

21.08.2019

רופא/ה רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא

Mycamine 50 mg powder for solution for infusion.
Mycamine 100 mg powder for solution for infusion.

חומר פעיל :

Mycamine 50 mg: Each vial contains 50 mg micafungin (as sodium).
Mycamine 100 mg: Each vial contains 100 mg micafungin (as sodium).

להלן עדכונים בעלון לרופא (טקסט מסומן ירוק משמעותו עדכון, טקסט מסומן צהוב משמעותו החמרה):

[...]

4.4 Special warnings and precautions for use

Hepatic effects:

The development of foci of altered hepatocytes (FAH) 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**. Liver function should be carefully monitored during micafungin treatment. To minimise the risk of adaptive regeneration and potentially subsequent liver tumour formation, early discontinuation in the presence of significant and persistent elevation of ALT/AST is recommended. Micafungin treatment should be conducted on a careful risk/benefit basis, particularly in patients having severe liver function impairment or chronic liver diseases known to represent preneoplastic conditions, such as advanced liver fibrosis, cirrhosis, viral hepatitis, neonatal liver disease or congenital enzyme defects, or receiving a concomitant therapy including hepatotoxic and/or genotoxic properties.

[...]

4.6 **Fertility**, pregnancy and lactation

[...]

4.8 Undesirable effects

[...]

System Organ aClass	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1,000 to < 1/100	Rare ≥ 1/10,000 to < 1/1,000	Not known (frequency cannot be estimated from available data)
Immune system disorders		anaphylactic / anaphylactoid reaction (see section 4.4), hypersensitivity		anaphylactic and anaphylactoid shock (see section 4.4)

[...]

העלון לרופא נשלח למאגר התרופות שבאתר משרד הבריאות www.health.gov.il לצורך העלאתו לאתר וניתן לקבלו מודפס על ידי פניה לבעל הרישום אסטלס פארמה אינטרנשונל בי.וי., ת.ד. 11458, ראש העין.

בברכה
גאי וגנר
רוקח ממונה