Direct Healthcare Professional Communication

Dec 2022

Risk of exaggerated hypotension with rapid bolus administration of Vancomycin.

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

Warning and precaution of Use:

Rapid bolus administration (e.g., over several minutes) may be associated with exaggerated hypotension, including shock, and, rarely, cardiac arrest. Vancomycin should be infused in a dilute solution over a period of not less than 60 minutes to avoid rapid infusion-related reactions. Stopping the infusion usually results in a prompt cessation of these reactions.

If red man syndrome occurs, slow the infusion rate to over 1½ to 2 hours and increase the dilution volume. Reactions are often treated with antihistamines and steroids.

The frequency and severity of thrombophlebitis can be minimized by administering the drug slowly as a dilute solution (2.5 to 5mg/ml) and by rotating the sites of infusion.

Background on the safety concern:

Monitoring Parameters:

"Periodic renal function tests, urinalysis, WBC; serum trough vancomycin concentrations in select patients

(e.g., aggressive dosing, unstable renal function, concurrent nephrotoxins, prolonged courses)".

Preparation of solution:

At the time of use, add 10ml of water for injections to the 500mg vial. Vials reconstituted in this manner will give a solution of 50mg/ml.

The reconstituted solution is clear and colourless.

Further dilution is required. Read instructions which follow:

1. Intermittent infusion is the preferred method of administration. Reconstituted solutions containing 500mg vancomycin must be diluted with at least 100ml diluent. 0.9% sodium chloride intravenous infusion or 5% dextrose intravenous infusion are suitable diluents. The desired dose should be given by

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470

intravenous infusion over a period of at least 60 minutes. If administered over a shorter period of time or in higher concentrations, there is the possibility of inducing marked hypotension in addition to thrombophlebitis. Rapid administration may also produce flushing and a transient rash over the neck and shoulders.

2.Continuous infusion (should be used only when intermittent infusion is not feasible). 1-2g can be added to a sufficiently large volume of sodium chloride intravenous infusion or 5% dextrose intravenous infusion to permit the desired daily dose to be administered slowly by intravenous drip over a 24 hour period

References

MEDSAFE: https://www.medsafe.govt.nz/profs/datasheet/v/VancomycinMylaninf.pdf

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470