



Bundesamt für  
Sicherheit im  
Gesundheitswesen  
**BASG**

Unternehmen/Frau/Herr  
Organisationseinheit (optional)  
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**Unser Zeichen:** PHV-100691130-A-220208  
**Ihr Zeichen:**

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

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Fentanyl (transdermales Pflaster, Injektionslösung) -PSUSAs (PSUSA/00001370/202104 ) kam das CMDh zu dem Schluss, dass Ergebnisse aus dem PSUR Assessment für alle transmucosalen Arzneimittel, die Fentanyl enthalten relevant sind.

Bei der Umsetzung in die Produktinformation der betroffenen Arzneyspezialitäten beachten Sie auch den CMDh Press release (Meeting vom 14-16 December 2021): <http://www.hma.eu/249.html>



## **Auszug aus dem Report from the CMDh meeting held on 14-16 December 2021**

Products containing fentanyl for transmucosal route of administration

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In the framework of the PSUSA on fentanyl (transdermal patches, solution for injection - nationally authorised product only), the PRAC considered that the increased risk of respiratory depression due to concomitant use of fentanyl (transdermal patches and fentanyl solution for injection) and gabapentinoids should be extrapolated to fentanyl containing medicinal products for transmucosal route of administration.

The following is proposed for all fentanyl containing products for transmucosal route of administration:

- SmPC section 4.5

MAHs should add **gabapentinoids (gabapentin and pregabalin)** to the existing warning on drugs that may potentiate the respiratory depression of opioids in the interaction section.

- PL section 2

In particular, tell your doctor or pharmacist if you are taking/using:

- **Some painkillers for nerve pain (gabapentin and pregabalin)**

The same timelines as for the present PSUSA would apply in accordance with the CMDh guidance on implementing variations.