Safety Alert
Rhabdomyolysis with fusidic acid and statins

Issue:
Rhabdomyolysis is a rare complication of statin monotherapy.1 However the risk of rhabdomyolysis is much higher when patients are exposed to the combination of systemic fusidic acid (as fusidic acid hemihydrate/sodium fusidate; hereafter referred to simply as ‘fusidic acid’) and a statin, compared with exposure to a statin alone.2

Fusidic acid should not be given with statins because of this risk of serious and potentially fatal rhabdomyolysis.3 Systemic formulations of fusidic acid include tablets, an oral suspension and an intravenous infusion. There is no evidence of this interaction in relation to the topical formulations of fusidic acid (creams, eye drops).4

Evidence of Harm:
It has been known for some time that there is an increased risk of rhabdomyolysis when systemic fusidic acid is used at the same time as some statins.5 In recent years, the number and severity of case reports of rhabdomyolysis suspected to be due to an interaction between fusidic acid and a statin have increased.6 Although the number of cases reported is small, the use of fusidic acid is low, making this a serious safety signal.7 Several cases, some with a fatal outcome, have been reported in Irish hospitals.1,2,5,6 The exact mechanism for this interaction is unknown and therefore could occur with some, or all, statins.3 Since June 2009, the concomitant administration of statins and fusidic acid is contraindicated (prior to this it was classified as a ‘warning’).7

How to Reduce the Risks:
- Systemic fusidic acid should not be given with statins because of a risk of potentially fatal rhabdomyolysis.3
- In patients for whom the use of systemic fusidic acid is essential, statin treatment should be temporarily discontinued throughout the duration of fusidic acid treatment.3
- To ensure clearance of systemic fusidic acid, statin therapy may be reintroduced no sooner than 7 days after the last dose of systemic fusidic acid.3
- Where a patient has acute coronary syndrome or a recent cardiac event, where temporarily stopping a statin is not desirable, discuss case with a Clinical Microbiologist who may be able to recommend an alternative antibiotic and with Cardiology regarding statin management.
- Patients should be clearly advised to seek medical advice immediately if they experience any symptoms of muscle weakness, pain, or tenderness during the period of treatment with a statin regardless of whether or not an interacting medication has been co-administered with the statin.3,8 Symptoms such as myalgia, and signs such as raised creatine kinase level and myoglobinuria, indicating rhabdomyolysis, may occur within days or weeks of commencing fusidic acid in a patient on statin therapy.3,8
- Consider adding a pop-up alert for systemic fusidic acid to pharmacy dispensing systems to advise pharmacists to check statins are not prescribed concomitantly.
- Ensure healthcare staff are aware of the interaction by updating local documentation, e.g. local Prescriber’s Guide and circulating this alert in electronic/written form.

References

Prepared by Eileen Relihan, Medication Safety Facilitator, St James’s Hospital, Dublin 8 on behalf of the Irish Medication Safety Network.
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Email: enquiries@imsn
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