



Mundipharma presents wealth of data for Pentrox® (methoxyflurane) at EUSEM Congress, demonstrating superiority compared to standard of care in trauma pain in adults

- New data demonstrate superiority of methoxyflurane vs intravenous (IV) morphine, paracetamol, ketoprofen and NSAIDs¹⁻⁴
- Methoxyflurane added to standard of care (SoC) demonstrates superiority over SoC plus placebo⁵

Cambridge, UK, 15th October 2019

Mundipharma presents new data for the inhaled analgesic Pentrox® (methoxyflurane)⁶ at the European Society for Emergency Medicine (EUSEM) Congress 2019, from 12–16 October. Five abstracts are being presented, advancing the understanding of the use of methoxyflurane in the treatment of moderate to severe trauma-related pain for adults in emergency settings in Europe:

MEDITA Study¹ #18647: the first study to directly compare the effectiveness of methoxyflurane to standard analgesic treatment (SAT) – IV morphine for severe pain, and IV paracetamol or ketoprofen for moderate trauma pain in Italy.

- Methoxyflurane was superior to IV morphine (severe pain) and IV paracetamol or IV ketoprofen (moderate pain) for the primary endpoint, defined as the change in pain intensity over the first 10 minutes (overall adjusted mean treatment difference: 5.94mm; 95% CI: 8.83, 3.06mm) following pain treatment administration.¹
- Methoxyflurane was rated as ‘excellent’, ‘very good’ or ‘good’ by significantly more patients in the methoxyflurane group, compared to the SAT group (72.7% vs 60.9%; $p=0.001$) and significantly more healthcare professionals rated the practicality of methoxyflurane as ‘excellent’, ‘very good’ or ‘good’, compared to SAT (90.3% vs 64.4%; $p<0.001$).¹

PenASAP Study⁵ #19302: a placebo-controlled study comparing the effectiveness of methoxyflurane plus standard of care (SoC) analgesia vs SoC analgesia plus placebo for the management of moderate to severe trauma pain in France.

- Results demonstrate the superiority of methoxyflurane in combination with SoC vs placebo plus SoC, in achieving pain relief for patients with moderate to severe trauma pain. For the primary endpoint, the median time to pain relief, defined as 30mm or less on the visual analogue scale, was 35 minutes in the methoxyflurane plus SoC group ($p<0.001$) and was not reached in the SoC plus placebo group.⁵



InMEDIATE Study²⁻⁴ #18659, #18660, #18661: sub-analyses from a study comparing methoxyflurane to existing SAT in acute moderate to severe trauma pain in Spain.

- Methoxyflurane use in the elderly (at least 65 years old) provided significantly faster pain relief than SAT (time to first pain relief of 5.55 vs 12.8 minutes, and time to first meaningful pain relief of 12.57 vs 25.07 minutes), respectively.²
- In patients with severe trauma-related pain (numerical rating scale score of 7 or more), decrease from baseline was significantly larger for methoxyflurane than SAT at all time points (3, 5, 10, 15 and 20 minutes) ($p < 0.001$), with the largest treatment difference reported at 10 minutes.³
- In patients with acute trauma pain (numerical rating scale score of 4 or more) who received first-step IV analgesic, the decrease from baseline was significantly larger for methoxyflurane than SAT at all time points (3, 5, 10, 15 and 20 minutes) ($p < 0.001$), with the largest treatment difference reported at 10 minutes.⁴

Methoxyflurane was generally well tolerated in all the studies, with most adverse events (AEs), primarily dizziness, being mild and transient but occurring more frequently than in the comparator groups.²⁻⁶ In the PenASAP study, two severe AEs occurred in the methoxyflurane plus SoC group, including one that was assessed as treatment-related.⁵

“We are very excited by these data demonstrating the superiority of methoxyflurane when compared directly with standard treatment, or compared with placebo when used in addition to SoC for moderate-to-severe trauma pain, in real-world settings in European countries” said Sara Dickerson, Medical Affairs Lead for Mundipharma. “We know that trauma pain is too often undertreated, or even untreated, which can be very distressing for patients and can lead to long-term effects. Results from these studies support the use of methoxyflurane as a simple, fast and effective non-opioid treatment option for adult patients experiencing trauma pain.”

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get to your local medicines regulatory authority.

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Notes to editors

About Pentrox[®] (methoxyflurane)

Pentrox is a small, light-weight, hand-held, inhaled non-opioid analgesic.^{6,7} It is indicated in Europe for the emergency relief of moderate to severe pain in conscious adults with trauma and associated pain.^{6,8} It is a self-administered analgesic (under supervision) and provides rapid pain relief within three minutes⁹ or six to ten inhalations.^{10,11} Methoxyflurane as an analgesic has been used by more than six million people over the



course of 40 years, in Australia and New Zealand.¹² It has an established tolerability profile and a body of supporting evidence in adult trauma pain.^{13,14}

Mundipharma International Corporation Limited has exclusive rights to Pentrox in 40 European markets, including France, Germany, Italy and Spain, but excluding the Republic of Ireland and the United Kingdom.

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[Click here to watch an animation about the management of trauma pain in Europe:](#)

www.mundipharma.com/media_video/taking-the-pain-out-of-trauma/

About Management of Trauma Pain in the Pre-Hospital Setting

33 million people across Europe visit the hospital emergency department due to injuries every year.¹⁵ Trauma pain requires fast, effective pain relief (analgesia).⁷ Although inadequate pain treatment can cause clinical deterioration, pain is undertreated in both the emergency department and pre-hospital setting, and remains a significant problem.^{7,16} Current analgesics have limitations in pre-hospital settings and there is a need for fast-acting, non-invasive, non-narcotic analgesia.^{7,17}

About the Mundipharma Network

Mundipharma is a global network of privately-owned independent associated companies whose purpose is to move medicine forward. With a high performing and learning organisation that strives for innovation and commercial excellence through partnerships, we successfully transformed and diversified our European portfolio of medicines to create value for patients, payers and wider healthcare systems across important therapeutic areas such as Diabetes, Respiratory, Oncology, Pain and Biosimilars.

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