Prescriber Checklist for prescription of

This Document has been approved by SFDA

Ezokamine® (micafungin)

This checklist reminds prescribers about certain aspects of EZOKAMINE® (micafungin) to ensure the product is prescribed appropriately. For complete prescribing information, please refer to the Summary of Product Characteristics.

The decision to use EZOKAMINE® should take into account the potential risk for the development of liver tumors. EZOKAMINE® 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:

Please attach patient label here

PRESCRIBER DETAILS:

Prescriber name:

Prescriber signature:

Date:

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

EZOKAMINE® should only be used if other antifungals are not appropriate

INIDCATION:

The following infections caused by Aspergillus species and Candida species:

☐ Candidaemia and invasive candidiasis
☐ Oesophageal candidiasis
☐ Prophylaxis of Candida infections
Other (please state): .....

CONTRAINDICATIONS:

Known hypersensitivity to the active substance (micafungin), other echinocandins, or lactose monohydrate.	Yes ☐	No ☐

If the above applies to your patient, DO NOT prescribe EZOKAMINE®

SPECIAL WARNINGS AND PRECAUTIONS:

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 ☐

If any of these apply to your patient,
PRESCRIBE ONLY AFTER a careful benefit/risk assessment

INTERACTIONS:

Is there concomitant therapy with sirolimus, nifedipine or itraconazole?	Yes ☐	No ☐

If Yes, patients should be monitored for sirolimus, nifedipine or itraconazole toxicity, and the dosage of these drugs must be reduced if necessary.

PREGNANCY:

Is the patient pregnant?	Yes ☐	No ☐

If Yes, do not use unless clearly necessary.

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.

For further information about this product or to report any Adverse Event, please contact:

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