



Direct Healthcare Professional Communication

November-2022

Risk of Hypertrophic cardiomyopathy after Systemic administration of Hydrocortisone

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

- Systemic administration of Hydrocortisone may increase risk of Hypertrophic cardiomyopathy.
- Hypertrophic cardiomyopathy was reported after administration of hydrocortisone to prematurely born infants.
- Diagnostic evaluation and monitoring of cardiac function and structure should be performed when given to prematurely born infants.

Further Information and recommendations

Hypertrophic cardiomyopathy (HCM) is a heterogeneous, usually familial disorder of heart muscle. The hypertrophic form of cardiomyopathy is frequently genetic, or as part of several neuromuscular disorders. In neonates, especially prematurity, HCM could also be secondary to corticosteroid treatment.

According to the published information related to the above mentioned risk; the decision was to add a cautionary statement for hypertrophic cardiomyopathy in neonates and infants in the Pediatric Use section, based on the following elements:

- Cases of hypertrophic cardiomyopathy have been reported in neonates and infants treated with hydrocortisone preparations overseas.
- Occurrence of transient hypertrophic cardiomyopathy in neonates and infants has been reported.
- Neonates and infants should be carefully monitored by cardiac function tests (such as echocardiogram) as necessary prior to and during administration of this drug.





References

PMDA

<https://www.pmda.go.jp/files/000241914.pdf>

<https://www.pmda.go.jp/files/000242540.pdf>

Call for reporting

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

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451

Fax: +202 – 23610497

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:

Hotline: 15301

