

Guidance Note on the Sale of Paracetamol-containing Medicinal Products by Non-pharmacy Retailers

Paracetamol is a widely used over-the-counter analgesic (pain reliever) and anti-pyretic (fever reducer). It is commonly used for the relief of headaches, other minor aches and pains, and is a major ingredient in numerous cold and flu remedies.

Paracetamol in non-pharmacy retail outlets is available for oral use in tablet, capsule and liquid suspension forms.

The Medicinal Products (Prescription and Control of Supply) Regulations 2003, S.I. No. 540 of 2003, as amended, sets out the requirements governing the sale of paracetamol and paracetamol containing products by non-pharmacy retail outlets such that

1. A non-pharmacy retailer may only supply one pack of a paracetamol medicinal product per sales transaction provided that the pack size meets the criteria below:

PRODUCT FOR ORAL USE	PRODUCT FOR ORAL USE IN CHILDREN UNDER 6
12 or fewer dosage units, each of which contains more than 120mg of paracetamol but not more than 500mg of paracetamol	Packs contain 12 or fewer dosage units, each of which contains no more than 120mg of paracetamol
10 or fewer dosage units, each of which contains more than 500mg of paracetamol but not more than 600mg of paracetamol	Pack size of liquid forms should contain 60ml or less with no more than 120mg of paracetamol contained in 5ml
Packs contain 6 or fewer dosage units, each of which contains more than 600mg of paracetamol but not more than 1000mg of paracetamol	

2. Paracetamol is the only active analgesic substance present and the medicinal product is not restricted to supply through pharmacies. Please refer to the HPRA's latest general sales product information list, which identifies the paracetamol containing medicinal products that can be sold by non-pharmacy retailers which can be found on the HPRA website at: http://www.hpra.ie/img/uploaded/swedocuments/latest_general_sales_list.pdf
The disclaimer at the start of the list should be noted.
3. When supplied in solid unit dosage form (tablet or capsule), each unit dosage form must be individually contained in a blister pack or equivalent form of packaging.