



Bundesamt für  
Sicherheit im  
Gesundheitswesen  
**BASG**

Unternehmen/Frau/Herr  
Organisationseinheit (optional)  
(z. H.) Vorname Nachname  
Straße  
PLZ Ort

**Datum:** 17.12.2021  
**Kontakt:** Ing. Veronika Heimlich, B.Sc.  
**Tel:** +43 50555 36247  
**E-Mail:** pv-implementation@basg.gv.at  
**Unser Zeichen:** PHV-100522375-A-211216-EUIM  
**Ihr Zeichen:**

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### **PHV-issue: Fentanyl (transmucosal)**

Sehr geehrte Damen und Herren,  
Aufgrund eines PSUR Follow-Up Assessments (PSUFU) durch den Ausschuss für Risikobewertung im Bereich Pharmakovigilanz (PRAC), dessen Ergebnis durch das CMDh bestätigt wurde, kommt es zu der Änderung der Genehmigungen für das Inverkehrbringen der Arzneimittel mit dem Wirkstoff Fentanyl (transmucosal).

(siehe: <http://www.hma.eu/611.html>)

## Recommendations

Based on the review of data submitted, the LMS considers that the product information should be updated as follows.

The following changes to the product information of medicinal products containing the active substance fentanyl are recommended (new text **underlined and in bold**, deleted text ~~strike through~~):

The MAH should put the requested warnings in a clearly visible place, **in bold** and with appropriate font size.

- **To AUROBINDO**

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

7. OTHER SPECIAL WARNING(S), IF NECESSARY

**This product must only be used by patients already taking other opioids for chronic cancer pain.**

~~**Use only as prescribed.**~~

~~**Accidental use can cause serious harm and be fatal.**~~

- **To GRUNENTHAL**

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

~~**Accidental ingestion of this medicine by a child could be seriously harmful or fatal.**~~

7. OTHER SPECIAL WARNING(S), IF NECESSARY

~~**Take RECIVIT strictly as prescribed.**~~

~~**Accidental ingestion use of this medicine could be seriously harmful or fatal.**~~

This product must only be used by patients already taking other opioids **for chronic cancer pain.**  
Read enclosed leaflet for important warnings and directions.

- **To MYLAN (VIATRIS)**

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

7. OTHER SPECIAL WARNING(S), IF NECESSARY

**This product must only be used by patients already taking other opioids for chronic cancer pain.**

~~**Use only as prescribed.**~~

~~**Accidental use can cause serious harm and be fatal.**~~

- **To TEVA**

- Annex IIIa - LABELLING

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

~~**Accidental ingestion of this medicine by a child could be seriously harmful or fatal.**~~

7. OTHER SPECIAL WARNING(S), IF NECESSARY

This product must only be used by patients already receiving maintenance opioid therapy for **chronic** cancer pain. Read enclosed leaflet for important warnings and directions.

~~**Accidental use can cause serious harm and be fatal.**~~

- **To STADA**

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

7. OTHER SPECIAL WARNING(S), IF NECESSARY

~~**Use only as prescribed.**~~

~~**This product must only be used by patients already taking other opioids for chronic cancer pain.**~~

~~**Accidental use can cause serious harm and be fatal.**~~

- **To YES PHARMACEUTICALS**

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

7. OTHER SPECIAL WARNING(S), IF NECESSARY

~~**Use only by patients already taking other opioids for chronic cancer pain.**~~

~~**Use only as prescribed.**~~

~~**Accidental use can cause serious harm and be fatal.**~~

- **To ANGELINI FARMACEUTICA S.A.**

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children ~~at all times.~~

~~Accidental ingestion of this medicine by a child could be seriously harmful or fatal.~~

7. OTHER SPECIAL WARNING(S), IF NECESSARY

This product ~~should~~ **must** only be used by patients already taking other opioids **for chronic cancer pain.** Read enclosed leaflet for important warnings and directions.

~~**Use only as prescribed.**~~

~~**Accidental use can cause serious harm and be fatal.**~~

- **To KYOWA KIRIN HOLDINGS B.V.**

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

7. OTHER SPECIAL WARNING(S), IF NECESSARY

~~**This product should ONLY be used as prescribed. Only for use by people patients already taking other opioid medicines daily for persistent cancer pain.**~~ If the product is used by anyone else, it could represent a ~~SERIOUS~~ risk to their health ~~it can cause serious harm and be fatal.~~

- **To Aristo Pharma**

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

7. OTHER SPECIAL WARNING(S), IF NECESSARY

~~**Use only as prescribed.**~~

~~**This product must only be used by patients already taking other opioids for chronic cancer pain.**~~

~~**Accidental use can cause serious harm and be fatal.**~~

- **To FONTUS HEALTH LIMITED**

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

7. OTHER SPECIAL WARNING(S), IF NECESSARY

~~**Use only by patients already taking other opioids for chronic cancer pain.**~~

~~**Accidental use can cause serious harm and be fatal.**~~

- **TO THE OTHER MAHs**

To date, no reply has been received or established with proposed changes, the LMS considers that these MAHs must propose a revision of the EU labelling if necessary. The following changes to the product information of medicinal products containing the active substance fentanyl are recommended (new text underlined and in **bold**, deleted text ~~strike through~~):

- Annex IIIa - LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

7. OTHER SPECIAL WARNING(S), IF NECESSARY

~~**Use only as prescribed.**~~

~~**This product must only be used by patients already taking other opioids for chronic cancer pain.**~~

~~**Accidental use can cause serious harm and be fatal.**~~