

Pentrox[®]
3mL inhalation vapour, liquid
(methoxyflurane)

▼ **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. See the end of section 4 for how to report side effects.**

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

1. What Pentrox[®] is and what it is used for

Pentrox[®] contains the active substance methoxyflurane. It is a medicine which is used to reduce pain. It is inhaled through the custom-built Pentrox[®] Inhaler. Pentrox[®] is intended to reduce the severity of pain, rather than stop it completely.

2. What you need to know before you use Pentrox[®]

Do not use this medicine if you:

- are allergic to methoxyflurane, any inhalation anaesthetics or any of the ingredients listed in section 6
- have a history or family history of malignant hyperthermia or if you or your family have a history of severe side effects to methoxyflurane. 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
- 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
- are suffering from severe circulatory problems
- have shallow breathing or difficulty in breathing

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

Children

Do not give this medicine to children.

Other medicines and Pentrox[®]

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 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.

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.

Taking this medicine 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.

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. Pentrox[®] may cause drowsiness or dizziness in some people.

Butylated hydroxytoluene

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 Pentrox[®]

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

Adults

One or two 3 mL bottles of Pentrox[®] can be used per administration. The maximum dose is two 3mL bottles per administration. Do not inhale more than the maximum dose.

How to use Pentrox[®]

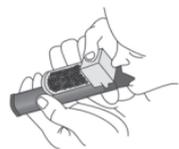
1. Your healthcare professional will prepare the Pentrox[®] Inhaler and place the wrist loop over your wrist.



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 Pentrox[®] than you should

The healthcare professional giving the Pentrox[®] 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, Pentrox[®] 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.

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

Other side effects

Common side effects (affects between 1 and 10 people in 100 patients)

- Dizziness
- Drowsiness
- Euphoria
- Difficulty in speaking
- Memory loss
- Anxiety or depression
- Taste disturbance, loss of taste or dry mouth
- Headache or nausea
- Numbness
- Low blood pressure
- Coughing
- Feeling drunk
- Sweating

Uncommon side effects (affects between 1 and 10 people in 1000 patients)

- Tingling or numbness of the hands or feet
- Double vision
- Mouth discomfort
- Tiredness
- Feeling abnormal
- Increased appetite
- Shivering

Other side effects (frequency unknown)

- Restlessness or agitation
- Feeling of being disconnected from reality
- Disorientation
- Altered state of consciousness
- Altered mood
- Choking
- Shortness of breath
- Blood pressure fluctuation
- Vomiting
- Blurred vision

Reporting of side effects:

If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at

www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Pentrox®

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

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions and should be stored in its original container. Your healthcare professional will keep Pentrox® combination pack in a locked cabinet, rather than an open shelf.

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

6. Contents of the pack and other information

What Pentrox® contains

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

The other ingredient is Butylated hydroxytoluene (E321).

What Pentrox® looks like and contents of the pack

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

Pentrox® is supplied in the following presentations:

- a) 3 mL bottle with a tear off tamper-evident seal (packs of 10), or
- b) Combination pack with one 3 mL bottle, one Pentrox® 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 UK Ltd.
Causeway House
1 Dane Street,
Bishop's Stortford
Herts CM23 3BT
United Kingdom

Manufacturer

Mawdsley-Brooks & Company Ltd
Unit 22, Quest Park,
Wheatley Hall Road,
Doncaster DN2 4LT
United Kingdom

Distributor

Galen Limited
Seagoe Industrial Estate
Craigavon BT63 5UA
United Kingdom

This leaflet was last revised in 03/2017.

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Information for Healthcare Professionals

The following information is intended for healthcare professionals only: Instructions on the preparation of the Pentrox® Inhaler and correct administration are provided in the Figures below:

1. Ensure the Activated Carbon (AC) Chamber is inserted into the dilutor hole on the top of the Pentrox® Inhaler. 
2. Remove the cap of the bottle by hand. Alternatively, use the base of the Pentrox® Inhaler to loosen the cap with a ½ turn. Separate the Inhaler from the bottle and remove the cap by hand. 
3. Tilt the Pentrox® Inhaler to a 45° angle and pour the total contents of one Pentrox® bottle into the base of the Inhaler whilst rotating. 
4. Place wrist loop over patient's wrist. Patient inhales through the mouthpiece of Pentrox® Inhaler to obtain analgesia. First few breaths should be gentle and then breathe normally through Inhaler. 

5. Patient exhales into the Pentrox® 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. 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. 
8. Replace cap onto Pentrox® bottle. Place used Pentrox® Inhaler and used bottle in sealed plastic bag and dispose of responsibly. 