Number	Expiry Date	Pack Size	First Distributed
X17653	02/2021	60	24/11/19
Y06710	08/2021	60	18/11/19

Atrolak XL 300mg Prolonged-release tablets PL 20075/0215

Batch Number	Expiry Date	Pack Size	First Distributed
Y06909	09/2021	60	04/10/19
X21602	05/2021	60	07/04/19
X19649	03/2021	60	03/07/19
X19866	03/2021	60	11/06/19

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Atrolak XL 400mg Prolonged-release tablets PL 20075/0216

Batch Number	Expiry Date	Pack Size	First Distributed
X21825	05/2021	60	10/10/19
X18765	03/2021	60	05/07/19

Active Pharmaceutical Ingredient: quetiapine fumarate

Brief description of the problem
Accord Healthcare Ltd has informed us that the Patient Information Leaflet (PIL) within the packs for the above batches is missing the side effects identified from post-marketing experience that are documented in Section 4. (Possible Side Effects) of the PIL:

- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).** Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). Stop using Atrolak XL [quetiapine] if you develop these symptoms and contact your doctor or seek medical attention immediately.

It is important that any patients who notice the symptoms seek immediate medical advice.

Advice for healthcare professionals

When dispensing this product, please check the Marketing Authorisation Holder and the batch number; if any of the above batch numbers are being dispensed, ensure that patients are aware of any missing information.

The current PILs includes the special warning and precautions and should be issued when this product is dispensed. Click here for Atrolak XL PILs available from the electronic medicines compendium (emc).

Further Information
For more information or medical information queries, please contact: Accord Medical Information Department on 01271 385257.

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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