MPS 2787
MMS 2005

HSC Business Services Organisation

DRUG ALERT

CLASS 1 MEDICINES RECALL

Action Now - Including Out of Hours

Patient / Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Zentiva Pharma UK Limited

PL 17780/0046

Co-codamol 30/500 Effervescent Tablets

Batch Number	Expiry Date	Pack Size	First Distributed
1K10121	December 2023	100	March 2021

Active Pharmaceutical Ingredients: 30mg codeine phosphate hemihydrate, 500mg paracetamol

Brief description of the problem

Zentiva Pharma UK Limited is recalling the above batch of Co-codamol 30/500 Effervescent Tablets as a precautionary measure due to an issue with the homogeneity of the batch. This issue means 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. The current investigation has highlighted that tablets have been identified where the content of both codeine and paracetamol is less than the label claim.

Due to the potential for some tablets to contain higher amounts of the active ingredients than claimed, there is a risk, in severe cases of overdose. This recall is extended to patient level as this risk may be more significant in patients in the following risk groups:

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- 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 information side effects and what to look out for can be found in the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL).

- SmPC: https://www.medicines.org.uk/emc/product/464/smpc#gref
- PIL: https://www.medicines.org.uk/emc/files/pil.464.pdf

Advice for healthcare professionals

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

- Contact all patients who have been dispensed the impacted batch and ask them to urgently return this stock to the pharmacy for replacement.

- See page 3 and 4 for a suggested patient letter to assist with contacting patients. However, local practices may differ. The most important thing is that affected patients are contacted as soon as possible.

- Patients should be advised to report any side effects to their healthcare professional and via the MHRA Yellow Card Scheme https://yellowcard.mhra.gov.uk/

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Advice for patients

- If you are in possession of the impacted batch, you should return your pack urgently to the pharmacist, doctor, or healthcare professional who dispensed it to you. They will be able to provide you with a replacement.

- If you are in any doubt, please contact your pharmacist, doctor or healthcare professional for advice as to whether you are in possession of an affected batch.

Further Information

For more information or medical information queries please contact 0800 0902408 or email UKMedInfo@zentiva.com

For supply queries, please contact 0844 8793188 or email gfd-customerservices@zentiva.com.
Please contact claims@zentiva.com to arrange return and replacement of affected packs in your possession.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

Pharmaceutical Services
2 Franklin Street
BELFAST
BT2 8DQ

Telephone No. 028 9536 0333

Pharmaceutical website: http://www.hscbusiness.hscni.net

16th June 2021

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Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

INFORMATION FOR PATIENTS – MEDICINES RECALL

Zentiva Pharma UK Limited

PL 17780/0046

Co-codamol 30/500 Effervescent Tablets 100s

Zentiva Pharma UK Limited is recalling a specific batch of Co-codamol 30/500 Effervescent Tablets (Pack Size 100 tablets) as a precautionary measure due to an issue with the consistency of the batch. You are being contacted because we think you might have been provided with this medicine.

This specific batch may contain too little medicine or too much medicine. If it contains too much medicine, there is a risk of overdose of paracetamol and the opioid medicine codeine. Overdose of these medicines can be dangerous.

If you are in possession of a pack bearing the following information:

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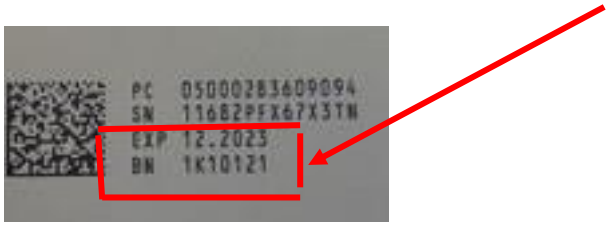
BATCH NUMBER (BN): 1K10121
EXPIRY DATE (EXP): 12.2023

You should return your pack urgently to the pharmacist, doctor, or healthcare professional who dispensed it to you. They will be able to provide you with a replacement.

You will find the Batch Number and Expiry Date on the end panel of your pack



If you are in any doubt, please contact your pharmacist, doctor or healthcare professional for advice as to whether you are in possession of an affected batch.

The leaflet provided with your medicine contains symptoms of paracetamol or opioid overdose to be aware of.

Your pharmacist, doctor or healthcare professional is aware of this recall and can answer any questions you may have and arrange to dispense an alternative pack to you.

If you have any questions that cannot be answered by your pharmacist, doctor or healthcare professional you can contact Zentiva using the email address UKMedInfo@zentiva.com

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.