

PENTHROX® (methoxyflurane) Checklist for administration

IMPORTANT RISK MINIMISATION INFORMATION FOR HEALTHCARE PROFESSIONALS

This checklist is essential to ensure the safe and effective use of methoxyflurane and appropriate management of important selected risks.

Before using methoxyflurane ...**please CHECK ALLL.**

The patient is not known to have:

- C** Clinically evident cardiovascular instability
- H** Hypersensitivity to methoxyflurane, any fluorinated anaesthetic or to any of the excipients
- E** Established or genetically susceptible to malignant hyperthermia or a history of severe adverse reactions to inhaled anaesthetics in either patient or relatives
- C** Consciousness altered (due to any cause, including head injury, drugs or alcohol)
- K** Kidney impairment
- A** Age below 18 years
- L** Lung or respiratory impairment (clinically evident)
- L** Liver impairment (including history of signs of liver damage after previous methoxyflurane use or halogenated hydrocarbon anaesthesia)
- L** Last administration of methoxyflurane (consecutive days not recommended and previous exposure in last 3 months may increase hepatic injury risk)

If patient has any of the conditions listed here or is taking any of the drugs listed on the reverse **DO NOT administer** methoxyflurane.

Instruct patient on the correct administration of methoxyflurane.

Reminder: Please read SmPC before administering and give patient PIL and Alert Card.

Ensure lowest required dose is administered and maximum dose of 6ml (2 vials) is not exceeded.

Patient is not taking:

CYP-450 enzyme inducers (e.g. alcohol, isoniazid, phenobarbital, rifampicin, carbamazepine, efavirenz or nevirapine). Antibiotics with known nephrotoxic effect (e.g. tetracycline, gentamicin, colistin, polymyxin B or amphotericin B).

Concomitant use of methoxyflurane with CNS depressants may produce addictive depressant effects and patients should be observed closely.

Healthcare professionals are asked to report any suspected adverse reactions via Freepost, HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: 01 6764971; Fax: 01 6762517.

Website: <http://www.hpra.ie>; Email: medsafety@hpra.ie.

Any suspected adverse reactions should also be reported to Galen Pharma Ireland Limited on 048 3833 4974 and select the customer services option, or e-mail customer.services@galen-pharma.com.

Reminder: Give "Patient Alert Card"