



## SFDA SAFETY SIGNAL

*“A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature”*

26-02-2026

### **Saudi Food and Drug Authority (SFDA) – Safety Signal of Octreotide and the Risk of Hyperkalaemia**

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Hyperkalaemia** associated with the use of **Octreotide**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

#### **Introduction**

Octreotide acetate injection exerts pharmacologic actions similar to the natural hormone, somatostatin. It is an even more potent inhibitor of GH, glucagon, and insulin than somatostatin. It is indicated for acromegaly, carcinoid tumors and vasoactive intestinal peptide tumors. <sup>[1]</sup> Hyperkalemia is defined as a serum or plasma potassium level above the upper limits of normal, usually greater than 5.0 mEq/L to 5.5 mEq/L. While mild hyperkalemia is usually asymptomatic, high potassium levels may cause life-threatening cardiac arrhythmias, muscle weakness, or paralysis. <sup>[2]</sup> The aim of this review is to evaluate the risk hyperkalaemia associated with the use of Octreotide and to suggest regulatory recommendations if required.

#### **Methodology**

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the potential link between Hyperkalaemia and Octreotide use. The search conducted on January 2026.

#### **Results**

**Cases Review:** Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 42 global case reports while the NPC database resulted in 9 local case reports, which triggers this investigation. The authors used signal detection tool (Vigilyze) to retrieve global cases. <sup>[3]</sup> The author applied WHO Causality assessment tool on all available cases. Four cases were probably linked to Octreotide, six cases resulted in possible association, Three cases resulted in unlikely association, while the remaining twenty-nine cases were unassessable.

**Datamining:** The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicate less statistical association. The IC result is (0.5) for this drug/ADR combination which reflects positive statistical association. <sup>[3]</sup>



**Literature:** The signal team conducted a literature search to identify publications linking this adverse drug reaction to Octreotide. The search identified two published studies suggesting a possible association between the drug and this potential risk. <sup>[4]. [5]</sup>

### **Conclusion**

The weighted cumulative evidence identified from assessed local and global cases, disproportionality analysis and literature are suggestive for causal association between Octreotide and Hyperkalemia. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

### **Report Adverse Drug Events (ADRs) to the SFDA**

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)  
Saudi Food and Drug Authority-Drug sector  
4904 northern ring branch rd  
Hittin District  
Riyadh 13513 – 7148  
Kingdom of Saudi Arabia  
Toll free number: 19999  
Email: [NPC.Drug@sfd.gov.sa](mailto:NPC.Drug@sfd.gov.sa)

### **References**

- 1- DailyMed - OCTREOTIDE ACETATE injection, solution (2024) Nih.gov. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2344ae7a-c2f0-433b-9133-1dcb16bb18a0>.
- 2- Simon LV, Hashmi MF, Farrell MW. Hyperkalemia. [Updated 2023 Sep 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK470284/>
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- 4- Sargent, A.I. et al. (1994) ‘Octreotide-Induced Hyperkalemia’, *Pharmacotherapy The Journal of Human Pharmacology and Drug Therapy*, 14(4), pp. 497–501. Available at: <https://doi.org/10.1002/j.1875-9114.1994.tb02843.x>.
- 5- Sasidharan, S. et al. (2024) ‘Octreotide Causing Hyperkalemia: A Case Report and Review of the Literature’, *Cureus* [Preprint]. Available at: <https://doi.org/10.7759/cureus.68246>.