



Napp Pharmaceuticals Limited

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23rd June 2017

Dear Sir/Madam,

As the appointed distributor for DepoCyte® (cytarabine) in the UK, please find enclosed a Direct Healthcare Professional Communication (DHPC) letter on behalf of Pacira Limited, the Marketing Authorisation Holder for this product. Please note that Napp Pharmaceuticals Limited is part of the same group of independent associated companies as Mundipharma (mentioned within the letter).

This DHPC letter has been generated in agreement with the EMA and MHRA and contains information about a continuing DepoCyte stock shortage across Europe.

The UK stock position remains the same. Unfortunately, Napp have not been able to supply DepoCyte since December 2016 and, as with the rest of Europe, it is still not known when we will be resupplied.

We request that this information is also shared with any other relevant healthcare professionals involved in the usage of DepoCyte.

Should you have any questions about this new safety information please email Napp Medical Information at: MedicalInformationUK@napp.co.uk or call on 01223 424444.

Yours faithfully,

Dr Paul Schofield
Medical Director
Napp Pharmaceuticals Limited

UK/CORP-17029

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Direct Healthcare Professional Communication

26 June 2017

DepoCyte (cytarabine): Follow-up DHPC letter on EU Supply Issue

Dear Healthcare professional,

Pacira Pharmaceuticals, Inc., the manufacturer for DepoCyte[®], and Mundipharma who distribute the product across the EU, in agreement with the European Medicines Agency and the National Competent Authority in your country, would like to update you regarding the supply situation for DepoCyte[®] in the EU:

Summary

- In December 2016 healthcare professionals were initially advised of supply problems with DepoCyte[®].
- Stocks have now run out in some European countries and there will be no DepoCyte[®] stock available across Europe by the end of June 2017. Patients should be transferred to a suitable alternative such as immediate release cytarabine, where available. The treating physician must check whether potential alternative medicinal products are approved for intrathecal use for the treatment of lymphomatous meningitis, as not all strengths of immediate-release cytarabine include this route of administration and/or indication.
- It is not known when Europe will be re-supplied with DepoCyte[®].
- While the shortage is ongoing any remaining stock should only be used for patients who are already being treated with Depocyte. No new patients should be started on treatment with Depocyte[®].
- In addition, when placing an order, healthcare professionals should confirm that the order relates to a patient currently undergoing treatment with DepoCyte[®] and should limit their order to a maximum of 2 vials per order.

Background on the supply shortage

DepoCyte[®] is indicated for the intrathecal treatment of lymphomatous meningitis. In the majority of patients such treatment will be part of palliative care of the disease.

Pacira Pharmaceuticals, Inc., advised Mundipharma of a manufacturing issue with the supply of DepoCyte[®] in October 2016. This manufacturing issue remains to be corrected and Pacira will be unable to deliver new supplies until it has been resolved. Pacira Pharmaceuticals, Inc. is currently working to rectify the issue. However, it is not known when the issue will be resolved.

DepoCyte[®] stock levels in Europe are very limited and in a number of countries there is no stock. In countries where DepoCyte[®] stock remains, Mundipharma is advising to continue to order a maximum of 2 vials at a time to ensure that available stocks of Depocyte[®] are used for existing patients with the most immediate needs.

Lymphomatous meningitis is a serious complication of lymphoma and the majority of patients are simultaneously treated with other systemic anti-cancer therapies. Therefore, a decision on which alternative medicine can be used instead of Depocyte[®] can only be made by a treating physician based on the pharmacokinetic activity and tolerability profile as well local availability of these medicines.

Mundipharma and Pacira are working closely with the National Competent Authorities and the European Medicines Agency to keep them informed of the product supply situation.

DHPC letters were previously distributed in December 2016 and February 2017 advising of the supply shortage. This follow-up letter is being sent to clarify that currently there is an out of stock situation in a number of countries, which will extend into all countries by the end of June 2017.

Company contact point

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