PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Date: ***[Draft – tbd]***

Subject:	Re: Important Identified Risks related to the use of Dzuveo® : Respiratory depression
Product Name:	Dzuveo®
INN:	Sufentanil
Marketing Authorisation Number:	EU/1/18/1284/001 EU/1/18/1284/002

Dear Healthcare Professional,

Aguettant, in agreement with the Health Products Regulatory Authority (HPRA), would like to inform you of an important identified risk related to the use of Dzuveo® 30 micrograms sublingual tablets (sufentanil). Please find enclosed educational material consisting of a prescribing guide which has been approved by the HPRA.

Summary:

- **Dzuveo® is indicated for the management of acute moderate to severe pain in adult patients.**
- **Dzuveo® is to be administered no more frequently than once per hour (minimal dosing interval is one sublingual tablet per hour) and should not be used beyond 48 hours.**
- **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 to be administered by Healthcare Professionals in a medically monitored setting only where appropriate equipment and trained personnel are available to detect and manage hypoventilation and administer supplementary oxygen and opioid antagonists such as naloxone.**
- **Dzuveo® must not be dispensed to patients for pain management outside of a medically monitored healthcare facility or service.**
- **Dzuveo® is contraindicated in patients with significant respiratory depression or pulmonary compromise.**

Background on the safety concern

There is a potential risk of respiratory depression in patients associated with the use of Dzuveo®. To prevent any risk of respiratory depression, Healthcare Professionals should read the information guide on risk minimisation and consider the following when prescribing:

Indication

Dzuveo® is indicated for the management of acute moderate to severe pain in adult patients.

Setting
Dzuveo® is to be administered by experienced Healthcare Professionals in a medically monitored setting only, where appropriate equipment and trained personnel are available to detect and manage hypoventilation and administer supplementary oxygen and opioid antagonists such as naloxone. Dzuveo® must not be dispensed to patients for pain management outside of a medically monitored healthcare facility or service.

Precautions
Healthcare Professionals prescribing Dzuveo® should review concomitant medications and consult the SmPC for further information. In particular, use of CYP3A4 inhibitors, calcium channel or beta blockers and central nervous system (CNS) depressants should be avoided as these can increase the systematic exposure to sufentanil, increase the incidence and degree of bradycardia and hypotension or may enhance respiratory depression and therefore lead overdose.

Contraindications
Dzuveo® is contraindicated in significant respiratory depression or pulmonary compromise.

Further information

For further information about this product, please contact
LABORATOIRE AGUETTANT
1, rue Alexander Fleming – 69007 Lyon – France
Tel : +33 (0)4 78 61 51 39
GuichetPV guichetPV@aguettant.fr

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

Call for reporting

▼ **Reporting of suspected adverse events or reactions**
Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions (see details below).

Where possible, healthcare professionals should report adverse events or reactions by brand name and batch number.

In the event of a suspected adverse event, please report it to:	**Alternatively, suspected adverse reactions should be reported to:**
JensonR+ Ltd Email: pvg@jensongroup.com	HPRA Pharmacovigilance, Website: www.hpra.ie

Yours sincerely

LABORATOIRE AGUETTANT