



## Direct Healthcare Professional Communication

July 2023

### *Calcium Gluconate < Product Name > potential risk of underdosing with calcium gluconate in severe hyperkalaemia*

Dear Healthcare Professional,

<MAH> in agreement with 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:**

- Calcium gluconate and Calcium chloride salts are not equivalent in terms of calcium dose.
- Ensure the correct dose is administered to avoid underdosing of calcium. If treated sub-optimally, hyperkalaemia can be fatal.
- Be alert to the risk of inadvertent underdosing if calcium gluconate is used instead of calcium chloride and verify the calcium salt details before administration: 30ml of calcium gluconate 10% provides 6.8mmol of calcium (equivalent to 10ml of calcium chloride 10%).
- Calcium gluconate therapy should be started only in cases of documented severe hyperkalaemia. It should not be routinely administered during cardiac arrest.
- Global 6 incidents showed incorrect calcium gluconate administration (5 fatal, 1 unknown outcome) related to calcium gluconate underdosing; lack of repeat dosing where indicated; lack of potassium-lowering treatment and lack of or inappropriate ECG monitoring.

#### **Background on the safety concern:**

Calcium salts (either calcium chloride or calcium gluconate) are used to stabilize the myocardium and prevent cardiac arrest inpatients experiencing severe hyperkalaemia. However, the two salts are not equivalent in terms of calcium dose.

Treatment of severe hyperkalaemia (plasma concentration  $\geq 6.5$  mmol/l) is a medical emergency and treatment must not be delayed. Calcium gluconate is used to stabilize the myocardium and prevent arrhythmias and cardiac arrest.

Calcium gluconate therapy should be started only in cases of documented severe hyperkalaemia. It should not be routinely administered during cardiac arrest.





The guideline recommends use of either calcium chloride or calcium gluconate. However, the salts are not equivalent in terms of calcium dose. To achieve the recommended calcium dose of 6.8 mmol, 30ml of calcium gluconate 10% or 10ml calcium chloride 10% must be used.

## References

MHRA <https://www.gov.uk/drug-safety-update/calcium-chloride-calcium-gluconate-potential-risk-of-underdosing-with-calcium-gluconate-in-severe-hyperkalaemia>

## Call for reporting

<Company Contacts>:

<EPVC Contacts>

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](mailto:pv.followup@edaegypt.gov.eg)

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

QR Code:



Hotline: 15301

