**Novartis New Zealand Ltd**
12 Madden Street
Auckland 1010
New Zealand
Telephone: 0800 354 335

29 May 2023

Dear Healthcare Professional,

**Product Labelling and Data Sheet updates – Fentanyl Sandoz Transdermal patch**

| Product Name | Sponsor |
|---|---|
| Fentanyl Sandoz Transdermal patch, 12.5 mcg/h (Currently available) | Novartis New Zealand Ltd |
| Fentanyl Sandoz Transdermal patch, 37.5 mcg/h (Not currently marketed) | |
| Fentanyl Sandoz Transdermal patch, 25 mcg/h (Currently available) | |
| Fentanyl Sandoz Transdermal patch, 50 mcg/h (Currently available) | |
| Fentanyl Sandoz Transdermal patch, 75 mcg/h (Currently available) | |
| Fentanyl Sandoz Transdermal patch, 100 mcg/h (Currently available) | |

Sandoz, a division of Novartis, recognises the importance of supplying essential medicines in New Zealand and would like to advise you of the following changes:

1. **Change in expression of strength for Fentanyl Sandoz (fentanyl) 12.5 mcg/h and 37.5 mcg/h with no change to product**

   The expression of strength is an editorial change, with no change to the product itself.

   This change aligns with Duragesic® in other jurisdictions, as well as Fentanyl Sandoz worldwide. There are no changes to the product in terms of formulation, strength, duration or rate of release and no impact to prescribing or/and dispensing practices.

   This update to the description of product strength will be reflected in (but not limited to) the Product packaging and the Data Sheet in alignment with the reference product, Durogesic (fentanyl), and other fentanyl transdermal patch products, please refer to ***Attachment 1.***

   The release rate of the medications remains the same, 12.5 mcg/h and 37.5 mcg/h. As indicated in the Data Sheet, the lowest dose is designated as 12 micrograms/hour (however, the actual dosage is 12.5 micrograms/hour) to distinguish it from a 125 micrograms/hour dosage that can be prescribed by using multiple patches.

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**Table 1: Pharmacode of NZ registered product**

| | Previously registered product | Updated registered product |
|---|---|---|
| | Fentanyl Sandoz<br>Transdermal patch, 12.5 mcg/h | Fentanyl Sandoz<br>Transdermal patch, **12** mcg/h |
| **Pharmacode** | 2472872 | TBC |
| | Fentanyl Sandoz<br>Transdermal patch, 37.5 mcg/h | Fentanyl Sandoz<br>Transdermal patch, **37** mcg/h |
| **Pharmacode** | Not marketed | Not marketed |

The Sponsor acknowledges that this change does not impact the other marketed product strengths (25 mcg/h, 50 mcg/h, 75 mcg/h and 100 mcg/h) expressed on their labels and Data Sheet.

## 2. Minor design change of all Fentanyl Sandoz labels (Carton box and Sachet)

With the change in expression of strength, Fentanyl Sandoz product packaging (carton boxes and sachets) has been updated. The total content of fentanyl in each patch detailed in Table 2, has been relocated under the tradename (i.e., fentanyl 2.1 mg and fentanyl 6.3 mg).

**Table 2: Content of active ingredient per Fentanyl Sandoz patch**

| Fentanyl strength (µg/h) | Quantity of active ingredient (mg/patch) | Effective area ($cm^2$) |
|---|---|---|
| **12.5 µg/h** | 2.1 | 5.25 |
| **25 µg/h** | 4.2 | 10.5 |
| **37.5 µg/h** | 6.3 | 15.75 |
| **50 µg/h** | 8.4 | 21 |
| **75 µg/h** | 12.6 | 31.5 |
| **100 µg/h** | 16.8 | 42 |

*Note: This information is also included in Section 2 of the Fentanyl Sandoz Data Sheet.*

Also, the Controlled Drug Category has been updated from B3 to B1 for all affected presentations effective from 01st of July 2023. We request the information provided is communicated to all staff to ensure safe and correct use of the product.

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**Pharmacovigilance reporting**

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Suspected adverse events should be reported to CARM https://nzphvc.otago.ac.nz/report/ or to Novartis Patient Safety at patientsafety.aunz@novartis.com

Alternatively, any adverse events experienced with the products must be reported by Healthcare Professionals and patients to Sandoz by phone: 0800 354 335 or email patientsafety.aunz@novartis.com

Any product complaints must be reported to Sandoz by phone: 0800 354 335 or email medical.information@sandoz.com

**Further information**

Before prescribing, please review the full Data Sheet and Consumer Medicine Information available on the Medsafe website https://www.medsafe.govt.nz/profs/datasheet/f/fentanylsandozpatch.pdf and https://www.medsafe.govt.nz/consumers/cmi/f/fentanylsandoz.pdf

We anticipate the implementation of the new product labelling in early 2024.

Please forward this information to all relevant staff members in your organisation.

Yours faithfully,

DocuSigned by:
LIZ JOSHI
ACEF26BECDAB4A0...

**Liz Joshi**
Director, Medical, Regulatory Affairs and Quality Assurance
Sandoz Pty Ltd

*Attachment 1 - Data Sheet changes (previous vs updated)*

SANDOZ A Novartis Division

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***Attachment 1 – Data Sheet changes (previous vs updated)***

| Data Sheet Section | Previous | Updated | Comments |
|---|---|---|---|
| **1, 2, 3, 4.2 and 5.2** | 12.5 mcg<br>37.5 mcg | **12** mcg<br>**37** mcg | Minor editorial change (dosage expression) from 12. 5 and 37.5 mcg to 12 and 37 mcg. |
| **2** | NA | Fentanyl Sandoz 12***** mcg<br>Fentanyl Sandoz 37****** mcg<br><br>****The lowest dose is designated as 12 micrograms/hour (however, the actual dosage is 12.5 micrograms/hour) to distinguish it from a 125 micrograms/hour dosage that could be prescribed by using multiple patches.***<br><br>***** actual dosage is 37.5 micrograms/hour.*** | Addition of dosage expression clarification for 12.5 mcg/h and 37.5 mcg/h |

**Note:** We anticipate the implementation of the new product labelling in early 2024.