30.05.2018

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):

[...]

4.2 Posology and method of administration

Treatment with Mycamine should be initiated by a physician experienced in the management of fungal infections.

Posology

Specimens for fungal culture and other relevant laboratory studies (including histopathology) should be obtained prior to therapy to isolate and identify causative organism(s). Therapy may be instituted before the results of the cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly.
The dose regimen of micafungin depends on the body weight of the patient as given in the following tables:

[...]
Oesophageal candidiasis: micafungin should be administered for at least one week after resolution of clinical signs and symptoms.

Prophylaxis of *Candida* infections: micafungin should be administered for at least one week after neutrophil recovery.

[...]

Treatment duration
Invasive candidiasis: The treatment duration of *Candida* infection should be a minimum of 14 days. The antifungal treatment should continue for at least one week after two sequential negative blood cultures have been obtained and ***after*** resolution of clinical signs and symptoms of infection.

Prophylaxis of *Candida* infections: micafungin should be administered for at least one week after neutrophil recovery. Experience with Mycamine in patients less than 2 years of age is limited.

Hepatic impairment
No dose adjustment is necessary in patients with mild or moderate hepatic impairment (see section 5.2). There are currently insufficient data available for the use of micafungin in patients with severe hepatic impairment and its use is not recommended in these patients (see section 4.4 and 5.2).
Renal impairment

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No dose adjustment is necessary in patients with renal impairment (see section 5.2).

Paediatric population
The safety and efficacy in children (including neonates) less than 4 months of age of doses of 4 and 10 mg/kg for the treatment of invasive candidiasis with CNS involvement has not been adequately established in controlled clinical studies.

Method of administration
For intravenous use.
After reconstitution and dilution, the solution should be administered by intravenous infusion over approximately 1 hour. More rapid infusions may result in more frequent histamine mediated reactions.
For reconstitution instructions see section 6.6.

[...]

4.4 Special warnings and precautions for use

[...]

Patients receiving sirolimus, nifedipine or itraconazole in combination with micafungin should be monitored for sirolimus, nifedipine or itraconazole toxicity and the sirolimus, nifedipine or itraconazole dosage should be reduced if necessary (see section 4.5).

[...]

4.5 Interaction with other medicinal products and other forms of interaction
[...]
Patients receiving sirolimus, nifedipine or itraconazole in combination with micafungine should be monitored for sirolimus, nifedipine or itraconazole toxicity and the sirolimus, nifedipine or itraconazole dosage should be reduced if necessary (see section 4.4).

[...]

4.7 Effects on ability to drive and use machines

Micafungin has no or negligible influence on the ability to drive or use machines. However, patients should be informed that dizziness has been reported during treatment with micafungin (see section 4.8).

4.8 Undesirable effects

Summary of the safety profile
Based on clinical trial experience, overall 32.2% of the patients experienced adverse drug reactions. The most frequently reported adverse reactions were nausea (2.8%), blood alkaline phosphatase increased (2.7%), phlebitis (2.5%, primarily in HIV infected patients with peripheral lines), vomiting (2.5%), and aspartate aminotransferase increased (2.3%).

Tabulated list of adverse reactions

In the following table adverse reactions are listed by system organ class and MedDRA preferred term. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

[...]

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

[...]

6.5 Nature and contents of container

10 ml Type I glass vial with an isobutylene-isoprene (PTFE-laminated) rubber stopper and a flip-off cap. The vial is wrapped with an UV-protective film.

Pack size: packs of 1 vial.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

Mycamine must not be mixed or co-infused with other medicinal products except those mentioned below. Using aseptic techniques at room temperature, Mycamine is reconstituted and diluted as follows:

1. The plastic cap must be removed from the vial and the stopper disinfected with alcohol.
2. Five ml of sodium chloride 9 mg/ml (0.9%) solution for infusion or glucose 50 mg/ml (5%) solution for infusion (taken from a 100 ml bottle/bag) should be aseptically and slowly injected into each vial along the side of the inner wall. Although the concentrate will foam, every effort should be made to minimise the amount of foam generated. A sufficient number of vials of Mycamine must be reconstituted to obtain the required dose in mg (see table below).
3. The vial should be rotated gently. DO NOT SHAKE. The powder will dissolve completely. The concentrate should be used immediately. The vial is for single use only. Therefore, unused reconstituted concentrate must be discarded immediately.
4. All of the reconstituted concentrate should be withdrawn from each vial and returned into the infusion bottle/bag from which it was originally taken. The diluted infusion solution should be used immediately. Chemical and physical in-use stability has been demonstrated for 96 hours at 25°C when protected from light and diluted as described above.
5. The infusion bottle/bag should be gently inverted to disperse the diluted solution but NOT agitated in order to avoid foaming. The solution must not be used if it is cloudy or has precipitated.
6. The infusion bottle/bag containing the diluted infusion solution should be inserted into a closable opaque bag for protection from light.

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
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רוקח ממונה