Direct Healthcare Professional Communication

1st April 2020

Dear Healthcare professional,

Zentiva Paracetamol 500mg Capsules (pack size 100 capsules) supplied with incorrect information in Patient Information Leaflet

PL 17780/0185 POM; Batch numbers 9NG004 to 9NG027

Summary

- To avoid stock shortages due to Covid-19, Zentiva has released stock of Paracetamol 500mg Capsules (pack size 100) into the market with an anomaly in the patient information leaflet (PIL) within the pack; some text in the PIL is not relevant to paracetamol capsules (see details below)
- If dispensing this product, please inform the patient of this error in the leaflet and direct them to the correct PIL on eMC https://www.medicines.org.uk/emc/product/4195/pil
- Provide reassurance to patients that there are no safety, quality or efficacy issues with these batches of paracetamol 500mg Capsules.

Details of the safety concern

Section 2 of the PIL includes cautionary information from the PIL for co-codamol and which is not appropriate for paracetamol under the following headings (outlined below in bold):

Do not take paracetamol and tell your doctor if:

- **You are taking medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIS are medicines such as moclobemide, phenelzine, tranylcypromine.**

Tell your doctor or pharmacist if you are taking any of the following medicines, or have taken them in the past 2 weeks:

- **Medicines which make you drowsy or sleepy (CNS depressants or a benzodiazepine) such as sleeping tablets, sedatives, tranquilisers, hypnotics and medicines used to treat anxiety or anaesthetics.**
- **Anti-depressant medicines such as imipramine, amitrytyline, tranylcypromine, dosulepin, mirtazapine or chlorpromazine**.

Tell your doctor if you are taking any other medicines:

- **Chloramphenicol – an antibiotic used for infections**
- **The oral contraceptive pill**

No patients will be at risk of taking the medicine inappropriately, as there is no missing safety information.

Call for reporting of adverse events

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme.

It is easiest and quickest to report ADRs online via the Yellow Card website - https://www.gov.uk/yellowcard or via the Yellow Card app available from the Apple App Store or Google Play Store.

Suspected adverse reactions should also be reported to Zentiva: Tel: +44 (0) 800 090 2408 or email: PV-United-Kingdom@zentiva.com

Company contact point:

Should you have any questions or require additional information please contact Zentiva Medical Information: Tel: +44 (0) 800 090 2408 or email: UKMedInfo@zentiva.com.

Yours faithfully

Janet Lewis

Head of Scientific Affairs