ZALVISO®

SUFENTANIL (Sublingual Tablet System)

HEALTHCARE PROFESSIONALS ADMINISTRATION GUIDE

This educational material is essential to ensure the safe and effective use of the product and appropriate management of the important selected risks. Please read carefully before prescribing/using the product.

INDICATION & USE

- ZALVISO® is indicated for the management of acute moderate to severe post-operative pain in adult patients
- It should not be used to treat any other type of pain not related to a surgical procedure
- It is not intended for long term use and should only be used in a hospital setting
- It should only be used by healthcare professionals who are experienced, knowledgeable and skilled in the management of opioid therapy, particularly opioid adverse reactions such as respiratory depression.

BEFORE PRESCRIBING/USING ZALVISO®

- Before setting up ZALVISO®, the healthcare professional should be trained on the correct product use and should be familiar with the "Instructions for Use" manual

PATIENT SELECTION

- Ensure the key sections of the SmPC are consulted when selecting patients

CONTRAINDICATIONS

- Do not prescribe if the patient is allergic to any of the ingredients, excipients or device material
- ZALVISO® is contraindicated in significant respiratory depression.

WARNINGS AND PRECAUTIONS

- **Respiratory depression**

  Sufentanil may cause respiratory depression, for which the degree/severity is dose related. Patients at higher risk are those with respiratory impairment or reduced respiratory reserve.

- **Intracranial pressure**

  Sufentanil should be used with caution in patients with brain tumours or who may be particularly susceptible to the cerebral effects of CO2 retention, such as those with evidence of increased intracranial pressure or impaired consciousness. Sufentanil may obscure the clinical course of patients with head injury.

- **Cardiovascular effects**

  Use with caution in patients with previous or pre-existing bradyarrhythmias as sufentanil may cause bradycardia. Sufentanil may cause hypotension, especially in hypovolemic patients.

- **Impaired hepatic or renal function**

  The duration of activity of sufentanil may be prolonged in patients with severe hepatic and renal impairment, therefore patients with moderate to severe hepatic or severe renal impairment should be monitored carefully for symptoms of sufentanil overdose.

- **Abuse potential and tolerance**

  Sufentanil is a controlled drug and has potential for abuse. This should be considered when prescribing or administering sufentanil where there is concern about an increased risk of misuse, abuse or diversion.

  Patients on chronic opioid therapy or opioid addicts may require higher analgesic doses than the ZALVISO® administration device can deliver.

- **Gastrointestinal effects**

  ZALVISO® should be used with caution in patients at risk of ileus as sufentanil is a μ-opioid receptor agonist and may slow the gastrointestinal motility.

  Sufentanil may cause spasm of the sphincter of Oddi and should be used with caution in patients with biliary tract disease, including acute pancreatitis.

HEALTHCARE PROFESSIONALS ADMINISTRATION GUIDE

DRUG-DRUG INTERACTIONS

- Review other medications that the patient takes or has already taken (e.g., analgesics taken at home, intraoperative medications, sedatives, opioids).
- Potent CYP3A4 inhibitors e.g. ketoconazole can significantly increase systemic exposure to sufentanil.
- The concomitant use of CNS depressants including barbiturates, benzodiazepines, neuroleptics or other opioids, halogen gases or other non-selective CNS depressants (e.g. alcohol) may enhance respiratory depression.
- Discontinuation of MAO inhibitors is generally recommended two weeks before ZALVISO® treatment, because severe and unpredictable potentiation by MAO inhibitors has been reported with opioid analgesics.

INFORMING PATIENTS

- Before use, the health-care professional should ensure that the patients have been appropriately instructed on how to operate the Zalviso administration device to self-administer tablets to manage their post-operative pain. Only patients who are able to understand and follow the instructions to operate the administration device should use Zalviso, taking into consideration the ability (e. g. visual or cognitive) of the patient to use the device appropriately.
- Inform patients about possible side effects and warnings from the 'Package Leaflet' (PL) and instruct them when and how to call a healthcare professional if needed.
- Patients should be advised never to let anyone else administer or use the product.
- Children should be prevented from playing with ZALVISO® as the medicine could be harmful to them.

WHEN MONITORING THE EFFECTS OF ZALVISO®

- As with other opioids patients receiving ZALVISO® should be evaluated at regular intervals for level of pain, alertness and vital signs, including respiratory rate, sedation level and oxygen saturation. Particular attention should be paid to the first 24 hours and at night, when hypoventilation and nocturnal hypoxia may occur.
- Sufentanil overdose is manifested by an exaggeration of its pharmacological effects. This may range from hypoventilation to respiratory arrest. Other symptoms that may occur are loss of consciousness, coma, cardiovascular shock and muscle rigidity.
- Healthcare professionals should follow an appropriate protocol for overdose management and have oxygen and opioid antagonist (e.g. naloxone) readily available.
- Primary attention should be given to obstruction of airways 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.
- In case of device failure during treatment, assess the patient for potential signs of sufentanil overdose or other adverse reactions, and ensure appropriate continuation of the safe treatment of the patient.