

## IN USE PRODUCT SAFETY ASSESSMENT REPORT FOR Dexamethasone injection

### SUMMARY OF ASSESSMENT AND ITS FINDINGS

#### BACKGROUND

There are two main issues with dexamethasone sodium phosphate injection –

1. Concerns continue to be raised about how the content and dose of dexamethasone are expressed in packaging and labelling as well as in standard resources such as the BNF. Incidents are still reported where confusion leads to dosage errors. Manufacturers use different approaches to describing dexamethasone content and dose.
2. Aspen has acquired the product license for the Organon preparation and re-formulated the injection to harmonise the formulations of dexamethasone solution for injection available from the company within the EU Market. This has resulted in changes to concentration (from 4mg/mL to 3.8mg/mL), storage conditions and presentation (see table below). With two other dexamethasone injections of lower concentration on the market and prescribers accustomed to prescribing 4mg (and multiples thereof) doses of dexamethasone, there may be a potential risk for administration of incorrect doses.

#### DETAILS OF PRODUCTS ASSESSED

	Organon	Aspen	Hameln	Hospira
Dexamethasone base (on packaging)	4.0mg/mL	3.8mg/mL	3.3mg/mL	3.3mg/mL
Volume equivalence to administer 4mg base	1ml	1.05ml	1.2ml	1.2ml
Dexamethasone sodium phosphate	5.25mg/mL	5.0mg/mL	4.3 mg/mL	4.3mg/mL
Dexamethasone phosphate	Not stated	Not stated	4.0mg/mL	4.0mg/mL
Propylene glycol content	None	None	20mg/mL	None
Sodium sulphite content	None	None	None	None in ampoule. 0.07mg/mL contained in vial
Storage	Store below 25°C	Store in a refrigerator (2-8°C)	Store below 25°C	Store below 25°C
Presentation	Glass ampoule (1mL)	Glass vial (1mL)	Glass ampoule (1mL and 2mL)	Glass ampoule (1mL) and glass vial (2mL)

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When dexamethasone is prescribed, doses are generally expressed in terms of dexamethasone base, therefore:

4mg dexamethasone base = 1.2mL of Hospira/Hameln preparations and 1.05mL of Aspen preparations

8mg dexamethasone base = 2.4mL of Hospira/Hameln preparations and 2.10mL of Aspen preparations

## CONCLUSION FOLLOWING APPLICATION OF VALIDATED ASSESSMENT TOOL

There are 4 key issues highlighted in this report -

**1. Dosage inconsistency** - the expression of dexamethasone doses varies, with different doses for similar or identical indications published in SPCs, in guidelines and in formularies. The dose of dexamethasone prescribed relates to dexamethasone base and familiarity with using 4mg/mL strength in practice may risk the inadvertent administration of only 1mL (instead of 1.2mL) of the Hameln/Hospira brand, and thus the potential to under-dose patients by about 20%; for the Aspen product, administration of 1mL will result in a dose of 3.8mg, a 5% under-dose. This lack of clarity means that some patients may receive an incorrect dose, how critical this is depends on area of use since for many doses adjustment is made based on clinical response. However, protocols and guidance should be consistent in how the dose is reflected.

**2. Storage** - the Aspen product requires storage at 2-8 deg C whereas the other products (Hameln/ Hospira) are stored at standard room temperature. There is a potential for confusion and risk of products being stored at the wrong temperature at pharmacy and ward/clinic level.

**3. Labelling** - the labelling on the amps/vials is not consistent with the terminology used on packaging and in product literature.

**4. Excipients** - a more detailed discussion about the excipients (sodium sulphite and propylene glycol) found in different brands of dexamethasone injection can be found in the [London and South East Regional MI memo](#).

The inconsistencies in presentation are not new. The addition of another dexamethasone product with a different strength to the available choices further increases the potential for errors in prescribing/administration and storage to occur.

Many hospitals have already produced internal guidance for prescribers about the differing strengths of dexamethasone to minimise confusion. They will have to update this guidance now that a product with a different strength and storage conditions has entered the market.

## POTENTIAL NEXT STEPS AND MITIGATION ACTIONS

- Local action** - Hospitals and CCGs need to ensure that all prescribers are aware of the differences between each product in terms of dose and storage and how this may affect their clinical practice. They need to have a process in place to ensure that all protocols and guidelines recommending use of 4mg dose are reviewed as well as correct storage in all settings.
- National action** - national bodies such as NHS England, the MHRA and NICE/BNF could work towards ensuring standardisation in the way that dose and content of dexamethasone products are expressed by manufacturers and in guidelines.
- UKMI** - to update Injectable Medicine Guide for dexamethasone injections.

Note: This is similar to the issue addressed by MHRA in 2013 where they advised that all caffeine products be named and prescribed consistently as caffeine citrate to avoid errors of dosing when prescribed as caffeine

(<http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON300399>)

This report was produced in September 2014 using photographic images (not physical products) of licensed dexamethasone sodium phosphate available at the time of assessment. Images were obtained primarily from pharmaceutical companies, but also from the Commercial Medicines' Unit PharmaQC database (<http://cmu.dh.gov.uk/medicines/pharmaqc-database/>) and from various sources within the NHS.

This report summarises individual product assessments undertaken by: South West Medicines Information and Training and East Anglia Medicines Information Service. Thanks to Northwick Park Medicines Information Centre and London and South East Medicines Information Centre for additional comments.

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For comments email [swmi@uhbristol.nhs.uk](mailto:swmi@uhbristol.nhs.uk)