

## Clarifying labelling changes to parenteral formulations of dexamethasone

### Dexamethasone formulations in the UK

- PO tablets are formulated as dexamethasone *base*
- the two parenteral preparations available are formulated as dexamethasone *sodium phosphate*, but are different strengths (see Table).

Table: Dexamethasone base and salt content in UK parenteral formulations

<i>Manufacturer</i>	<i>Presentation</i>	<i>Dexamethasone base (as on the label)<sup>a</sup></i>	<i>Dexamethasone phosphate</i>	<i>Dexamethasone sodium phosphate</i>
Organon	1mL amp	4mg	4.8mg	5.2mg
Hospira	1mL amp	3.3mg	4mg	4.3mg
Hospira	2mL vial	6.6mg	8mg	8.6mg

a. approximate equivalences; dexamethasone base 1mg = dexamethasone phosphate 1.2mg = dexamethasone sodium phosphate 1.3mg.

### Changes in product labelling

Although the products themselves have *not* altered, their product labels have changed (Organon in 2003; Hospira 2010) to express the amount of dexamethasone *base* per volume. This is in line with MHRA and NPSA guidance and is reflected in the BNF 60 (2010), which now provides separate dosing advice for each product, e.g. for cerebral oedema, initial parenteral dose 8–16mg/day (Organon) or 8.3mg (Hospira); this in itself is confusing.

There is scope for further confusion when:

- there is a need to switch between the two parenteral formulations (as was the case in recent shortages and the discontinuation of Organon 2mL vial)
- a patient is prescribed dexamethasone to be administered either by the PO or SC routes and Hospira is the parenteral formulation available.

For example, a prescription for dexamethasone 8mg PO/SC suggests that dexamethasone 8mg *base* should be given both PO and SC, i.e. 2.4mL for the Hospira product (dexamethasone *base* 6.6mg/2mL), which would involve the part use of a vial. This is overly complex, particularly as when the Hospira product was previously labelled as dexamethasone *phosphate* 8mg/2mL, a 2mL volume would have been routinely administered (see Table).

### Palliativedrugs.com advice

Because the dose of dexamethasone is generally adjusted according to response, the clinical relevance of the above is of minor significance. Nonetheless, confusion will be minimized by the consistent use of only one formulation of parenteral dexamethasone. The Organon brand 4mg/mL ampoule has the advantage of retaining familiar dose ranges and provides the simplest solution to situations where the option for either the PO or parenteral route of administration is required.