Prescriber Checklist for prescription of MICAFUNGIN REIG JOFRE (micafungin)

This checklist reminds prescribers about certain aspects of MICAFUNGIN to ensure the product is prescribed appropriately.

The decision to use MICAFUNGIN should take into account the potential risk for the development of liver tumours.

The development of foci of altered hepatocytes and hepatocellular tumours after a treatment period of 3 months or longer were observed in rats. The assumed threshold for tumour development in rats is approximately in the range of clinical exposure. The clinical relevance of this finding is not known.

MICAFUNGIN should therefore only be used if other antifungals are not appropriate.

Tick the boxes that apply. File the completed checklist in the patient`s notes!

PATIENT IDENTIFICATION:	**PRESCRIBER DETAILS:**
	Prescriber name:
	Prescriber signature:
	Date:

- Are other antifungals appropriate to be used? Yes ☐ No ☐

MICAFUNGIN should only be used if other antifungals are not appropriate.

Please check, if any of the following conditions apply to your patient:

1) Severe liver function impairment Yes ☐ No ☐

2) Chronic liver diseases known to represent pre-neoplastic conditions such as: advanced liver fibrosis, viral hepatitis, congenital enzyme defects, cirrhosis, neonatal liver disease Yes ☐ No ☐

3) Concomitant treatment with drugs that have hepatotoxic and/or genotoxic properties Yes ☐ No ☐

Patients should be carefully monitored for liver damage. Early discontinuation of MICAFUNGIN in the presence of significant and persistent elevation of ALT/AST is recommended to minimise the risk of adaptive regeneration and potentially subsequent liver tumour formation.

4) History of haemolysis or haemolytic anaemia Yes ☐ No ☐

Patients who develop clinical or laboratory evidence of haemolysis during MICAFUNGIN treatment should be monitored closely for evidence of worsening of these conditions and evaluated for the benefit/risk of continuing MICAFUNGIN.

5) History of renal impairment Yes ☐ No ☐

Patients should be carefully monitored for worsening of renal function.

If any of the questions (1-5) have been answered with "Yes" prescribe MICAFUNGIN only after a careful benefit/risk assessment.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reig Jofre UK Ltd. on +44(0)330 1359 434.