

Package leaflet: Information for the user

PENTHROX **99.9%, 3 ml inhalation vapour, liquid**

methoxyflurane

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your healthcare professional.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PENTHROX is and what it is used for
2. What you need to know before you use PENTHROX
3. How to use PENTHROX
4. Possible side effects
5. How to store PENTHROX
6. Contents of the pack and other information

1. What PENTHROX is and what it is used for

PENTHROX contains the active substance methoxyflurane. It is a medicine which is used to reduce pain in patients aged 6 years and older. It is inhaled through the PENTHROX Inhaler.

The intended purpose of the PENTHROX Inhaler is to administer the analgesic drug PENTHROX (methoxyflurane). PENTHROX is poured into the device and as you breathe in through the device you inhale the PENTHROX vapour. The attached Activated Carbon (AC) Chamber adsorbs the PENTHROX vapour you are exhaling through the PENTHROX Inhaler.

PENTHROX administered through the PENTHROX Inhaler, is intended to reduce the severity of pain, rather than stop it completely.

2. What you need to know before you use PENTHROX

Do not use this medicine if you:

- are allergic to methoxyflurane, any inhalation anaesthetics or any of the other ingredients of this medicine (listed in section 6).
- have a history or family history of malignant hyperthermia. Malignant hyperthermia is a condition where symptoms such as a very high fever, fast, irregular heartbeat, muscle spasms and breathing problems have occurred after you, or a related family member, have been given an anaesthetic
- or your family have a history of severe side effects to inhaled anaesthetics

- have previously had liver damage after using methoxyflurane or any inhalation anaesthetics
- have significant kidney impairment
- have a change in the level of consciousness due to any cause including head injury, drugs, or alcohol
- have significant heart or circulatory problems
- have shallow breathing or difficulty in breathing

This medicine must not be used as an anaesthetic.

If you are not sure whether you should be given this medicine, talk to your healthcare professional.

Warnings and precautions

Talk to your healthcare professional before using this medicine if you:

- have liver or kidney problems
- have a medical condition which may cause kidney problems
- are elderly

Respiratory depression, with symptoms such as too slow and shallow breathing or other difficulties in breathing, has been reported in association with treatment with PENTHROX (section 4). Tell your healthcare professional immediately if you experience any breathing problems.

Children

Do not give this medicine to children under 6 years of age.

Other medicines and PENTHROX

Tell your healthcare professional if you are taking or have recently taken any other medicines. In particular, tell your healthcare professional if you are taking any of the following:

- Isoniazid to treat tuberculosis
- Phenobarbital or carbamazepine to treat epilepsy
- Rifampicin or other antibiotics to treat infection
- Medicines, or illegal drugs, that have a dampening effect on the nervous system such as narcotics, pain killers, sedatives, sleeping pills, general anaesthetics, phenothiazines, tranquilisers, muscle relaxants and sedating antihistamines.
- Antibiotics and other medicines that may harm the kidney such as tetracycline, gentamicin, colistin, polymyxin B, amphotericin B and contrast agents.
- Efavirenz or nevirapine to treat HIV

Ask your healthcare professional if you are unsure.

If you need hospital treatment requiring general anaesthesia, tell the doctors treating you that you have used this medicine.

PENTHROX with food, drink and alcohol

Do not drink alcohol whilst taking this medicine as it may increase its effect.

You can eat and drink as normal whilst taking this medicine, unless advised by your healthcare professional.

Pregnancy, breast-feeding and fertility

Tell your healthcare professional before taking this medicine if you are pregnant, intending to become pregnant, are breast-feeding or intending to breast-feed. Your healthcare professional will discuss the possible risks and benefits of being given this medicine.

Driving and using machines

This medicine can affect your ability to drive or use machines safely. Make sure these abilities are not affected before you drive or operate machinery. PENTHROX may cause drowsiness or dizziness in some people.

PENTHROX contains Butylated hydroxytoluene (E321)

This medicine contains a stabiliser ingredient called butylated hydroxytoluene (E321). Butylated hydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. How to use PENTHROX

Always take this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

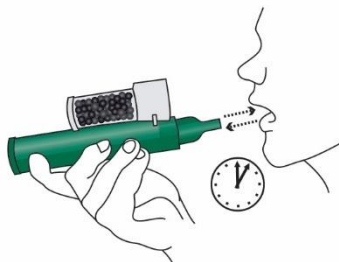
Adults and children aged 6 years and older

One or two bottles containing 3 ml of PENTHROX can be used per administration. The maximum dose is two bottles containing 3 ml per administration. Do not inhale more than the maximum dose.

The PENTHROX Inhaler is designed for use with PENTHROX (methoxyflurane) only.

How to use PENTHROX

1. Your healthcare professional will prepare the PENTHROX inhaler and place the wrist loop over your wrist.
2. Breathe in through the mouthpiece of the inhaler to obtain pain relief. Your healthcare professional will show you how if you are unsure. Accustom yourself to the fruity smell of the medicine by inhaling gently for the first few breaths. Breathe out through the inhaler. After the first few breaths breathe normally through the inhaler.
3. If you need stronger pain relief, cover the dilutor hole on the transparent chamber with charcoal with your finger during use. Your healthcare professional will show you where the hole is.
4. You do not need to breathe in and out of the inhaler all of the time. Your healthcare professional will encourage you to take breaks from the inhaler as this will make the pain relief last longer.
5. Continue using your inhaler until your healthcare professional tells you to stop, or when you have inhaled the maximum recommended dose.



Do not give this medicine to anyone else, even if they have the same condition as you.

If you use more PENTHROX than you should

The healthcare professional giving the **medicine** will be experienced in its use, so it is extremely unlikely that you will be given too much. You should not use more than 2 bottles at one time. If the maximum dose is exceeded, PENTHROX may cause damage to your kidneys. Tell your healthcare professional immediately if you think you may have taken too much of this medicine.

If you have any further questions on the use of this medicine, ask your healthcare professional.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your healthcare professional immediately if you experience any of the following:

- Serious allergic reaction, symptoms include difficulty breathing and/or swelling of the face
- Liver problems, such as loss of appetite, nausea, vomiting, jaundice (yellowing of the skin and/or eyes), dark coloured urine, pale coloured stools, pain/ache or sensitivity to touch in your right stomach area (below your ribs)
- Kidney problems such as reduced or excessive urination or swelling of feet or lower legs.
- Too slow and shallow breathing or other difficulties in breathing (symptoms of respiratory depression) (frequency cannot be estimated from available data)

The above side effects can be life threatening so tell your healthcare professional immediately.

Other side effects

Very common side effects: may affect more than 1 in 10 people

- Dizziness

Common side effects: may affect up to 1 in 10 people

- Drowsiness
- Headache or Nausea
- Feeling of extreme happiness
- Feeling drunk
- Taste disturbances
- Coughing
- Tiredness

Uncommon side effects may affect up to 1 in 100 people

- Anxiety or depression
- Disturbance in attention
- Inappropriate emotions or actions
- Repetition of words or difficulty in speaking
- Memory loss
- Tingling skin (pins and needles) in the hands or feet
- Numbness
- Vision impairment
- Flushing of the skin
- Low or high blood pressure
- Dry mouth
- Mouth discomfort or itch
- Increased salivation
- Increased appetite
- Vomiting
- Sweating
- Feeling abnormal

- Chills
- Feeling relaxed
- Mood swings
- Agitation
- Disorientation
- Low blood oxygen level

Not known: frequency cannot be estimated from the available data

- Hypersensitivity
- Restlessness
- Feeling of being disconnected from reality
- Altered state of consciousness
- Choking
- Shortness of breath
- Uncontrolled eye movements

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance,

Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store PENTHROX

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Your healthcare professional will dispose of any leftover PENTHROX liquid and the PENTHROX Inhaler in the appropriate way.

6. Contents of the pack and other information

What PENTHROX contains

The active substance is Methoxyflurane. Each sealed bottle contains 3 ml methoxyflurane 99.9%.

The other ingredient is Butylated hydroxytoluene (E321).

What PENTHROX looks like and contents of the pack

PENTHROX is a clear, almost colourless volatile liquid, with a characteristic fruity odour that becomes a vapour or gas when used with the PENTHROX Inhaler.

PENTHROX is supplied in the following presentations:

- a) One bottle with a tear off tamper-evident seal (packs of 10), or
- b) Combination pack with one bottle of 3 ml PENTHROX, one PENTHROX Inhaler and one Activated Carbon (AC) chamber (packs of 1 or 10).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Medical Developments MD&P Limited
21 Priory Office Park
Stillorgan Road, Blackrock
Dublin, Dublin
A94 F660, Ireland

Manufacturers

MIAS Pharma Limited
Suite 1, First Floor, Stafford House,
Strand Road,
Portmarnock,
Co. Dublin, D13 WC83
Ireland

Or

Ethypharm
Chemin De La Poudriere,
Le Grand Quevilly, 76120
France

Distributor

Galen Pharma Ireland Limited
Finnabair Industrial Estate
Dundalk
Co Louth
Ireland

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Information for Healthcare Professionals

The following information is intended for healthcare professionals only:

Instructions on the preparation of the PENTHROX Inhaler and correct administration are provided in the Figures below.

Before use, check for foreign objects, broken or deteriorated parts. Do not use this device if any are identified.

- 1** Ensure the Activated Carbon (AC) Chamber is inserted into the dilutor hole on the top of the 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 bottle into the base of the Inhaler whilst rotating.



- 4** Place wrist loop over patient's wrist. Patient inhales through the mouthpiece of PENTHROX inhaler 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 adsorb 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 physician, doctor, nurse, paramedic or person trained in administering, PENTHROX must provide and explain the Package Leaflet to the patient