<Date>

Jentadueto (linagliptin/metformin hydrochloride): printed package leaflets of specific batches intended for Sweden and Finland contain Norwegian text without the latest safety update

Dear Pharmacists,

Boehringer Ingelheim International in agreement with <the European Medicines Agency> and the <National Competent Authorities of Sweden and Finland> would like to inform you of the following:

Summary

- **Norwegian text has been included by mistake in the printed package leaflets of specific batches which are intended for Finland and Sweden only. This Norwegian text does not contain the latest safety information.**
- **The Finnish and Swedish texts are correct. The Norwegian text should be disregarded.**
- **When dispensing affected batches of Jentadueto inform patients that the Norwegian text in the printed package leaflet should be disregarded.**

Background on the safety concern

Jentadueto is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:

- in patients inadequately controlled on their maximally tolerated dose of metformin alone
- in combination with other medicinal products for the treatment of diabetes, including insulin, in patients inadequately controlled with metformin and these medicinal products;
- in patients already being treated with the combination of linagliptin and metformin as separate tablets.

An error has been identified in the printed package leaflets for Jentadueto 2.5 mg/850 mg and Jentadueto 2.5 mg/1 000 mg film-coated tablets. Norwegian text has been included by mistake in these package leaflets, although the product is marketed in Finland and Sweden only. This Norwegian text does not include the latest EMA-requested safety update stating that metformin is not recommended in patients with known or suspected mitochondrial diseases, including Mitochondrial Encephalopathy with Lactic Acidosis, and Stroke-like episodes (MELAS) syndrome and Maternal inherited diabetes and deafness (MIDD), due to the risk of lactic acidosis exacerbation and neurological complications. The Finnish and Swedish texts are current.

The issue affects the following batches currently on the market or soon to be released:

Sweden:

Product name (active substance)	**Strength**	**Pack size**	**Nordic item number**	**Batch number**	**Expiry date (MM/YYYY)**
Jentadueto *(linagliptin/ metformin hydrochloride)*	2.5 mg /850 mg	60 film-coated tablets	06 56 62	495317	03/2029

Jentadueto *(linagliptin/ metformin hydrochloride)*	2.5 mg /1 000 mg	60 film-coated tablets	56 31 84	484667	11/2028

Finland:

Product name (active substance)	**Strength**	**Pack size**	**Nordic item number**	**Batch number**	**Expiry date (MM/YYYY)**
Jentadueto *(linagliptin/ metformin hydrochloride)*	2.5 mg /850 mg	60 film-coated tablets	06 56 62	478976 489441	09/2028 02/2029
Jentadueto *(linagliptin/ metformin hydrochloride)*	2.5 mg /1 000 mg	60 film-coated tablets	56 31 84	472677 484667 497101 499116	07/2028 11/2028 01/2029 04/2029

Updated product information is available digitally at:

Sweden
FASS: www.FASS.se

Finland
Lääkeinfo: https://laakeinfo.fi/

Norway
Felleskatalogen: www.felleskatalogen.no

Call for reporting

Pharmacists are asked to report any suspected adverse drug reactions in accordance with the national spontaneous reporting system and include batch/Lot number if available. < Healthcare professionals are asked to report any suspected adverse drug reactions in accordance with the national spontaneous reporting system and include batch/Lot number if available>.

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Jentadueto (linagliptin/metformin hydrochloride)
Marketing authorisation holder(s)	Boehringer Ingelheim International GmbH
Safety concern and purpose of the communication	Printed package leaflets of specific batches intended for Sweden and Finland contain Norwegian text without the latest safety information.
DHPC recipients	Pharmacists, Hospital pharmacists The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	Finland, Sweden

Timetable *Delete steps which are not applicable*	**Date**
DHPC and communication plan (in English) agreed by CHMP/CMDh	23 July 2026
Submission of translated DHPCs to the national competent authorities for review	30 July 2026
Agreement of translations by national competent authorities	6 August 2026
Dissemination of DHPC	20 August 2026