

## Direct Healthcare Professional Communication

13<sup>th</sup> March 2020

**Fennings Paracetamol 120 mg/5 ml Oral Suspension (Crescent Pharma Ltd):  
200 ml pack size on a GSL authorisation which should have a maximum pack size of 100 ml**

Dear Healthcare professional,  
Crescent Pharma Ltd in agreement with the Medicines and Healthcare products Regulatory Agency would like to inform you of the following:

### Summary

- Fennings Paracetamol 120mg/5ml Oral Suspension with PL number of 20416/0523 is a GSL status product which should therefore be subject to the maximum pack size restriction of 100 ml.
- A pack size of 200 ml has been produced and released to market which bears the GSL indicator on the packaging but which is a pharmacy status medicine (P).
- Following agreement with the MHRA, the 200 ml packs of PL 20416/0523 bearing GSL status can be supplied via wholesalers to pharmacies or hospitals only, where they will be supplied strictly under control of a pharmacist.
- Pharmacy outlets receiving these 200 ml packs should ensure that these are not placed for open sale but remain under pharmacy only restriction.

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Registered in England. No: 4750933

## **Background on the safety concern**

In accordance with Schedule 15 of The Human Medicines Regulations 2012 (as amended), the maximum pack size of a paracetamol liquid for use in children under 12 years is 100 ml. However, the marketing authorisation concerned (PL 20416/0523) was authorised with a 200 ml pack size. This has resulted in 200 ml packs being produced and labelled as a GSL status medicine which is contrary to the aforementioned Regulations.

In discussion with MHRA, it has been agreed that the packs already manufactured and labelled with GSL status can continue to be supplied via wholesalers to pharmacies and hospitals where these will be supplied under the control of a pharmacist.

Where this control is in place then there is no potential for a safety issue to arise as the affected 200 ml packs bearing the GSL status indicator will only be available via pharmacies/hospitals in the same manner they would be albeit bearing the P status indicator.

## **Call for reporting**

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report ADRs online via the Yellow Card website <https://yellowcard.mhra.gov.uk/> or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing [yellowcard@mhra.gov.uk](mailto:yellowcard@mhra.gov.uk)
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the Yellow Card website (see link above)

## **Company contact point**

If you require further information, please contact Crescent Pharma Ltd, Tel: 01256 772730

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