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Committee for Medicinal Products for Human Use (CHMP)

# Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: micafungin

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## Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for micafungin, the scientific conclusions of CHMP are as follows:

With regard to the effectiveness of the risk minimisation measures to address the main safety concern of micafungin (development liver tumours observed in rats and the potential relevance of this finding for humans) the performed survey with physicians has shown room for improvement. Therefore the knowledge of physicians with regard to the restricted indication of micafungin in the EU and the educational materials including the checklist should be further improved to avoid exposure of patients without need to a drug which exhibits the important potential risk for hepatocellular tumour formation. This lack of knowledge is mirrored by steeply increasing EU patient exposure and reports on off-label usage. Therefore further amendments of the educational material are considered necessary to significantly improve the effectiveness of the risk minimisation measures.

The CHMP agrees with the scientific conclusions made by the PRAC.

## Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for micafungin the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing micafungin is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisations should be varied.