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SANDOZ A Novartis Division

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EU RMP V3.1 Feb 2021

Voriconazole Healthcare Professional Checklist

Voriconazole
Voricet 200 mg powder for solution for infusion
Voricet 200 mg film coated tablet

SANDOZ A Novartis Division

A) Minimizing the Risk of phototoxicity and skin squamous cell carcinoma

- Voriconazole has been associated with phototoxicity and pseudoporphyria. It is recommend that all patients, including children, avoid intense or prolonged exposure to direct sunlight during voriconazole treatment and use measures such as protective clothing and sunscreen with high sun protection factor (SPF).

- Squamous cell carcinoma (SCC) of the skin has been reported in patients taking voriconazole, some of whom have reported prior phototoxic reactions.

- If phototoxic reactions occur, multidisciplinary advice should be sought and the patient should be referred to a dermatologist. Voriconazole discontinuation would be considered.

- Dermatologic evaluation should be performed on a regular basis, whenever voriconazole is continued despite occurrence of phototoxicity-related lesions to allow early detection and management of premalignant lesions.

- Voriconazole should be discontinued if premalignant skin lesions or skin SCC are identified.

- The above severe events have been reported in relation with long-term voriconazole treatment. Treatment duration should be as short as possible and long tem treatment (greater than 6 months) should be considered only if the benefits outweigh the potential risks.

Please review and answer the questions below for each patient receiving voriconazole:

- Has your patient developed phototoxicity?

  Yes ☐ No ☐

  If Yes, please refer to the Summary of Product Characterisitcs (SmPC) for guidance.

- In case of phototoxicity, did you consider discontinuing treatment with voriconazole?

  Yes ☐ No ☐

  If Yes, please refer to the SmPC for further advice.
  If No, voriconazole discontinuation should be considered. Please refer to the SmPC for further instruction.

- Have you arranged regular dermatologic evaluation for the patient if he/she presented phototoxicity and voriconazole is not discontinued?

  Yes ☐ No ☐

  If Yes, please refer to the SmPC for further details.
  If No, regular dermatologic evaluation shoudkl be arranged promptly.

  Please refer to the SmPC for further details.

- In case of premalignant skin lesions or SCC, did oyu discontinue treatment with voriconazole?

  Yes ☐ No ☐

  If No, voriconazole should be discontinued. Please refer to the SmPC for further advice.

B) Important Information regarding voriconazole and liver function monitoring

- Patients receiving voriconazole must be carefully monitored for hepatic toxicity.
- Clinical management should include laboratory evaluation of hepatic function (specifically aspartate transaminase (AST) and alanine transaminase (ALT)) at the initiation of treatment with voriconazole and at least weekly for the first month of treatment. If there are no changes in these liver function tests (LFT) after one month, monitoring frequency can be reduced to monthly.
- If the LFTs become markedly elevated, voriconazole should be discontinued, unless the medical judgement of the risk-benefit balance of the treatment for the patient justifies continued use.
- There are limited data on the safety of voriconazole in patients with abnormal LFTs (AST, ALT, alkaline phosphatase (AP) or total bilirubin >5 times the upper limit of normal).
- Voriconazole has been associated with elevations in LFTs and clinical signs of liver damage, such as jaundice, and must only be used in patients with severe hepatic impairment if the benefit outweighs the potential risk.
- It is recommended that the standard loading dose regimens be used but that the maintenance dose be halved in patients with mild to moderate hepatic cirrhosis (Child Pugh A and B) receiving voriconazole.
- Voriconazole has not been studied in patients with seevre chronic hepatic cirrhosis (Child Pugh C).

Please review and answer the questions below for each patient receiving voriconazole:

- Have you recently checked LFT results for your patient?

  Yes ☐ No ☐

  If Yes, use these results to closely monitor hepatic drug toxicity. Please refer to the SmPC for guidance.

- Does your patient have hepatic cirrhosis?

  Yes ☐ No ☐

  If Yes, dose moderation is advised. Please refer to the SmPC for details.

- Have you arranged for routine monitoring of LFTs for your patient while he/she is receiving treatment with voriconazole?

  If Yes, please refer to the SmPC for further details.
  If No, routine monitoring shoud be arranged promptly. Please refer to the SmPC for further details.

C) Discussion with your patient

Regarding phototoxicity and skin SCC

- Have you discussed the risks of phototoxicity and skin SCC with voriconazole and the need of regular dermatological evaluation (if phototoxicity occurs)?

  Yes ☐ No ☐

  Have you discussed the need to avoid sunlight and sun exposure (including use of protective clothing and sunscreen with high SPF during treatment with voriconazole?

  Yes ☐ No ☐

- Have you discussed the signs and symptoms of phototoxicity that warrant contacting the doctor immediately?

  Yes ☐ No ☐

- Have you given the patient a patient alert card that was provided to you in the package?

  Yes ☐ No ☐

Regarding hepatotoxicity

- Have you discussed the risk of liver toxicity with voriconazole and the need for periodic monitoring of liver function?

  Yes ☐ No ☐

- Have you discussed the signs and symptoms of liver injury that warrant contacting the doctor immediately?

  Yes ☐ No ☐

Please retain the completed checklist in patient's medical record.

Please report any suspected adverse drug reaction related to voriconazole in the usual way.

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