Co-codamol 30/500 Effervescent Tablets recalled

People who use Co-codamol 30/500 Effervescent Tablets, widely used for pain relief, are today being asked to check the batch number on the labels of packs to ensure they are not one of 4,464 packs which are being recalled due to safety concerns. This advice follows a Class 1 National Patient Safety Alert that has been issued.

Manufacturer, Zentiva Pharma UK Limited informed the MHRA that packs of Co-codamol 30/500 Effervescent Tablets with Batch Number 1K10121 have been found to potentially have too little of the active ingredients (codeine phosphate and paracetamol) in them which may mean that the medicine does not work as it should do, and some tablets may also contain too much of the active ingredients and therefore potentially result in overdose.

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, renal failure may progress to encephalopathy, gastrointestinal bleeding, coma and death.

If patients have packs which match the label details below, they are advised to return them to their pharmacy for a replacement immediately. Patients should not use any tablets from these packs.

We are advising healthcare professionals to stop supplying the affected batch immediately, quarantine all remaining stock and return it to their supplier or the Marketing Authorisation Holder Zentiva Pharma UK Ltd.

MHRA Chief Quality and Access officer, Dr Samantha Atkinson, said:

> Patient safety is always our priority. It is vitally important that people urgently check their packs of Zentiva Pharma UK Ltd Co-codamol 30/500 Effervescent Tablets and if the batch number corresponds to 1K10121, they should stop using them and return them to their pharmacy for a replacement immediately.
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> We are advising people not to take any tablets from these packs given the potential risks of doing so. Healthcare professionals should check their stocks and recall tablets from this batch urgently.

If anyone is concerned then please speak to your healthcare professional and report any adverse reactions via the Yellow Card scheme.

The batch number details are below:

- 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

Notes to editors:

- Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

- MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). MHRA is an executive agency of the Department of Health and Social Care.

- Co-codamol 30/500 Effervescent Tablets contain 30mg codeine phosphate hemihydrate and 500mg paracetamol and are prescribed for the relief of severe pain which is not considered to be relieved by other analgesics such as paracetamol or ibuprofen alone.