DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

878/NDA/DPS/08/2018 31st August, 2018

CIRCULAR NO. 20/PS/08/2018

Dear Healthcare provider

RISK OF CRYSTALIZATION OF MANNITOL 20% IV SOLUTION

Mannitol solution for intravenous injection is an osmotic diuretic used to promote diuresis in acute kidney failure and to treat or prevent medical conditions that are caused by an increase in body fluids/water (e.g., glaucoma, kidney failure, cerebral edema).

The National Drug Authority has continued to receive market complaints concerning crystallization of Mannitol 20% IV solution under storage.

It should be noted that Mannitol solutions may crystallize when exposed to low temperature. At higher concentrations, the solutions have a greater tendency to crystallize.

To prevent crystallization of Mannitol solution, healthcare workers are advised to strictly store the product at room temperature (20°C to 30°C). This should include all bulk stores in the pharmacy, ward pharmacies and dispensing Units.

Due to the high tendency of Mannitol solutions to crystallize, NDA would like to advise healthcare workers to;

1) Inspect for crystals prior to administration. If crystals are visible;
   a) Do not attempt to administer the crystalline Mannitol Solution for injection.
   b) Re-dissolve by warming the solution up to 37°C followed by gentle agitation. Solutions should not be heated in water or in a microwave oven due to the potential for product contamination or damage. Only dry heat (for example: a warming cabinet) should be used.
   c) Allow the solution to cool to room or body temperature before re-inspection for crystals and use.
   d) If all crystals cannot be re-dissolved completely, the product must be discarded.
2) Use administration sets with an in-line filter because of the potential for Mannitol crystals to form.

Thank you for your continued cooperation.

Yours Sincerely,

Victoria Nambasa
FOR: DIRECTOR PRODUCT SAFETY

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OUR MISSION
Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

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