

## **Direct Healthcare Professional Communication on the association of daptomycin (Cubicin<sup>▼</sup>) with eosinophilic pneumonia**

**Dear Healthcare Professional**

### **Summary**

- **There have been rare but potentially serious reports of eosinophilic pneumonia associated with daptomycin use.\***
- **The most common symptoms of eosinophilic pneumonia include cough, fever and dyspnoea. The majority of cases have occurred after 2 weeks of treatment.**
- **Healthcare professionals should react promptly to signs of eosinophilic pneumonia with daptomycin treatment. Daptomycin should be discontinued immediately and the patient treated with corticosteroids if appropriate.**
- **Do not re-administer daptomycin to patients with suspected or confirmed cases of eosinophilic pneumonia.**

### **Further information on the safety concern**

Daptomycin (Cubicin) is indicated for the treatment of complicated skin and soft-tissue infections (cSSTI); right-sided infective endocarditis (RIE) due to *Staphylococcus aureus*; and *Staphylococcus aureus* bacteraemia when associated with RIE or with cSSTI.

Since daptomycin was licensed in 2006, there have been reports from Europe and around the world of eosinophilic pneumonia and pulmonary eosinophilia associated with its use. Although a large proportion of cases have been reported in patients who were receiving daptomycin for non-approved indications, use of daptomycin for approved indications has also been associated with this risk. \*While the exact incidence of eosinophilic pneumonia associated with daptomycin is unknown, to date the reporting rate of spontaneous reports is very low (<1/10,000).

The most common symptoms of eosinophilic pneumonia include cough, fever and dyspnoea. Diagnostic findings include increased eosinophils in the lung tissue or bronchoalveolar lavage fluid, along with diffuse infiltrates on chest radiographs. Although clinical suspicion should be raised if there is an elevated peripheral eosinophil count in the setting of pulmonary infiltrates, there have been cases of eosinophilic pneumonia with normal peripheral eosinophil counts. Therefore the absence of peripheral eosinophils does not exclude a diagnosis of eosinophilic pneumonia.

Prompt recognition of the clinical syndrome and its possible association with daptomycin is critical in the care of these patients. In severe cases, hypoxic respiratory insufficiency requiring mechanical ventilation may occur. Clinical management includes drug discontinuation and often includes treatment with corticosteroids.

The overall benefit/risk balance in the approved indications remains positive.

The content of this letter has been agreed with the European Medicines Agency.

**Call for reporting**

Please report any suspected adverse events associated with the use of daptomycin (Cubicin), please see below for details.

Please report suspected adverse reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme online at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk).

Alternatively, prepaid Yellow Cards for reporting are available:

upon request by mail: "FREEPOST YELLOW CARD"

at the back of the British National Formulary (BNF)

by telephoning the Commission of Human Medicines (CHM) free phone line: 0800-731-6789

Or by electronic download through the MHRA website (<http://yellowcard.mhra.gov.uk/downloads/>)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates

Adverse events should also be reported to Novartis Pharmaceuticals on 01276 698370.

**Communication information**

Should you have any questions or require additional information regarding the use of daptomycin (Cubicin) please contact Novartis Medical Information on 01276 698370.