







ENTONOX is used exclusively for the relief of pain.

Method of administration

ENTONOX is administered through a facemask or mouthpiece. The facemask or mouthpiece is connected to an ENTONOX supply through a demand valve system which allows the ENTONOX to be self-regulated by the patient. The demand valve is operated by the act of inhalation of the patient and closes down when the patient ceases to inhale.

ENTONOX should not be used for more than a total of 24 hours, or more frequently than every 4 days, without close clinical supervision and haematological monitoring (see sections 4.4 and 4.8).

Contraindications

ENTONOX should not be used in any condition where gas is entrapped within a body and where its expansion might be dangerous, such as with:

- Artificial, traumatic or spontaneous pneumothorax
- Air embolism
- Decompression sickness
- Following a recent dive
- · Following air encephalography
- Severe bullous emphysema
- Use during myringoplasty
- Gross abdominal distension
- In-patients having received recent intraocular injection of gas

In-patients taking other centrally acting depressant medicinal products, such as morphine derivatives and/or benzodiazepines, concomitant administration of ENTONOX may result in increased sedation, and consequently have effects on respiration, circulation and protective reflexes. If ENTONOX is to be used in such patients, this should take place under the supervision of appropriately trained personnel.

ENTONOX is non-flammable but strongly supports combustion and should not be used near sources of ignition.

Smoking is prohibited when using ENTONOX.

Under no circumstances should oils or grease be used to lubricate any part of the ENTONOX cylinder or the associated equipment used to deliver the gas to the patient.

Where moisturising preparations are required for use with a facemask or in nasal passages, oil based creams should not be used.

Check that hands are clean and free from any oils or grease.

Where alcohol gels are used to control microbiological cross-contamination ensure that all alcohol has evaporated before handling ENTONOX cylinders or equipment.

When ENTONOX is used as a sole analgesic/sedative agent, driving and use of complex machinery is not recommended until:

- The healthcare professional has judged that the patient has returned to their normal mental status
- The patient feels that they are competent to drive after the relevant procedure is completed
- At least 30 minutes has elapsed after the administration of ENTONOX has ceased

Undesirable effects

Events such as euphoria, disorientation, sedation, nausea, vomiting, dizziness and generalised tingling are commonly described. These events are generally minor and rapidly reversible.

Addiction may occur.

Prolonged exposure may result in bowel distension, middle ear damage and rupture of ear drums.

When used appropriately, there is no risk of overdose with ENTONOX. Inappropriate, unwitting or deliberate inhalation of ENTONOX will ultimately result in unconsciousness, passing through stages of increasing light headedness and intoxication. The treatment is removal to fresh air, mouth to mouth resuscitation and, if necessary, the use of an oxygen resuscitator.

ENTONOX strongly supports combustion and will cause substances to burn vigorously, including some materials that do not normally burn in air due to the high concentration of oxygen within the mixture.

It is highly dangerous in the presence of oils, greases, tarry substances and many plastics due to the risk of spontaneous combustion in the presence of oxygen in relatively high concentrations.

ENTONOX cylinders should be:

- Stored under cover, preferably inside, kept dry and clean
- Not stored near stocks of combustible materials
- Not subjected to extremes of heat or cold
- Stored separately from industrial and other non-medical cylinders
- Stored to maintain separation between full and empty cylinders
- Used in strict rotation so the cylinders with the earliest filling date are used first
- Stored separately from other medical cylinders within the store
- F size cylinders and larger should be stored vertically. D size cylinders and smaller may be stored horizontally

To ensure that the gas is suitable for immediate use, ENTONOX cylinders should be maintained at a temperature above 10c for at least 24 hours before use.

Care is needed when handling and using ENTONOX cylinders.

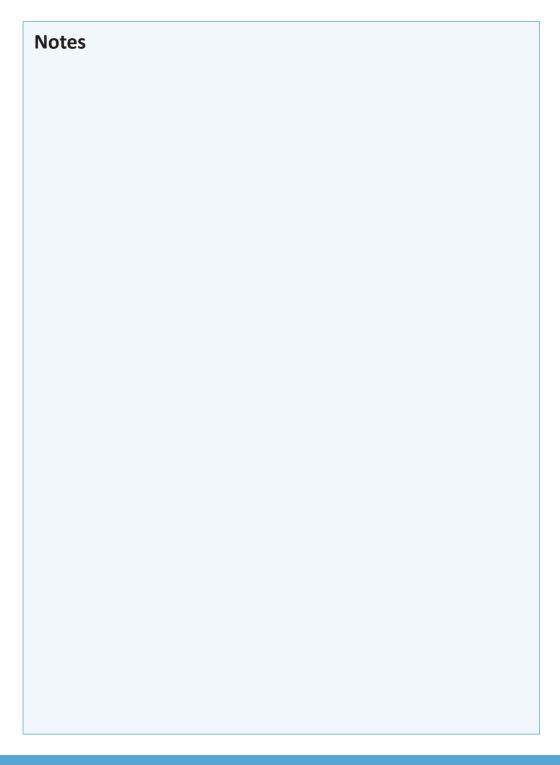
When ENTONOX cylinders are in use ensure that they are:

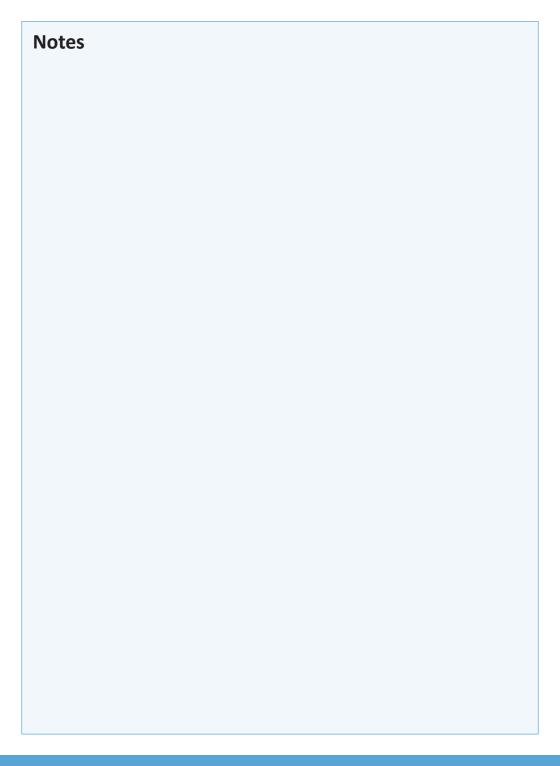
- Only used for medicinal purposes
- Turned off, when not in use, using only moderate force to close the valve
- Only moved with the appropriate size and type of trolley or handling device
- Not used in the vicinity of persons smoking or near naked lights
- Used in well ventilated areas

After use

When the ENTONOX cylinder is empty ensure that the:

- Cylinder valve is closed using moderate force only
- The valve cap is replaced (where fitted)
- Empty cylinders are immediately returned to the empty cylinder store for return to the supplier





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