

Ceftazidime

Recommendations:

Amendments to the Product Information

During the assessment of the information in the PSUR the following issue was considered:

Drug reaction with eosinophilia and systemic symptoms (DRESS)

It has been agreed that the following amendments to the Product Information are required:

SmPC wording

Section 4.8 table:

DRESS (frequency unknown) should be included in SOC Skin and subcutaneous disorders. A footnote should be added to the table *'There have been rare reports where DRESS has been associated with ceftazidime'*

Leaflet wording:

There have been rare reports of severe hypersensitivity reactions with severe rash, which may be accompanied by fever, fatigue, swelling of the face or lymph glands, increase of eosinophils (type of white blood cells), effects on liver, kidney or lung (a reaction called DRESS).