aspen pharma trading ltd

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18 September 2014

IMPORTANT UK PRODUCT UPDATE INFORMATION - REFORMULATION OF ORGANON'S DEXAMETHASONE 4 MG/ML INJECTION

Dexamethasone 3.8 mg/ml solution for injection (marketed by Aspen Pharma Trading Limited) is replacing Dexamethasone 4 mg/ml Injection (marketed by Organon Laboratories Limited) with changes to concentration, storage conditions and presentation.

Dear Healthcare Professional

Aspen Pharma Trading Limited would like to inform you that the formulation of dexamethasone solution for injection is changing.

The Marketing Authorisation for this product has recently been transferred from Organon Laboratories Limited to Aspen Pharma Trading Limited. This means that the re-formulated product will be marketed by Aspen Pharma Trading Limited.

Summary

- **From 01 October 2014, once all residual stock of Dexamethasone 4 mg/ml Injection is exhausted, all new orders will be supplied as Dexamethasone 3.8 mg/ml solution for injection**

- **The re-formulation has resulted in important changes to:**

  - **Concentration**
  - **Storage conditions**
  - **Presentation**

The information in this communication has been agreed with the Medicines and Healthcare products Regulatory Agency (MHRA).

Further information on the re-formulation of Dexamethasone 4 mg/ml Injection

The new formulation is called Dexamethasone 3.8 mg/ml solution for injection and will be replacing the current product called Dexamethasone 4 mg/ml Injection.

Important information about the new product:

- **Concentration:**

  The concentration of the active substance is now 3.8 mg per ml dexamethasone which is equivalent to 5.0 mg per ml of dexamethasone sodium phosphate.

- **Storage conditions:**

  The re-formulated product must be stored in the refrigerator at 2 – 8 °C.

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- **Presentation:**

  The re-formulated product will be available in a glass vial. Please note that only 1 ml of solution for injection will be available in each glass vial.

Other information on Dexamethasone 3.8 mg/ml solution for injection

Why has the product been reformulated?

The re-formulated product has been developed to harmonise the formulations of dexamethasone solution for injections available from the company within the EU market. Secondly as an improvement to the manufacturing process.

When does this change take place?

From 01 October 2014, once all residual stock of the Dexamethasone 4 mg/ml Injection has been exhausted, all new orders for Dexamethasone solution for injection will be supplied as the new formulation. It is recommended that you continue to use your stocks of the existing formulation prior to using the new formulation.

What are the differences between Dexamethasone 4 mg/ml Injection and Dexamethasone 3.8 mg/ml solution for injection?

A summary of the differences between the current formulation and the new formulation can be found in the following table:

Table 1: A summary of the differences between the current formulations and the new formulation

	Current Formulation	**New Formulation**
Product Trade name	**Dexamethasone 4 mg/ml Injection**	**Dexamethasone 3.8 mg/ml solution for injection**
Concentration of active substance in the form of dexamethasone sodium phosphate	5.25 mg/ml	5.0 mg/ml
Concentration of active substance as equivalent to dexamethasone	4 mg/ml	3.8 mg/ml
Storage conditions	Store below 25°C. Protect from light.	Store in a refrigerator (2 – 8°C). Do not freeze.
EAN number	5013257000681	5013945300529
PIP code	099-1968	117-5082
Presentation	1 ml in glass ampoule	1 ml in glass vial
List Price	£19.99	£19.99

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(from 1 October 2014)		
Manufacturer	N.V. Organon	N.V. Organon

Product livery	
Current Formulation	**New Formulation**
	

These changes are included in the Summary of Product Characteristics (SmPC) and we have revised the package labelling and Patient Information Leaflet (PIL) to also reflect this. A 'Technical Information Leaflet' is now available in all packs as part of the PIL. This is a detachable leaflet which is an extract of the SmPC to aid Healthcare Professionals with the correct administration of the product. Please see Annex 1.

Has the dosage changed?

No changes have been made to the dosage recommendations. However, due to the change in concentration, prescribers and users will have to amend their dilutions accordingly. Please see the Technical Information Leaflet provided in each pack as part of the PIL (text version provided in Annex 1). A dosing card has also been developed to help healthcare professionals administer the new product. You should have received a dosing card with this letter. For further supplies please contact the telephone number printed on the dosing card.

Please refer to the SmPC for information on dosage especially section 4.2 'Posology and method of administration'.

Will the packaging for the re-formulated product look like the previous product?

No. To help differentiate the new re-formulation the packaging has been re-designed with new colours. Please see the pack shot in Table 1.

Following the transfer of the Marketing Authorisation from Organon Laboratories Limited to Aspen Pharma Trading Limited, the new product will be available in Aspen livery and there will be no reference to Organon on the labelling.

The carton has been clearly marked with the statements "*NEW FORMULATION*", "*CHANGE IN CONCENTRATION*" and "*STORE IN A REFRIGERATOR*" to also help highlight the changes. Please see Table 1 for pack shots.

What other dexamethasone solution for injection products will be available from Aspen Pharma Trading limited?

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There will be no other dexamethasone solution for injection products available on the UK market from Aspen Pharma Trading Limited. Organon Laboratories Limited, Merck Sharp and Dohme or Aspen's Dexamethasone
4 mg/ml Injection will no longer be available once the re-formulated product is available on the market.

Adverse Event Reporting

Adverse events experienced with a medicine or vaccine, including any formulation of dexamethasone solution for injection should be reported to the MHRA through the Yellow Card Scheme (www.mhra.gov.uk/yellowcard) or by writing to: FREEPOST YELLOW CARD (no other address details necessary).

Adverse events to dexamethasone solutions for injection may also be reported to the Aspen Pharmacovigilance Department by phone on 0800 0087392 or email: DUB-GM-Drugsafety@ie.aspenpharma.com.

Communication information

For further information on Dexamethasone 3.8 mg/ml solution for injection, please contact Aspen by phone on 0800 0087392 or email:aspenmedinfo@professionalinformation.co.uk.

Please communicate and cascade this information within your local healthcare team using Dexamethasone 4 mg/ml Injection.

Yours sincerely,

Mr. Thomas McConnon
EU Qualified Person for Pharmacovigilance

Annexes:
1. Text of the revised PIL and Technical Information Leaflet
2. Dosing card
3. Medication error reporting form
4. Aspen adverse event reporting form