

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your healthcare professional (i.e., doctor, dentist, pharmacist, nurse, etc.).

1. Why am I using PENTHROX[®]?

PENTHROX[®] contains the active ingredient methoxyflurane. This medicine is used to reduce pain and is inhaled through the PENTHROX[®] Inhaler. For more information, see Section [1. Why am I using PENTHROX[®]](#) in the full CMI.

2. What should I know before I use PENTHROX[®]?

Do not use if you have ever had an allergic reaction to methoxyflurane, any fluorinated anaesthetic or Butylated Hydroxy Toluene (BHT). **Talk to your healthcare professional if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use PENTHROX[®]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PENTHROX[®] and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PENTHROX[®]?

One bottle of PENTHROX[®] (medicine) is poured into the base of the PENTHROX[®] Inhaler by the healthcare professional and is absorbed into the wick. You will inhale medicine directly from the prepared PENTHROX[®] Inhaler.

One bottle of PENTHROX[®] (3 mL) to be used initially. The maximum recommended dosage is 6 mL of PENTHROX[®] in one day and 15 mL in one week. More instructions can be found in Section [4. How do I use PENTHROX[®]?](#) in the full CMI.

5. What should I know while using PENTHROX[®]?

Things you must do	<ul style="list-style-type: none">Use PENTHROX[®] following the instructions in Section 4. How do I use PENTHROX[®]? In the full CMI. Remind your healthcare professional if you have used PENTHROX[®] recently.
Things you must not do	<ul style="list-style-type: none">Do not give PENTHROX[®] to anyone else, even if they have the same condition as you.Do not perform tasks that require alertness, PENTHROX[®] may cause drowsiness or dizziness.You should not use more than 6 mL in one day and not more than 15 mL in one week.
Driving or using machines	<ul style="list-style-type: none">Make sure you know how you react to PENTHROX[®] before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy, or not alert.
Drinking alcohol	<ul style="list-style-type: none">Ask your doctor when you can drink alcohol after having PENTHROX[®]. Alcohol may increase PENTHROX[®] potential toxicity.
Storage of Medicine	<ul style="list-style-type: none">Your healthcare professional will ensure medicine is stored below 30°C in its original container.

For more information, see Section [5. What should I know while using Penthrox?](#) in the full CMI.

6. Are there any side effects?

PENTHROX[®] is well tolerated, but it may occasionally have unwanted side effects that you may experience and require urgent medical attention.

Liver symptoms: loss of appetite, nausea, vomiting, yellowing of skin/eyes (jaundice), dark coloured urine, pale stools, or pain/tenderness in right abdominal area (below your ribs).

Kidney symptoms: reduced or excessive urination, swelling in feet or lower legs.

Respiratory symptoms: slow and shallow breathing, or difficulties in breathing (symptoms of respiratory depression).

Common side effects: dizziness, headache, drowsiness, feeling of extreme happiness or nausea.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PENTHROX[®]

Active ingredient: *methoxyflurane*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PENTHROX[®].

You should speak to healthcare professional if you would like further information or if you have any concerns or questions about being given this medicine.

Keep this leaflet in a safe place. You may need to read it again.

Where to find information in this leaflet:

- [1. Why am I using PENTHROX[®]?](#)
- [2. What should I know before I use PENTHROX[®]?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PENTHROX[®]?](#)
- [5. What should I know while using PENTHROX[®]?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PENTHROX[®]?

PENTHROX[®] is a medicine which is used to reduce pain.

It is inhaled through the PENTHROX[®] Inhaler.

PENTHROX[®] belongs to a family of medicines called inhalation anaesthetics. At the recommended dose, PENTHROX[®] provides pain relief without producing anaesthesia.

Pain relief should start after 6-10 breaths. PENTHROX[®] is intended to reduce the severity of pain, rather than completely eliminate it.

Ask your healthcare professional if you have any questions about why PENTHROX[®] has been prescribed for you.

2. What should I know before I use PENTHROX[®]?

Warnings

Do not use PENTHROX[®] if:

- You are allergic to: methoxyflurane, any fluorinated anaesthetic, or any of the ingredients listed at the end of this leaflet.
- Symptoms of an allergic reaction may include:
 - Shortness of breath, wheezing or difficulty breathing
 - Swelling of the face, lips, tongue or other parts of the body
 - Rash, itching or hives on the skin

- You must not be given PENTHROX[®] if you have, or are suspected of having, an inherited tendency for a condition called malignant hyperthermia. This is a condition where, when you or a related family member has been given an anaesthetic, symptoms such as a very high fever, fast, irregular heartbeat, muscle spasms and breathing problems have occurred.
- You must not be given PENTHROX[®] if you have heart disease, kidney disease or reduced function of your kidneys, difficulty breathing or head injury.

Check with your healthcare professional if you:

- Have, or have had, any medical conditions, especially the following:
 - Kidney problems
 - Liver problems
- Experience any breathing problems. 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[®].

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your healthcare professional if you are pregnant or intending to become pregnant.

Tell your healthcare professional if you are breastfeeding or intending to breastfeed.

Your healthcare professional will discuss the possible risks and benefits of being given PENTHROX[®] during pregnancy and breast-feeding.

3. What if I am taking other medicines?

Tell your healthcare professional if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with PENTHROX[®] and affect how it works.

Medicines that may interfere with PENTHROX[®] and increase the risk of side effects include:

- Isoniazid to treat tuberculosis
- Barbiturates, such as phenobarbital to treat epilepsy
- Rifampicin to treat infection
- Medicines, or illegal drugs, that have a dampening effect on the nervous system such as narcotics.

- Antibiotics or other medicines that may harm the kidney such as tetracycline, gentamicin, kanamycin, colistin, polymyxin B, cephaloridine or, amphotericin B
- Intravenous adrenaline
- Beta-blockers to treat high blood pressure.

Your doctor may have more information on medicines to be careful with around the time you receive PENTHROX®.

Check with your healthcare professional if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PENTHROX®.

4. How do I use PENTHROX®?

How much is given

- One bottle of PENTHROX® (3 mL) to be used initially. Another additional bottle may be used if required. The maximum recommended dosage is 6 mL of PENTHROX® per day and 15 mL per week.
- PENTHROX® should not be used on consecutive days. You should not inhale more than the maximum dose because PENTHROX® may damage your kidneys.

How is it given

- PENTHROX® is poured into the base of the PENTHROX® Inhaler by the healthcare professional and is absorbed into the wick. You will then inhale PENTHROX® directly from the PENTHROX® Inhaler.

How the PENTHROX® Inhaler is given

1. Your healthcare professional will prepare the PENTHROX® Inhaler (with or without the optional Activated Carbon (AC) Chamber), and place wrist loop over your wrist.



2. Breathe in through the mouthpiece of the PENTHROX® 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.

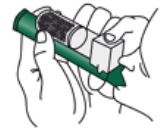


You must breathe out through the PENTHROX® Inhaler when the AC Chamber is attached for the AC Chamber to adsorb any exhaled methoxyflurane. After the first few breaths, breathe normally through the PENTHROX® Inhaler. Pain relief should commence after approximately 6-10 consecutive breaths.

After the initial 6-10 breaths, you can inhale PENTHROX® continuously or intermittently as instructed by your healthcare professional. For intermittent dosing, a top-up of 6 breaths may be given before each of the more painful parts of a

procedure.

3. If you need stronger pain relief, cover the dilutor hole on the PENTHROX® Inhaler or on the AC Chamber with your finger during use. Your healthcare professional will show you where the dilutor hole is.



4. You do not need to breathe in through the PENTHROX® Inhaler all of the time. Your healthcare professional will encourage you to take breaks from the PENTHROX® Inhaler as this will increase the duration of use.



How long is it given

- Continue using your medicine until your healthcare professional tells you to stop or when you have inhaled the maximum recommended dose.
- One 3 mL bottle of PENTHROX® provides approximately 20-25 minutes of pain relief when inhaled continuously.
- A second 3 mL bottle of PENTHROX® can be given to extend the period of pain relief to approximately 50-55 minutes when inhaled continuously.
- Intermittent inhalation will increase the time of analgesia.

If you use too much PENTHROX®

The healthcare professional giving you PENTHROX® will be experienced in its use, so it is extremely unlikely that you will be given too much. The dose of PENTHROX® is limited by the amount contained in each bottle.

You should not use more than 6 mL in one day and not more than 15 mL in one week.

Administration of consecutive days is not recommended. If the maximum dose is exceeded PENTHROX® may cause irreversible damage to your kidneys.

If you think that you have used too much PENTHROX®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your healthcare professional, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using PENTHROX®?

Things you should do

- You should breathe in through the mouthpiece, initially ensuring that the “dilutor” hole of the PENTHROX® Inhaler is not covered.
- Accustom yourself to the characteristic fruity smell of the PENTHROX® by inhaling gently for the first few breaths through the PENTHROX® Inhaler. You must breathe out through the PENTHROX® Inhaler, if an AC Chamber is attached.
- If further relief is required, you may cover the “dilutor” hole with your finger for a higher inhaled concentration of PENTHROX®.
- **Use PENTHROX® intermittently as required to provide pain relief.**
- You are in control of the level of your pain relief by directly inhaling PENTHROX® from the PENTHROX® Inhaler.
- The aim of PENTHROX® is to relieve pain until you feel comfortable. Relief will commence after approximately 6-10 breaths. Relief will continue for several minutes after ceasing use of PENTHROX®.

Things you should not do

- Do not give PENTHROX® to anyone else, even if they have the same condition as you.
- You should not use more than 6 mL in one day and not more than 15 mL in one week.

Driving or using machines

Do not drive or operate machinery until you know how PENTHROX® affects you.

PENTHROX® may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to PENTHROX® before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Drinking alcohol

Tell your healthcare professional if you drink alcohol.

Alcohol may increase its potential toxicity and should be avoided when PENTHROX® is administered.

Looking after your Medicine

Your healthcare professional will ensure that PENTHROX® is carefully stored below 30°C in its original container.

Getting rid of unwanted Medicine

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your healthcare professional if you have any further questions about side effects.

Less Serious Side Effects

If you are taking PENTHROX® for trauma and associated pain

Less serious side effects	What to do
<p>PENTHROX® may cause:</p> <ul style="list-style-type: none"> • Feeling sick or nauseous • Vomiting • Coughing (usually in the first few breaths) • Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills • Nose and throat inflammation • Pain in the mouth and throat • Dry mouth • Dizziness • Migraine • Loss of memory • Headache • Drowsiness • Difficulty in speaking • Low blood pressure • Feeling drunk • Toothache • Viral infection • Back pain • Fall • Joint sprain • Increase in blood enzyme levels, including alanine aminotransferase, aspartate aminotransferase and blood lactate dehydrogenase • Painful menstrual periods • Rash 	<p>Speak to your healthcare professional if you have any of these less serious side effects and they worry you.</p>

If you require PENTHROX® for surgical procedures

Less serious side effects	What to do
PENTHROX® may cause: <ul style="list-style-type: none">•Dizziness•Feeling of extreme happiness•Feeling sick or nauseous•Sweating•Taste disturbance or loss of taste•Flushing•High blood pressure•Feeling anxious•Depression•Numbness or weakness of the arms and legs•Drowsiness•Vomiting•Confusion	Speak to your healthcare professional if you have any of these less serious side effects and they worry you.

Serious Side Effects

Serious side effects	What to do
<ul style="list-style-type: none">• You experience any symptoms of 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 abdominal area (below your ribs)• You experience any symptoms of kidney problems such as reduced or excessive urination or swelling of feet or lower legs.• You experience too slow and shallow breathing or other difficulties in breathing (symptoms of respiratory depression)	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your healthcare professional if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects (for example changes to blood enzyme levels) can only be found when your doctor does tests from time to time to check your progress.

Reporting Side Effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What PENTHROX® contains

Active ingredient (main ingredient)	Methoxyflurane 99.9%
Other ingredients (inactive ingredients)	Approximately 0.01% Butylated Hydroxy Toluene as stabilising agent
Potential allergens	Hypersensitivity to methoxyflurane, any fluorinated anaesthetic, or to any of the ingredients listed above.

Do not take this medicine if you are allergic to any of these ingredients.

What PENTHROX® looks like

PENTHROX® is a clear, almost colourless liquid with a characteristic fruity smell that becomes a vapour or gas when it is used with the PENTHROX® Inhaler. (Aust R 43144).

PENTHROX® (methoxyflurane) is supplied in the following presentations:

- Pack of ten 3 mL bottles,
- Combination Pack containing one 3 mL bottle, one PENTHROX® Inhaler and Activated Carbon (AC) Chamber,
- Combination Pack (Starter Pack) containing one 3 mL bottle, one PENTHROX® Inhaler and Activated Carbon (AC) Chamber,
- Single Combination Pack containing ten 3 mL bottles and ten PENTHROX® Inhalers
- Double Combination Pack containing two 3 mL bottles, one PENTHROX® Inhaler and Activated Carbon (AC) Chamber (Pack of ten)
- Combination Pack containing one 1.5 mL bottle, one PENTHROX® Inhaler and Activated Carbon (AC) Chamber.
- Single Combination Pack containing ten 1.5 mL bottles and ten PENTHROX® Inhalers

Not all packs may be marketed.

Who distributes PENTHROX®

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