Important Safety Information

Micafungin Biocon 50 mg and 100 mg

Prescriber Checklist

This document is approved by the Executive Directorate of Pharmacovigilance, at SFDA

Version: 2.0
Date of last revision: November-2024

Micafungin Biocon 50 mg and 100 mg (micafungin) Prescriber Checklist

This checklist reminds prescribers about certain aspects of Micafungin Biocon 50 mg and 100 mg to ensure the product is prescribed appropriately. For complete prescribing information, please refer to the Summary of Product Characteristics. **Please tick the boxes that apply and file the completed checklist in the patient's notes.**

PATIENT IDENTIFICATION:	**PRESCRIBER DETAILS:**	
Please attach patient label here	Prescriber name:	
	Prescriber signature:	
	Date:	

The decision to use Micafungin Biocon 50 mg and 100 mg should take into account the potential risk for the development of liver tumours. Micafungin Biocon 50 mg and 100 mg should therefore only be used if other antifungals are not appropriate.

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

INDICATION:
The following infections caused by Aspergillus species and Candida species: - Candidaemia and invasive candidiasis ☐ - Oesophageal candidiasis ☐ - Prophylaxis of Candida infections ☐ Other (please state):

CONTRAINDICATIONS: If the following applies to your patient, **DO NOT** prescribe Micafungin Biocon 50 mg and 100 mg	
Known hypersensitivity to the active substance (micafungin), other echinocandins,or lactose monohydrate	Yes ☐ No ☐

SPECIAL WARNINGS AND PRECAUTIONS: If any of these apply to your patient, **PRESCRIBE ONLY AFTER** a careful benefit/risk assessment	
• Severe liver function impairment	Yes ☐ No ☐
• Chronic liver diseases known to represent pre-neoplastic conditions (see note), such as: - Advanced liver fibrosis - Viral hepatitis - Congenital enzyme defects - Cirrhosis - Neonatal liver disease	Yes ☐ No ☐
• Concomitant therapy with drugs that have hepatotoxic and/or genotoxic properties	Yes ☐ No ☐
• Concomitant therapy with amphotericin B desoxycholate	Yes ☐ No ☐
• History of haemolysis, haemolytic anaemia or renal impairment	Yes ☐ No ☐
NOTE: Patients should be carefully monitored for liver damage and for worsening of renal function. Early discontinuation 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. During administration of micafungin, anaphylactic/anaphylactoid reactions including shock may occur. Patients who develop clinical or laboratory evidence of haemolysis during micafungin therapy should be monitored closely for evidence of worsening of these conditions and evaluated for the benefit/risk of continuing micafungin therapy.	

INTERACTIONS: Is there concomitant therapy with sirolimus, nifedipine oritraconazole? If Yes, patients should be monitored for sirolimus, nifedipine or itraconazoletoxicity, and the dosage of these drugs must be reduced if necessary.	Yes ☐ No ☐

PREGNANCY: Is the patient pregnant? If Yes, do not use unless clearly necessary.	Yes ☐ No ☐

Please report adverse events through the following channels:
You can report any problem or adverse events through:

The National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA)):

SFDA Call Centre:	19999
E-mail:	npc.drug@sfda.gov.sa
Website	https://ade.sfda.gov.sa/
QR code:	

Or

Marketing authorization Holder Information

Company:	Biocon Pharma Limited
QPPV:	Ammar Alyahia
Address:	4196 Prince Mohamed Bin Salman Road- Hiteen District – Riyadh 13516-6752 Saudi Arabia
Email:	Ammar.alyahia@sarfidapharma.com
Phone:	00966112489103/ 00966504236833 (24 hours)

Biocon

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