

Pharmacy & Therapeutics Committee
Trovafloracin (Trovan®)
7/99

Recommendation: MEC approved

Removal of Trovafloracin/alatrofloracin (Trovan®) from the formulary is recommended after discussion with infectious disease and pulmonary specialists. When further data is available from the FDA formulary status will be reconsidered.

Findings:

The FDA recommended limiting Trovan use in June of 1999 due to liver toxicity.

There have been 100 reports of clinically symptomatic liver toxicity in patients receiving Trovan. Some of these patients developed serious liver injury leading to liver transplant and/or death. At present, FDA is aware of 14 cases of acute liver failure that are strongly associated with Trovan exposure. Four of these patients required liver transplant (one of whom subsequently died). Five additional patients died of liver-related illness. Three patients recovered without transplantation, and the final outcome is still pending on two patients.

Trovan-associated liver failure appears to be unpredictable. It has been reported with both short-term (as little as 2 days exposure) and longer-term drug exposure; therefore the efficacy of liver function monitoring is acceptable managing this risk is uncertain.

Trovan use exceeding 2 weeks duration appears to be associated with a substantially increased risk of acute liver failure.

Liver failure has also been reported following Trovan re-exposure.

See the accompanying letter form the FDA.



Memorial Regional Medical Center
Pharmacy & Therapeutics Committee

Dear Professional Staff,

The Pharmacy & Therapeutics Committee and MEC have approved conversion of Trovan(trovafloxacin/alatrofloxacin mesylate) to non-formulary status due to liver toxicity. Trovan will not be routinely stocked in the pharmacy. Pharmacy will call physicians ordering Trovan to inform them of its non-formulary status. The Committee has recommended a drug usage evaluation for patients placed on Trovan.

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Thank you for your attention to this matter.

Marshall Pierce