

## Miconazole and warfarin - reminder of the potential for interaction

Miconazole is known to enhance the anticoagulant effect of warfarin and reports of significant bleeding episodes associated with concomitant use of these medicines have been well documented in the literature and spontaneously notified to medicines agencies, including the HPRA. The currently approved Summary of Product Characteristics (SmPC) for Daktarin Oral Gel warns that because miconazole inhibits CYP2C9, caution should be exercised in patients on oral anticoagulants, such as warfarin, and the anticoagulant effect monitored (warfarin dose reduction may be needed). The Package Leaflets (PL) for miconazole products advises users to tell their doctor or pharmacist if they are taking warfarin.

In the context of continuing submission of reports of raised **international normalised ratio** (INR) resulting in haemorrhage when miconazole and warfarin are used concomitantly, healthcare professionals are reminded of the following recommendations.

### Advice for Healthcare Professionals

- All miconazole products, including those available OTC (creams, powders and oral gels) can enhance the anticoagulant effect of warfarin. If miconazole and warfarin are used concurrently, the anticoagulant effect should be carefully monitored and, if necessary, the dose of warfarin reduced.
- Patients should be advised to tell their doctor or pharmacist if they are receiving warfarin before using products that contain miconazole (including OTC products).
- Patients should also be advised to seek medical advice immediately if they observe signs of over-anticoagulation during treatment such as sudden unexplained bruising, nosebleeds or haematuria.

### Key Message

- Reports of clinically significant increases in INR due to interaction between miconazole (including OTC preparations) and warfarin have been received by the HPRA. If patients are taking miconazole and warfarin concurrently, the anticoagulant effect should be monitored and the warfarin dose reduced, if necessary.
- Patients should be advised to read the package leaflet that accompanies all medicines, including OTC medicines, and should tell their doctor and pharmacist if they are receiving warfarin before using any products that contain miconazole.

*Further information on miconazole-containing products is available from [www.hpra.ie](http://www.hpra.ie)*

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