# Direct Healthcare Professional Communication

**December 2022**

## Hydroxyethyl Starch Solution for Infusion– Reminder of Safety Measures to Minimize Risk of Kidney Injury and Death

## 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:*


- In 2013 the use of Hydroxyethyl Starch (HES) solutions for infusion was restricted because of an increased risk of kidney injury and mortality in certain patient populations.
- Despite extensive measures in place to protect vulnerable patient populations, final results of a drug utilization study have shown continued high non-adherence to the product information including non-adherence to contraindications.
- **According to EDA technical committee decision; Hydroxyethyl starch infusion must not be used in patients with sepsis, kidney impairment, burns or critically ill patients.**
- **It can be used when in need in case of severe bleeding in emergency situations**.
- Ensure the proper and safe use of its Hydroxyethyl starch (HES)-containing infusion solutions according to their approved product information (the treatment of hypovolaemia in adults and children only if crystalloids are not sufficient to stabilize the patient, and if the anticipated benefit justifies the risk).


**Background on the safety concern & recommendations for Health care professionals:**

Hydroxyethyl starch (HES) solutions for infusion are artificial colloids for volume replacement and are currently indicated for the treatment of hypovolemia due to acute blood loss when crystalloids alone were not considered sufficient.

HES containing products have been the subject of several European assessments of their benefit risk balance over years.

In October 2013, a safety review was completed about an increased risk of kidney dysfunction and mortality in patients with sepsis or critical illness in large randomized clinical trials. The review concluded to restrict the use of HES solutions for infusion to the current indication. The product information was updated, including new contraindications and warnings.



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In October 2017, an additional review of the results of two drug utilization studies (DUSs) was performed. These studies raised concerns because key restrictions are not adhered to in clinical practice and that there was use in contraindicated populations.

Subsequently, in 2018, additional measures have been put in place to reinforce adherence to the authorized conditions of use, including restricting supply of HES solutions for infusion only to hospitals/centers where healthcare professionals expected to prescribe or administer them have undergone a mandatory training on the appropriate conditions of use (i.e. a controlled access programme), and more prominent warnings on the packaging of these solutions. Physicians were advised not to use HES solutions for infusion outside the terms of the marketing authorization as detailed in the summary of product characteristics (SmPC) as this could result in serious harm to their patients.

The marketing authorization holders were requested to conduct an additional DUS to check adherence to the product information, and to demonstrate the effectiveness of these risk minimization measures.

In February 2022, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) assessed the final results of this DUS and concluded that non-adherence to the product information remains despite the extensive additional risk minimization measures implemented in 2018.

The purpose of this communication is to remind healthcare professionals not to use HES solutions for infusion outside the terms of the marketing authorization as detailed in the summary of product characteristics (SmPC) as this could result in serious harm to their patients.

## References

**EMA** https://www.ema.europa.eu/en/news/hydroxyethyl-starch-solutions-infusion-recommended-suspension-market

## 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



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