1. Ensure the Activated Carbon (AC) Chamber is inserted into dilutor hole on the top of Penthrox inhaler.

2. Remove the cap of the bottle by hand. Alternatively, use the base of the Penthrox inhaler to loosen the cap with a ½ turn. Separate the inhaler from the bottle and remove the cap by hand.

3. Tilt the Penthrox inhaler to a 45° angle and pour the total contents of one Penthrox into the base of the Inhaler whilst rotating.

4. Place wrist loop over patient’s wrist. Patient inhales and exhales Penthrox through the mouthpiece to obtain analgesia. First few breaths should be gentle and then breathe normally through Inhaler.

5. Patient exhales into the Penthrox inhaler. The exhaled vapour passes through the AC Chamber to absorb any exhaled methoxyflurane.

6. If stronger analgesia is required, patient can cover dilutor hole on the AC chamber with finger during use.

7. If further pain relief is required, after the first bottle has been used, use a second bottle if available. Alternatively use a second bottle from a new combination pack. Use in the same way as the first bottle in step 2 and 3. No need to remove the AC Chamber. Put used bottle into the plastic bag provided.

8. Patient should be instructed to inhale intermittently to achieve adequate analgesia. Continuous inhalation will reduce duration of use. Minimum dose to achieve analgesia should be administered.

9. Replace cap onto Penthrox bottle. Place used Penthrox inhaler and used bottle in sealed plastic bag and dispose of responsibly.

The doctor, nurse, paramedic or person trained in administering Penthrox, must provide and explain the Package Leaflet to the patient.
REFERENCES

References:

Penthrox European Prescribing Information

Penthrox® 99.9%, 3mL inhalation vapour, liquid. Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Essential Information

Presentation: Each bottle of Penthrox contains 3mL of methoxyflurane 99.9%, a clear almost colourless, volatile liquid, with a characteristic fruity odour. Each Penthrox combination pack consists of one 3mL bottle, one Penthrox inhaler and one Activated Carbon (AC) chamber.

Indication: Emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain.

Dosage and administration: Penthrox should be self-administered under supervision of a person trained in its administration, doctor, nurse, paramedic using the hand held Penthrox inhaler.

Adults: One bottle of 3mL Penthrox as a single dose, administered using the device provided. A second bottle should only be used where needed. The dose should not exceed 6mL in a single administration. Dosing on consecutive days is not recommended, and the total dose to a patient in a week should not exceed 15mL. Onset of pain relief is rapid and occurs after 6-10 inhalations. Patients are able to titrate the amount of Penthrox inhaled and should be instructed to inhale intermittently to achieve adequate pain control. Continuous inhalation provides analgesic relief for up to 25–30 minutes; intermittent inhalation may provide longer analgesic relief.

Children: Penthrox should not be used in children or adolescents under 18 years of age.

Contraindications: Use as an anaesthetic agent, hypersensitivity to methoxyflurane, any fluorinated anaesthetics or excipient; malignant hyperthermia; patients with known or genetically susceptible to malignant hyperthermia; patients of patients with a known family history of severe adverse reactions after receiving inhaled anaesthetics; patients who have a history of showing signs of liver damage after previous methoxyflurane use or halogenated hydrocarbon anaesthesia; clinically significant renal impairment; altered level of consciousness due to any cause including head injury, drugs, or alcohol; clinically evident cardiovascular instability; clinically evident respiratory depression.

Warnings and Precautions: Methoxyflurane causes significant nephrotoxicity at high doses. Nephrotoxicity is also related to the rate of metabolism. Drugs that induce hepatic enzymes and subgroups of people with genetic variations that may result in fast metaboliser status may increase the risk of toxicity with methoxyflurane. The lowest effective dose should be administered especially in the elderly or patients with other known risk factors of renal disease. Methoxyflurane should be used cautiously in patients with conditions that would pre-dispose to renal injury. Penthrox should be used with caution in patients with underlying hepatic conditions or with risks for hepatic dysfunction. Previous exposure to halogenated anaesthetics especially if the interval is less than 3 months, may increase the potential for hepatic injury. Cautious clinical judgement should be exercised when Penthrox is to be used more frequently than on one occasion every 3 months. Caution required in the elderly due to possible reduction in blood pressure. Cautious CNS effects such as sedation, euphoria, amnesia, ability to concentrate, altered sensorimotor co-ordination and change in mood are also known class-effects. The Activated Carbon (AC) Chamber should be used to adsorb exhaled methoxyflurane, reducing the risk of occupational exposure. Penthrox is not appropriate for providing relief of breakthrough pain/exacerbations in chronic pain conditions or for the relief of trauma related pain in closely repeated episodes for the same patient.

Interactions: There are no reported drug interactions when used at the analgesic dosage (3 – 6 mL). Enzyme inducers can increase the rate of methoxyflurane metabolism. Enzyme inducers for CYP 2E1 (e.g. alcohol or isoniazid) and CYP 2A6 (e.g. phenobarbital or rifampicin) should be avoided concomitantly with methoxyflurane as they may increase its potential toxicity.

Concomitant use of Penthrox with CNS depressants, such as opioids, sedatives or hypnotics, general anaesthetics, phenothiazines, tranquillisers, skeletal muscle relaxants, sedating antihistamines and alcohol may produce additive depressant effects. Concomitant use of methoxyflurane with antibiotics known to have a nephrotoxic effect (e.g. tetracycline, gentamicin, colistin, polymyxin B and amphotericin B) should be avoided as there may be an additive effect on nephrotoxicity. Sefovlurane anaesthesia should be avoided following the use of Penthrox, as sevoflurane increase serum fluoride levels and methoxyflurane nephrotoxicity is associated with raised serum fluoride.

Fertility, pregnancy and lactation: No clinical data on effects of methoxyflurane. No clinical data on effects of methoxyflurane on fertility are available. As with all medicines care should be exercised when administered during pregnancy especially the first trimester. There is insufficient information on the excretion of methoxyflurane in human milk. Caution should be exercised when methoxyflurane is administered to a nursing mother.

Effects on ability to drive and use machines: Methoxyflurane may have a minor influence on the ability to drive and use machines. Patients should be advised not to drive or operate machinery if they are feeling drowsy or dizzy.

Undesirable effects: Common: Amnesia, anxiety, depression, Common or very common: Amnesia, dizziness, dysarthria, drowsiness, euphoric mood, headache, somnolence, hypotension, cough, dry mouth, nausea, feeling drunk. Uncommon but potentially serious: Paresthesia, diplopia, peripheral sensory neuropathy, depression.

Post-marketing experience: Isolated reports of hepatic failure/hepatitis have been observed with analgesic use of methoxyflurane (frequency not known).

Legal Category: POM. Shelf life: 36 months.

Special precautions for storage: No special temperature storage conditions.

Date of preparation: November 2018

Adverse events should be reported. Reporting to the applicable regulatory authorities should be in accordance with National Requirements and to the applicable holder of the marketing authorisation for Penthrox, details of which can be found on product packaging and/or inserts.

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