What is this leaflet?

This leaflet answers some of the common questions people ask about PENTHROX® (methoxyflurane). It does not contain all the information known about PENTHROX®.

It does not take the place of talking to your healthcare professional (i.e., doctor, dentist, pharmacist, nurse, etc.).

All medicines have risks and benefits. Your healthcare professional has weighed the risks of you being given PENTHROX® against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your healthcare professional.

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

What PENTHROX® is used for

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

It is inhaled through the custom-built PENTHROX® INHALER.

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

PENTHROX® belongs to a family of medicines called inhalation anaesthetics. At the recommended dose, PENTHROX® provides pain relief without producing anaesthesia. **Ask your healthcare professional if you have any questions about why PENTHROX® has been prescribed for you.**

Before you are given PENTHROX®

When you must not be given it

You must not be given PENTHROX® if you have an allergy to methoxyflurane, other inhalation anaesthetics or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- Shortness of breath, wheezing or difficultly to breathe
- 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.

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

Before you are given it

PENTHROX® should only be used if the package is undamaged and the expiry date marked on the bottle has not been passed.

Tell your healthcare professional if you have allergies to:

- Any other medicines
- Any other substances such as foods, preservatives or dyes
- Any ingredients listed at the end of this information leaflet

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

Your healthcare professional will discuss the possible risks and benefits of being given PENTHROX® during pregnancy.

Tell your healthcare professional if you are breast-feeding or intending to breast-feed.

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

Tell your healthcare professional if you have, or have had, any medical conditions, especially the following:

- Kidney problems
- Liver problems

If you have not told your healthcare professional about any of the above, tell them before you are given PENTHROX®.

You may still be able to use PENTHROX®, but your healthcare professional will need to assess the risks against the potential benefits.

Taking other medicines

Tell your healthcare professional if you are taking any other medicines, including medicines that you buy without a prescription at the chemist, supermarket or health food shop.

Some medicines and PENTHROX® may interfere with each other. Your healthcare professional needs to know if you are taking any of these medicines to accurately assess the risks and benefits of administering PENTHROX®. These include:

- Tetracycline
- Gentamicin
- Kanamycin
- Colistin
- Polymyxin B
- Cephaloridine
- Amphotericin B
- Barbiturates

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

How PENTHROX® is given

How much is given

One bottle of PENTHROX® (1.5 mL or 3 mL) to be used initially. Additional bottle(s) may be used if required. The maximum recommended dosage is 6mL 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.

Relief will commence after approximately 6-10 breathes. First take a few gentle breath and hold breath briefly to get used to the fruity smell. Then continue to breathe normally in and out through the Inhaler. Breathing through the Inhaler directs your exhaled breathe through the Activated Carbon (AC) Chamber (if used) which adsorbs exhaled methoxyflurane.

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

How long is it given for

Continue using your medicine until your healthcare professional tells you to or when you have inhaled the maximum recommended dose.

One 3mL 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 analgesic.

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 inhale PENTHROX® either directly from the custom built PENTHROX® INHALER or with the assistance of a face mask.

Overdose

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.** If the maximum dose is exceeded PENTHROX® may cause irreversible damage to your kidneys.

Immediately contact your healthcare professional or **the Poisons Information Centre (telephone 13 11 26**) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much PENTHROX®. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are being given PENTHROX®

Things you must 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 may breathe out through the PENTHROX® INHALER, if an AC Chamber is attached, or through your nose.
If further relief is required you may cover the “dilutor” hole for a

higher inhaled concentration of PENTHROX®.
Use PENTHROX® intermittently as required to provide pain relief.

Things you must not do
Do not give PENTHROX® to anyone else, even if they have the same condition as you.

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.

Things that may be helpful
You are in control of the level of your relief by directly inhaling PENTHROX® from the custom-built 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®.

Side Effects

Tell your healthcare professional as soon as possible if you do not feel well after you have been given PENTHROX®.

PENTHROX® is well tolerated, but it may occasionally have unwanted side effects. All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your healthcare professional to answer any questions you may have.
Other side effects not listed below may occur in some patients.
Do not be alarmed by this list of possible side effects. You may not experience any of them.

<u>If you are taking PENTHROX® for Trauma and associated pain</u>

Tell your healthcare professional if you notice any of the following side effects and they worry you.
PENTHROX® may cause:
- Feeling sick or nauseous
- Dry mouth
- Coughing (usually in the first few breaths)
- Vomiting
- Dizziness
- Loss of memory
- Headache
- Migraine
- Drowsiness
- Low blood pressure
- Feeling drunk
- Toothache
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- Viral infection
- Nose and throat inflammation
- Fall
- Joint sprain
- Increase in blood enzyme levels, including alanine aminotransferase, aspartate aminotransferase and blood lactate dehydrogenase
- Painful menstrual periods
- Pain in the mouth and throat
- Rash
- Back pain
- Difficulty in speaking

<u>If you require PENTHROX® for surgical procedures</u>

Tell your healthcare professional if you notice any of the following side effects and they worry you.
PENTHROX® may cause:
- 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

These lists include the more common side effects of PENTHROX®. They are usually mild and only last a short time.

Contact your doctor immediately if:
- **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.**

Tell your healthcare professional if you notice anything else that is making you feel unwell.
Other sides effects not listed above may also occur in some people. Some of these side effects (for examples changes to blood enzyme levels) can only be found when your doctor does tests from time to time to check your progress.

After being given PENTHROX® (methoxyflurane)

Storage
PENTHROX® should be carefully stored below 30℃ in its original container.

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

Product Description

What it 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

PENTHROX® is supplied in the following presentations:

a) 3 mL sealed bottle with a tear off tamper-evident seal (packs of 10),
b) Combination pack with one 3 mL sealed bottle and one PENTHROX® INHALER (packs of 1 or 10), with/without optional activated carbon chamber
c) Combination pack with two 3 mL sealed bottles and one PENTHROX® INHALER (packs of 10), and
d) Combination pack with one 1.5 mL sealed bottle and one PENTHROX Inhaler (packs of 1 or 10) with AC Chamber.

Healthcare professionals can also obtain additional PENTHROX® INHALER separately.

Ingredients
Active Ingredient:
- Methoxyflurane 99.9%

There is a small amount (approximately 0.01% Butylated Hydroxy Toluene) of stabilising agent in PENTHROX®.

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This leaflet was revised in May 2015.

Australian Registration Number:
AUST R 43144