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**Unser Zeichen:** 16c-151009-00129-A-PHV  
**Ihr Zeichen:**

**Betreff: Sufentanil Citrat – hältige Arzneispezialitäten – Änderungen der Fach- und Gebrauchsinformationen aufgrund des HBD – PSUR Worksharing Projektes**

Sehr geehrte Damen und Herren,

basierend auf der Evaluierung des PSURs im EU-HBD-worksharing Projekt (Verfahrensnummer: PT/H/PSUR/0010/002) kommt es zu der Empfehlung, folgende Ergänzungen in die **Fach- und Gebrauchsinformation** aller Sufentanil Citrat – hältigen Arzneispezialitäten zur aufzunehmen.

Sollten diese bereits aufgenommen worden sein, betrachten Sie dieses Schreiben als gegenstandslos.

**Amendments to the Product Information**

Sections 4.4, 4.5, 4.6 and 4.8 of the SmPC and the corresponding sections of the PL should be amended/updated as specified below in order to update the safety-related information.

**SmPC wording**

**4.4 Warnings and special precautions for use.** The sentence *"Intravenous use in labour or before clamping of the cord during caesarean section is not recommended due to the possibility of respiratory depression in the newborn infant. This is in contrast to the epidural use in labour, during which sufentanil in doses up to 30 µg does not influence the condition of the mother or the newborn."* should be deleted from section 4.4 of the SmPC as it is already present in section 4.3 as a contraindication.

**4.5 Interactions with other medicinal products and other forms of interaction.** The sentence *"However, several reports describe the uneventful use of fentanyl, a related opioid, during surgical or anaesthetic procedures in patients on MAO-inhibitors"* should be deleted from the SmPC as this information is not directly applicable to sufentanil and is not present in the CSP.

**4.6. Fertility, pregnancy and lactation.** The sentence *"Controlled clinical studies during labour (...) but intravenous use is not recommended in labour."* should be amended in section 4.6 of the SmPC to *"Controlled clinical studies during labour (...) but intravenous use is contraindicated in labour."* as agreed in the last CSP.



Oben angeführte Textabschnitte stellen eine Mindestanforderung dar, zusätzliche nationale Hinweise in diesen Abschnitten sind zu belassen.

