National Patient Safety Alert

MHRA

Recall of Co-codamol 30/500 Effervescent Tablets, Batch 1K10121, Zentiva Pharma UK Ltd due to precautionary risk of causing overdose

Date of Issue:	16-Jun-21	Reference No:	NatPSA/2021/004/MHRA

This alert is for action by: primary and secondary care, specifically those involved in pharmacy services, including dispensing general practices.

This is a safety critical and straightforward National Patient Safety Alert. Implementation should be coordinated by a senior member of staff e.g. Chief Pharmacist/Superintendent Pharmacist

DMRC Medicines Defect Classification	NatPSA equivalent to Class 1 Recall Notification

Explanation of identified safety issue:

Zentiva Pharma UK Limited have notified the MHRA of an issue related to the homogeneity of a batch of Co-codamol 30/500 Effervescent Tablets that could result in a potential underdose and lack of efficacy or an overdose.

Active Pharmaceutical Ingredients:

- 30mg codeine phosphate hemihydrate
- 500mg paracetamol

The specific batch is being recalled as a precautionary measure due to the outcome of an ongoing investigation by the Marketing Authorisation Holder (MAH) which has concluded that there is the potential for some tablets to have too little active ingredients (codeine phosphate and paracetamol) in them and some tablets to contain too much active ingredients.

Due to the potential for some tablets to contain higher amounts of the active ingredients than claimed, there is a risk, in severe cases, that overdose could lead to symptoms of circulatory and respiratory depression, which may be life-threatening and can be fatal.

Additionally this risk may be more significant in elderly patients, patients with severe renal and hepatic impairment and also in patients treated with paracetamol/codeine combination long-term and whose dosage is close to the maximum daily dose (8 tablets in 24 hours for adults and children above 16 years; 4 tablets in 24 hours for children 12-15 years).

Actions required

Co-codamol 30/500 Effervescent Tablets

- **Company Name:** Zentiva Pharma UK Ltd
- **PL 17780/0046**
- Batch Number: **1K10121**
- Expiry Date: **December 2023**
- Pack Size: **100 tablets**
- Batch Size: **4464 packs**
- First Distributed: **05 March 2021**

Actions to complete by 21-Jun-21:

The action to recall should be coordinated by the Chief Pharmacist/Superintendent Pharmacist and Dispensing GPs.

1. Stop supplying the above batch immediately.
2. Identify and contact all patients and customers who have been dispensed the impacted batch after 05 March 2021.
3. Ask patients to urgently return this stock to the pharmacy for replacement.
4. Quarantine all remaining stock and return it to your supplier/MAH using your supplier's approved process.

For further detail, resources and supporting materials see: www.gov.uk/drug-device-alerts

For any enquiries about this alert contact: DMRC@mhra.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to regulatory action

Additional information:

Product Information:

Zentiva Pharma UK Limited

Co-codamol 30/500 Effervescent Tablets			PL 17780/0046
Batch Number	**Expiry Date**	**Pack Size**	**First Distributed**
1K10121	December 2023	100	March 2021

Defective Medicines Report Centre Reference: MDR 144-06/21

Further information:

The MAH have concluded that due to potential for higher amounts of active ingredients than the label claim, risk may be more significant in patients in the following risk groups:

- elderly patients;
- patients with severe renal and hepatic impairment;
- and also, in patients treated with paracetamol/codeine combination chronically and whose dosage is close to the maximum daily dose (8 tablets in 24 hours for adults and children above 16 years; 4 tablets in 24 hours for children 12-15 years).

General symptoms of opioid toxicity include coma, confusion, somnolence, shallow breathing, small pupils, nausea, vomiting, constipation and lack of appetite. In severe cases this may include symptoms of circulatory and respiratory depression, which may be life-threatening and can be fatal.

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur.

In severe poisoning, hepatic failure may progress to encephalopathy, gastrointestinal bleeding, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is likely in adults who have taken 10g or more of paracetamol. More details related to Co-codamol adverse events could be found in the Summary of Product Characteristics.

As this recall only affects one specific batch and there is no expected shortage or supply concern, therefore alternative batches of this product and alternative products are available.

Reference Information:

1. Class 1 Medicines Recall Notification including patient communication letter– Click Here

2. Summary of Product Characteristics: https://www.medicines.org.uk/emc/product/464/smpc#gref

Defective Medicines Report Centre/Medicines and Healthcare products Regulatory Agency
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574

Please check website www.gov.uk/drug-device-alerts for when actions should be ceased or advice to check for date restriction are lifted.