

MSD
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9th January 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Januvia® 100 mg film-coated tablets (Sitagliptin) - Temporary supply of Januvia® 100 mg film-coated tablets in German language packs

Dear Healthcare Professional,
MSD, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you of the following:

Summary:

- **There is a current interruption of the Great Britain (GB) supply of Januvia 100 mg film-coated tablets.**
- **To resolve the temporary issue a number of Januvia 100 mg film-coated tablets originally destined for Germany (batch numbers and expiry dates shown below), have been repurposed for GB, and are expected to be on the market from early January 2023.**
- **The product from Germany is manufactured according to the same manufacturing process and quality controls as the Great Britain product.**
- **The only change between the GB and the German product is the language on the packaging (carton and patient information leaflet), the marketing authorisation holder and licence number. The aluminium foil, branding, colour and layout is the same. Please see additional details and mock-up below.**
- **To ensure the English patient information leaflet (PIL) is available to patients, please print the leaflet from the website location provided below and provide this to the patient.**
- **To provide a GB EAN Barcode: 4150008171038**
- **When dispensing these batches or if a patient or caregiver contacts you with concerns about seeing a different packaging for Januvia 100 mg film-coated tablets, check the batch numbers and expiry dates below, and if they match, please reassure them that this product is the same as their usual GB product and is a legitimate licensed product.**

Background

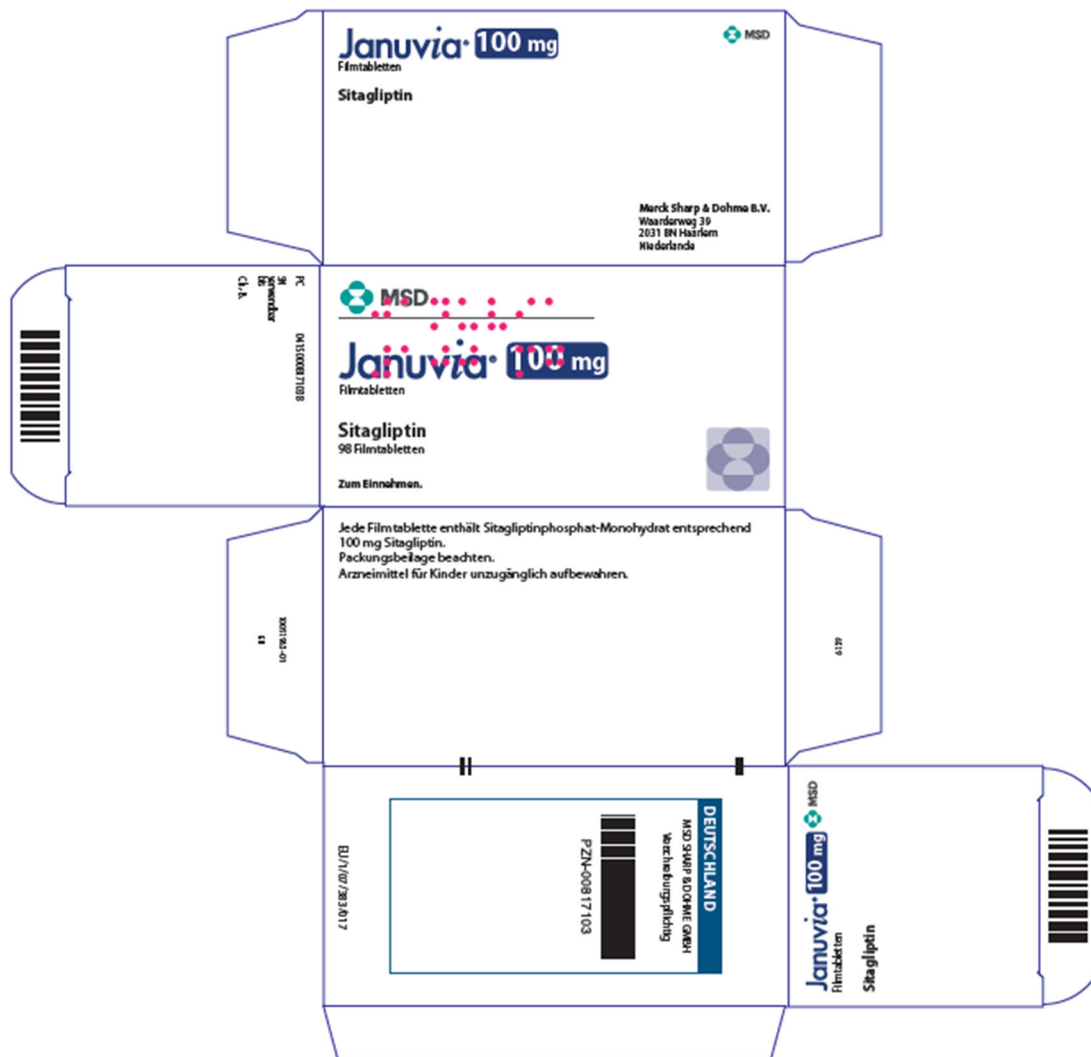
There is a current interruption in the GB supply of Januvia 100 mg film-coated tablets. This interruption is temporary, with re-supply of MSD GB stock anticipated by March 2023. The MHRA have agreed that, to support supply, a limited number of Januvia 100 mg film-coated tablets originally produced for use in Germany can be redirected for use in GB.

The product from Germany is manufactured according to the same manufacturing process and quality controls as the Great Britain product. The only differences between the GB and German product are detailed below. The main difference is the language on the carton and leaflet. The aluminium foil and the branding, colour and layout are the same.

To ensure the English patient information leaflet (PIL) is available for GB patients receiving Januvia 100 mg film-coated tablets, please access the PIL at the URL below, print and provide this to the patient:

<https://www.medicines.org.uk/emc/product/7887/pil>

Please find below an image of the German carton, followed by a list of differences:



	GB product	German Product
Language	English	German
Marketing Authorisation holder	Merck Sharp & Dohme (UK) Limited 120 Moorgate London EC2M 6UR United Kingdom	Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN Haarlem Niederlande
Licence number	PLGB 53095/0037	EU/1/07/383/017
Pack size	28 tablets	98 tablets
Presentation	Film-coated tablets	Filmtabletten
Route of Administration	Oral use	Zum Einnehmen.
Other Info	Each tablet contains sitagliptin phosphate monohydrate equivalent to 100 mg of sitagliptin. Read the package leaflet before use. Keep out of the sight and reach of children.	Jede Filmtablette enthält Sitagliptinphosphat-Monohydrat entsprechend 100 mg Sitagliptin. Packungsbeilage beachten. Arzneimittel für Kinder unzugänglich aufbewahren.

The Batch numbers and expiry dates of the German packs are as follows:

Product Strength	Pack Size	Batch Numbers	Expiry
Januvia 100 mg film-coated tablets	98 tablets	W036048	30 Sep 2025
Januvia 100 mg film-coated tablets	98 tablets	W036049	30 Sep 2025
Januvia 100 mg film-coated tablets	98 tablets	W036050	30 Sep 2025
Januvia 100 mg film-coated tablets	98 tablets	W036051	30 Sep 2025

The EAN barcode is not provided on the German pack. Should this be required for scanning purposes, please enter the following code manually: 4150008171038.

When dispensing these batches or if a patient or caregiver contacts you with concerns about seeing different packaging for Januvia 100 mg film-coated tablets, carefully check the batch numbers and expiry dates below, and if they match, please reassure the patient or caregiver that this product is the same as their usual GB product.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

Call for reporting

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://yellowcard.mhra.gov.uk/>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS, SystemOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or require more information about Januvia 100 mg film-coated tablets, please contact medicalinformationuk@msd.com or call MSD Medical Information services on 0208 1548000.

Yours Sincerely,

A handwritten signature in blue ink, appearing to read 'Dilruwan Herath', with a horizontal line underneath.

Dr Dilruwan Chaminda Herath

Country Medical Director
MSD UK