

## Systemic fusidic acid and interaction with statins - Reminder of risk of rhabdomyolysis

HMG-CoA reductase inhibitors, collectively known as 'statins', are a class of medicines authorised in Ireland as an adjunct to diet for the treatment of hypercholesterolaemia, when the response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. They are also authorised as an adjunct to treatment in the secondary prevention of major cardiac events in patients with cardiovascular disease.

Statins can cause a spectrum of muscle disorders ranging from asymptomatic increases in serum creatine kinase concentration to myalgia, myopathy and rarely rhabdomyolysis. The risk of statin myotoxicity is a dose-dependent, class effect, however, the potential for induction of these disorders varies across the individual products due to differences in pharmacokinetics and lipophilicity. The authorised product information accessible from the HPRA website ([www.hpra.ie](http://www.hpra.ie)) includes up to date, detailed information relevant to the individual products, including the potential for interaction with medicines administered concomitantly which may increase the risk of rhabdomyolysis. The HPRA has also previously highlighted the risk of statin associated muscle disorders in its Drug Safety Newsletter (Editions 15 and 26), reminding healthcare professionals of the precautionary measures to take prior to initiation and during treatment to reduce the risk of myotoxicity and rhabdomyolysis during statin therapy.

Fusidic acid and its salts (including sodium fusidate) are antistaphylococcal agents used for the treatment of serious or deep-seated infections requiring good tissue or bone penetration, such as osteomyelitis. Systemic formulations of fusidic acid include tablets, suspensions and intravenous infusions. The co-administration of statins with certain other drugs, including systemic fusidic acid (Fucidin), may increase the potential for myotoxicity. There is no evidence that topical formulations (creams and eye drops) interact with statins.

### Advice to Healthcare Professionals

- Systemic fusidic acid should not be prescribed/administered in conjunction with statins because of a risk of serious and potentially fatal rhabdomyolysis;
- Statin therapy should be temporarily discontinued throughout the duration of fusidic acid treatment. To ensure clearance of fusidic acid, statin therapy may be reintroduced 7 days after the last dose of systemic fusidic acid;
- Patients should always be advised to seek medical advice immediately if they experience any symptoms of muscle weakness, pain or tenderness while treated with a statin.

Cases of rhabdomyolysis (including some with a fatal outcome) suspected to be due to an interaction between fusidic acid and a statin have been reported to the HPRA and other European medicines agencies. The exact mechanism for this interaction is unknown and therefore may occur with some, or all, statins. The product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)) for systemic fusidic acid indicates that concomitant treatment with statins is contraindicated, while as above, the product information for the individual statins highlights the need to temporarily discontinue statin therapy, when treatment with fusidic acid is considered essential.

### Key message

- Rhabdomyolysis is a rare, but potentially fatal complication of statin monotherapy. This risk increases when patients are administered systemic fusidic acid and a statin together, so these medicines should not be co-administered.

*\*Further details on statins and fusidic acid preparations marketed in Ireland available at [www.hpra.ie](http://www.hpra.ie)*

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