Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	17 October 2019
Reference:	CEM/CPhA/2019/26
Category:	Class 4: For Information
Title:	Class 4 Drug Alert, For Information / Action, Alliance Pharmaceuticals Limited, Xonvea 10 Mg/10 Mg Gastro-Resistant Tablets
For Action by:	Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack' Community Pharmacists Hospital pharmacies Chief Pharmacists
For Information:	See Annex 2 – Distribution List
What is this about:	Full details are set out below.
Why has it been sent:	For your information, action and to pass on to colleagues.

Issue:

Alliance Pharmaceuticals Ltd has informed the MHRA that the Patient Information Leaflet (PIL) for Xonvea 10 mg/10 mg gastro-resistant tablets (doxylamine succinate and pyridoxine hydrochloride) is missing the possible side effects from post-marketing experience and the associated class effects that are documented in the Summary of Product Characteristics (SmPC).

Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website https://www.gov.uk/drug-device-alerts.

Appendix 1

To: Chief Executives of Health Boards and NHS Trusts

To: Medical Directors of Health Boards

To: Nurse Directors Health Boards

To: Directors of Public Health

To: Hospital Principals and Chief Pharmacists to action as per alert

To: **NHS Wales Shared Services Partnership to forward to:**

Dispensing General Practitioners

Community Pharmacists

Deputising services

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales

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: 16 October 2019 EL (19)A/26 Our Ref: MDR 025-10/19

Dear Healthcare Professional,

Alliance Pharmaceuticals Limited

Xonvea 10 mg/10 mg gastro-resistant tablets PL 16853 / 0147

(doxylamine succinate and pyridoxine hydrochloride)

Batch Number	Expiry Date	Pack Size	First Distributed
1510	30 November 2021	1 x 20	25 September 2018
1525	31 December 2021	1 x 20	05 December 2018
1527	31 January 2022	1 x 20	17 December 2018

Brief description of the problem
Alliance Pharmaceuticals Ltd has informed us that the Patient Information Leaflet (PIL) is missing the possible side effects from post-marketing experience and the associated class effects that are documented in the Summary of Product Characteristics (SmPC). The change concerns:

Possible side effects (not present on the PIL):

- hypersensitivity (allergic reactions)
- feeling anxious, difficulty sleeping (insomnia), nightmares, feeling disorientated
- headaches or migraines
- tingling, pricking or numbness of skin
- restlessness and a need to move constantly
- problems with eyesight or blurred vision
- sensation of spinning dizziness
- difficulty breathing, awareness of heartbeat or increased heart rate
- full or bloated feeling, stomach pains, constipation or diarrhoea
- excessive sweating, skin reactions such as itchiness or rash
- difficulties or pain with passing urine
- discomfort in the chest
- general discomfort, feeling irritable

Class effects (not present on the PIL):

- Anticholinergic effects (blockage of the activity of organs that receive nerve impulses through a substance called acetylcholine) include: dry nose and throat; double vision (diplopia); ringing or humming in the ears (tinnitus); inflammation of the inner ear which develops within a short time (acute labyrinthitis); shaking (tremors) and nervousness; involuntary repetitive movements of the face (facial dyskinesia). In addition, feeling of tightness in the chest, thick mucus in the chest (bronchial secretions); high-pitched whistling sound often associated with difficulty in breathing (wheezing); stuffy nose, feeling chills; early menses; altered state of mind such as hallucinations, delusions, confusion and disturbed thoughts (toxic psychosis); or feeling faint have been reported.

- Rarely, in patients using some antihistamines, low levels of white blood cells (agranulocytosis), reduced blood in the body due to increased destruction of blood cells (haemolytic anaemia), decreased clotting blood cells (thrombocytopenia), decreased red, white and clotting cells in the blood (pancytopenia), and increased appetite, sometimes with weight gain, have been reported.

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

Alliance Pharmaceuticals Ltd is in process of updating the PIL and this will be effective on release of all new batches to the market.

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 SmPC includes the missing side effects and class effects:

https://www.medicines.org.uk/emc/product/9344

Further Information
For more information or medical information queries, please contact: medinfo@alliancepharma.co.uk

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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