



## Direct healthcare-professional communication (DHPC)

02-Sep-2025

**Glucagon-like peptide-1 receptor agonists (GLP-1 RAs): Reiteration of information regarding the risk of acute pancreatitis associated with GLP-1 RA products Liraglutide (Victoza®, Saxenda®, Zelyssa®, Evonanz®, Ligma®) Insulin Degludec, Liraglutide (Xultophy®), Semaglutide (Ozempic®, Rybelsus®, Wegovy®, Tasylev®), Lixisenatide (SOLIQUA SOLOSTAR® (in combination with INSULIN GLARGINE)), Tirzepatide (Mounjaro®), Dulaglutide (Trulicity®).**

Dear Healthcare professional,

The marketing authorization holders of medicines containing Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) (Novo Nordisk, Eli Lilly and Company, SANOFI AVENTIS Groupe, Boston Oncology Arabia, AJA Pharmaceutical Industrie), in agreement with Saudi Food and Drug Authority (SFDA) would like to remind you about the risk of acute pancreatitis associated with the use of GLP-1RAs:

### Summary

- This DHPC is being issued at the request of the SFDA.
- GLP-1 RAs are a class of medications used in the treatment of type 2 diabetes mellitus and weight management in accordance with approved indications in Saudi Summary of Product Characteristics (SmPC).
- Use of GLP-1 RAs has been associated with a risk of developing acute pancreatitis. The Saudi local prescribing information and patient leaflet for GLP-1 RAs already contain information regarding the warnings and recommended actions in relation to the risk of acute pancreatitis.
- This communication is not triggered by any new safety data, and no changes have been made to the existing prescribing information and patient leaflet for GLP-1 RAs in context of risk of pancreatitis.
- The risk of acute pancreatitis is already described in the Saudi (SmPC) of GLP-1 RAs under one or both of the following sections<sup>1-13</sup>:
  - Section 4.4 – Special warnings and precautions for use
  - Section 4.8 – Undesirable effects"

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- Patients on GLP-1 RAs should be advised to recognize symptoms of acute pancreatitis. They should be instructed to get immediate medical advice if symptoms occur.
- Treatment with GLP-1 RAs should be discontinued if pancreatitis is suspected and once the diagnosis is confirmed, these products should not be restarted. Caution should be exercised in patients with a history of pancreatitis.

**Further information on the safety concern and the recommendations**

This communication is issued to reinforce awareness among the prescribers, with no change to current labelling or clinical guidance.


Acute pancreatitis has been observed in patients treated with GLP-1 RAs. A class labelling exists for all incretin-based therapies (i.e., GLP-1RA, GIP/GLP-1 RA and DPP-4 inhibitors) concerning the risk of pancreatitis. However, the effects of incretin-based therapy on exocrine function and pancreatic morphology remain unclear. HCPs are requested to refer product information for risk related details including frequency and severity.

**Advice for Healthcare Professionals:**

- HCPs are requested to inform patients of the characteristic symptoms of acute pancreatitis. Symptoms of pancreatitis include but are not limited to persistent, severe abdominal pain, which may radiate to the back, and which may or may not be accompanied by vomiting.
- HCPs are recommended to discontinue treatment with GLP-1 RAs immediately if pancreatitis is suspected and once the diagnosis is confirmed, these products should not be restarted and to initiate appropriate clinical management.
- HCPs are advised to exercise caution when prescribing GLP-1 RAs to patients with a history of pancreatitis.
- HCPs are requested to follow product SmPCs for dosing recommendations.
- HCPs are requested to remind their colleagues of these actions, particularly if they are known to be prescribers of the affected products.

**Call for reporting**






Adverse events related to GLP-1 RAs products should be reported to respective Marketing Authorisation Holders (MAH) or to local authorities in accordance with the national spontaneous reporting system:

National Pharmacovigilance Center (NPC) - Saudi Food and Drug Authority (SFDA)	
<ul style="list-style-type: none"><li>• SFDA call center: 19999</li><li>• E-mail: <a href="mailto:npc.drug@sFDA.gov.sa">npc.drug@sFDA.gov.sa</a></li><li>• Website: <a href="http://ade.sFDA.gov.sa/">http://ade.sFDA.gov.sa/</a></li></ul>	

Product	Company	Reporting Channel
<b>Liraglutide (Victoza®), Saxenda® Insulin Degludec, Liraglutide (Xultophy®), Semaglutide (Ozempic®, Rybelsus®, Wegovy®)</b>	<b>Novo Nordisk Saudi Arabia</b>	E-mail: <a href="mailto:nngulfsafety@novonordisk.com">nngulfsafety@novonordisk.com</a> Website: <a href="https://www.novonordisk.com.sa/">https://www.novonordisk.com.sa/</a>
<b>Tirzepatide (Mounjaro®), Dulaglutide (Trulicity®)</b>	<b>Eli Lilly and Company</b>	E-mail: <a href="mailto:Saudi_Pharmacovigilance@lilly.com">Saudi_Pharmacovigilance@lilly.com</a> Website: <a href="#">Home   Lilly Saudi Arabia</a>
<b>Insulin Glargine &amp; Lixisenatide (SOLIQUA SOLOSTAR®)</b>	<b>Sanofi Aventis Groupe</b>	E-mail: <a href="mailto:Ksa_pharmacovigilance@sanofi.com">Ksa_pharmacovigilance@sanofi.com</a> Mobile: +966544284797 For more information please contact: Email : <a href="mailto:ksa.medicalinformation@sanofi.com">ksa.medicalinformation@sanofi.com</a>
<b>Liraglutide (Zelyssa®, Evonanz®) Semaglutide (Tasylev®)</b>	<b>Boston Oncology Arabia</b>	E-mail: <a href="mailto:Pv@Bostononcology.com">Pv@Bostononcology.com</a> Website: <a href="https://bostononcology.com/boston-oncology-arabia/">https://bostononcology.com/boston-oncology-arabia/</a>
<b>Liraglutide (Ligra®)</b>	<b>AJA Pharmaceutical Industrie</b>	E-mail : <a href="mailto:pv@ajapharma.com">pv@ajapharma.com</a> Website: <a href="https://ajapharma.com/">https://ajapharma.com/</a> Landline: +966114515726 Mobile: +966550113712

Sincerely,

**Qualified Persons Responsible for Pharmacovigilance (QPPVs):**

Company	QPPV name and contacts information	Signature
<b>Novo Nordisk Saudi Arabia</b>	Shoug Alamer +96650068169 +966112728888 <a href="mailto:USGA@novonordisk.com">USGA@novonordisk.com</a>	DocuSigned by:  69AD665F52F54B8...
<b>Eli Lilly and Company</b>	Maryam Alessa +966 56 786 8843 +966 11 461 7800 <a href="mailto:Alessa_Maryam@lilly.com">Alessa_Maryam@lilly.com</a>	Signed by:  7D730692470B4A4...
<b>Sanofi Aventis Groupe</b>	Mossab Shafy Mobile: +966544284797 <a href="mailto:Ksa_pharmacovigilance@sanofi.com">Ksa_pharmacovigilance@sanofi.com</a>	Signed by:  68E4717B65BD4D9...
<b>Boston Oncology Arabia</b>	Thanwa Almehailb +966547643672 <a href="mailto:Talmehailb@Bostononcology.com">Talmehailb@Bostononcology.com</a>	Signed by:  A0BE4B8864F74DE...
<b>AJA Pharmaceutical Industrie</b>	Lama Alzaidi +966114515726 +966542032615 E-mail : <a href="mailto:Lama.alzaidi@ajapharma.com">Lama.alzaidi@ajapharma.com</a>	DocuSigned by:  267FAEA5AA9B43D...

## **Annexes References:**

### **Novo Nordisk**

1. Victoza® Summary of Product Characteristics (SFDA Label).
2. Saxenda® Summary of Product Characteristics (SFDA Label).
3. Xultophy® Summary of Product Characteristics (SFDA Label).
4. Wegovy® Summary of Product Characteristics (SFDA Label).
5. Ozempic® Summary of Product Characteristics (SFDA Label).
6. Rybelsus® Summary of Product Characteristics (SFDA Label).

### **Sanofi Aventis Groupe**

7. Soliqua Solostar® Summary of Product Characteristics (SFDA Label).

### **Eli Lilly and Company**

8. Mounjaro® Summary of Product Characteristics (SFDA Label).
9. Trulicity® Summary of Product Characteristics (SFDA Label).

### **Boston Oncology Arabia**

10. Zelyssa® Summary of Product Characteristics (SFDA Label).
11. Evonanz® Summary of Product Characteristics (SFDA Label).
12. Tasylev® Summary of Product Characteristics (SFDA Label).

### **AJA Pharmaceutical Industrie**

13. Ligra® Summary of Product Characteristics (SFDA Label).

This letter approved by SFDA