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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

27 August 2024

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 DRUG ALERT 40 2024 – CLASS 4 MEDICINES DEFECT
INFORMATION – CAUTION IN USE – CHEMIDEX PHARMA LTD – PONSTAN 250MG
CAPSULES AND PONSTAN FORTE 500MG TABLETS MEFENAMIC ACID**

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 NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 27 August 2024

EL (24)A/40

Our Ref: DMRC-31085549

Dear Healthcare Professional,

Chemidex Pharma Ltd

Ponstan 250mg Capsules

PL 17736/0006

SNOMED Code: 1862111000001104

Batch No	Expiry Date	Pack Size	First Distributed
23I114	Sep-2028	100	20Mar2024
23I115	Sep-2028	100	25Jan2024
23I120	Sep-2028	100	20Mar2024
23I121	Sep-2028	100	27Mar2024
23I122	Sep-2028	100	27Mar2024

Ponstan Forte 500mg Tablets

PL 17736/0007

SNOMED Code: 1867211000001108

Batch No	Expiry Date	Pack Size	First Distributed
23J153	Oct-2027	100	24Jun2024
23J155	Oct-2027	100	22Mar2024
23J172	Oct-2027	100	22Mar2024

Active Pharmaceutical Ingredient: Mefenamic acid

Brief description of the problem

Chemidex pharma ltd has informed the MHRA that the patient information leaflet (PIL) in the cartons for the batches listed in the tables above for Ponstan 250mg capsules and Ponstan Forte 500mg tablets include an out of date PIL, dated March 2020 and January 2021 respectively. The latest PIL, authorised in February 2023 includes updated information related to the use of the product during pregnancy, which is not mentioned in the out of date PILs.

Advice for healthcare professionals

Healthcare professionals are advised to review the information contained within this notification and take this into account when prescribing these products. When product from batches included in the tables are supplied or dispensed, please ensure that patients are aware of the missing information.

The electronic versions of the SmPC are up to date and can be accessed via the following links:

[Ponstan Capsules 250mg - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)



Medicines & Healthcare products Regulatory Agency

[Ponstan Forte Tablets 500mg - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

Advice for patients

Patients should continue to take medicines from the impacted batches as prescribed by your healthcare professional. This does not affect the quality of the product. There is a warning in the patient information leaflet (PIL) which accompanies the medicine, for the patient to contact their doctor in case of pregnancy. The updated PIL can be accessed via the following link:

[Ponstan Capsules 250mg - Patient Information Leaflet \(PIL\) - \(emc\) \(medicines.org.uk\)](#)

[Ponstan Forte Tablets 500mg - Patient Information Leaflet \(PIL\) - \(emc\) \(medicines.org.uk\)](#)

If you have any concerns about the information provided with your medicine, please speak with your pharmacy team in the first instance. If you have concerns about a medicine you may be using, please contact your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please email essentialpharmaUK@EU.ProPharmaGroup.com, or telephone +44 (0)1423 850700.

For stock control enquiries please email commercial@essentialpharmagroup.com.

Recipients of this Medicines Recall 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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