This document is part of the risk management plan for Dzuveo 30 micrograms sublingual tablets (sufentanil)

Important information for healthcare professionals regarding risk minimisation

INFORMATION GUIDE INTENDED FOR HEALTHCARE PROFESSIONALS

This guide aims to inform you on the important identified risks related to the use of Dzuveo®: Respiratory depression.

INDICATION AND POSOLOGY

- **Dzuveo® is indicated for the management of acute moderate to severe pain in adult patients.**
- **Dzuveo® <u>should not be administered more than once per hour</u>** (minimum dosing interval is one sublingual tablet per hour) and should not be used beyond 48 hours.

IMPORTANT INFORMATION FOR USE

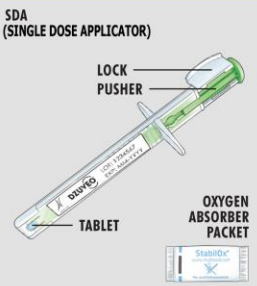
- Dzuveo® should only be used by Healthcare Professionals who are experienced, knowledgeable, and skilled in the management of opioid therapy and particularly the management of opioid adverse reactions, such as respiratory depression.
- Dzuveo® is only to be administered by a Healthcare Professional in a medically monitored setting.
- A medically monitored setting must have the appropriate equipment and personnel trained to detect and manage hypoventilation, with the availability of supplemental oxygen and opioid antagonists, such as naloxone.
- Close monitoring of signs and symptoms of respiratory depression is required.
- Dzuveo® must not be dispensed for pain management at home or continued after the patient is discharged or released from the medically monitored healthcare facility or service.

WHAT ARE THE CONTRAINDICATIONS?

- Do not prescribe Dzuveo® if the patient is allergic to any of the ingredients or excipients.
- Dzuveo® is contraindicated in significant respiratory depression or pulmonary compromise.

INSTRUCTIONS FOR USE

FIGURE 1
DZUVEO® Pouch contents



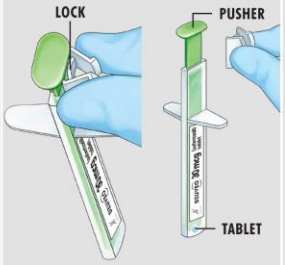
1. Only when ready to administer the medication, **TEAR OPEN** the notched pouch across the top.

The pouch contains one clear plastic Single Dose Applicator (SDA) with a single blue-colored tablet housed in the tip, and an oxygen absorber packet.

REMOVE SDA from pouch.

DISCARD the oxygen absorber packet.

FIGURE 2
Lock removal



2. REMOVE the white Lock from the green Pusher by squeezing the sides together and detaching from Pusher.

DISCARD the Lock.

NOTE: To prevent ejecting the tablet accidentally:
- Do not remove Lock until ready to administer.
- Avoid touching the green Pusher before placing the SDA in the patient's mouth for administration.

FIGURE 3
SDA placement for Administration

3. TELL the patient to open their mouth and touch their tongue to the roof of their mouth if possible.

4. REST the SDA lightly on the patient's lower teeth or lips.

5. PLACE the SDA tip under the tongue and aim at the floor of the patient's mouth or sublingual space.

NOTE: Avoid direct mucosal contact with the SDA tip.

6. GENTLY DEPRESS the green Pusher to deliver the tablet to the patient's sublingual space.

FIGURE 4
Tablet placement in sublingual space

7. VISUALLY CONFIRM tablet placement in the sublingual space.

NOTE: If tablet is NOT in the patient's mouth, it is important to retrieve and dispose of the tablet according to controlled drug waste procedures.

8. DISCARD the used SDA in biohazard waste after administration.

WHAT ARE THE PRECAUTIONS OF USE WHEN PRESCRIBING Dzuveo®?

- Before prescribing Dzuveo®, carefully read the Summary of Product Characteristics.
- Review other medications that the patient takes or has already taken. In particular, inhibitors of CYP3A4, calcium channel or beta blockers, and Central Nervous System (CNS) depressants as these can increase the systemic exposure to sufentanil, increasing the incidence and degree of bradycardia and hypotension or may enhance respiratory depression and therefore lead to an overdose and life-threatening condition.
- Reassess the appropriateness of the use of Dzuveo® at regular intervals.
- Refer the patient to the Patient Information leaflet which contains information about Dzuveo® symptoms of respiratory depression.
- Provide the patient with instructions and information about Dzuveo® administration:
  - The sublingual tablet should be dissolved under the tongue and should not be chewed or swallowed.
  - The patient should not eat or drink and should not talk for a minimum of 10 minutes after each dose of Dzuveo®. Visually inspect that the Dzuveo® tablet has been successfully delivered to the patient's sublingual space and is visible under the patient's tongue.

HOW TO MONITOR THE EFFECTS OF Dzuveo®

- Monitor for signs and symptoms of respiratory depression (unusual tiredness and daytime sleepiness, shortness of breath and slow and shallow breathing, bluish lips, toes and/or fingers, confusion, headache, seizures, some people may experience faster breathing).
- Be vigilant about other signs and symptoms of sufentanil overdose (loss of consciousness, coma, cardiovascular shock, muscle rigidity).
- Follow an appropriate protocol for overdose management and have an emergency kit and opioid antagonist (e.g., naloxone) readily available.
- Particular attention should be given to hypoventilation and the necessity of assisted or controlled ventilation.
- Repeat antagonist administration or infusion may be required as the duration of respiratory depression may last longer than the duration of the effect of the antagonist.

Patients on chronic opioid therapy or with a history of opioid use may require higher (or more frequent) analgesic doses than are available with Dzuveo®. Therefore, these patients should be evaluated frequently to ensure they are receiving adequate analgesia.

Dzuveo® should not be administered more frequently than once per hour.

For more information, please consult the Summary of Product Characteristics available on

https://www.ema.europa.eu/en/medicines/human/EPAR/dzuveo

Call for reporting

We remind you of the importance of reporting any suspected adverse reactions related to Dzuveo®, including overdose and respiratory depression to your local competent authority.
HPRA Pharmacovigilance website: www.hpra.ie
Or to: JensonR+ Ltd
Email: pvg@jensongroup.com

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