STATUTORY WARNINGS FOR ALL MEDICINES CONTAINING PARACETAMOL

Although the majority of statutory label warnings for medicines have been removed, the Human Medicines Regulations 2012 [SI 2012/1916] retain statutory warnings for all medicines which contain paracetamol. These warnings are set out in Part 4 of Schedule 25 to the regulations. The warnings have been subject to formal user testing and are more patient-accessible than those used previously.

For ease of reference the statutory warnings are replicated below. You should be aware that there is no transitional period for these provisions. Marketing authorisation holders must take account of these new warnings with any application being submitted to the MHRA which requires updates to labelling and/or patient information leaflets. This is with immediate effect.

Further information is available from *patient.information@mhra.gsi.gov.uk* or by telephoning 020-3080-6000

Medicines Labelling:

Schedule 25
PART 4
Medicines containing paracetamol

14. If the product contains paracetamol, except where the name of the product includes the word "paracetamol" and appears on the outer and immediate packaging, the words "Contains paracetamol".

15. If the product contains paracetamol the words "Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor", which must appear adjacent to either the directions for use or the recommended dosage.

16. If the product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Do not take anything else containing paracetamol while taking this medicine" and—

(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 16 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well"; or

(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".

17. If the product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Do not give anything else containing paracetamol while giving this medicine" and—

(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 17 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well"; or

(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".

18. If the product is required by this Part of this Schedule to show the words set out in paragraphs 14, 16 or 17, those words must appear in a prominent position.

Patient Information Leaflets:

Schedule 27
PART 2
Paracetamol

16. If a medicinal product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if you take too much

of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".

17. If a medicinal product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".