



Prescribing Tip No. 191 Date: 1st February 2018



MHRA Guidance – Miconazole Oral Gel Interaction with Warfarin

In March 2016, the Medicines and Healthcare products Regulatory Agency (MHRA) received a Prevention of Future Deaths report from a coroner regarding the death of a patient from intracerebral haemorrhage. The coroner raised concerns about the risks for a drug interaction between miconazole oral gel and warfarin, and a possible lack of awareness of the interaction among healthcare professionals.

In response to this report, the MHRA initiated a review of available data about this interaction. The Commission on Human Medicines was asked to advise on whether measures were needed to minimise risk to patients.

- Since June 2016, the MHRA received 25 Yellow Card reports, bringing the total possible drug interactions with miconazole and warfarin to 175.
- The most common events reported have been increased INR (135 reports), contusion (23 reports), and haematuria (19 reports). A fatal outcome was reported in 3 cases.

Advice for healthcare professionals:

- Bleeding events, some with fatal outcome, have been reported with use of miconazole oral gel by patients prescribed warfarin;
- patients taking warfarin should not use over-the-counter miconazole oral gel (Daktarin[®] Sugar Free 2% Oral Gel) available from pharmacies;
- if the concomitant use of miconazole oral gel with an oral anticoagulant such as warfarin is planned, exercise caution and ensure that you monitor and titrate the anticoagulant effect carefully;
- advise patients taking prescription-only miconazole oral gel and warfarin that if they experience signs of over-anticoagulation, such as sudden unexplained bruising, nosebleeds, or blood in urine, they should stop using miconazole and seek immediate medical attention.

The current “Management of Infection Guidance in Primary Care” recommends avoiding the first line choice of miconazole oral gel for oral candidiasis if the patient is prescribed an oral coumarin such as warfarin, where possible. Instead the recommended second-line option would be:

- Nystatin oral suspension 100 000 units/ml 1ml qds for one week (to advise patient to continue treatment for 2 days after the symptoms resolve).

To contact the Medicines Optimisation Team please phone 01772 214302