

Package Leaflet: Information for the patient
Doxapram Hydrochloride 2 mg/ml Solution for infusion
Doxapram Hydrochloride

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 doctor or nurse

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Doxapram Hydrochloride is and what it is used for

Doxapram Hydrochloride 2 mg/ml Solution for infusion (also referred to Doxapram Hydrochloride in the remainder of this leaflet) is used to help you breathe after you have been given an anaesthetic, when your breathing may not be as good as it should be. Also some pain-killers used in anaesthesia have the side effect of decreasing your breathing and Doxapram Hydrochloride can prevent this problem.

Your doctor can also use Doxapram Hydrochloride to speed up your recovery after an anaesthetic and also from associated sleepiness. Doxapram Hydrochloride works by increasing the amount of air that goes in and out of your lungs and increases your rate of breathing.

Doxapram Hydrochloride is therefore useful in conditions where breathing properly may be difficult.

2. What you need to know before you are given Doxapram Hydrochloride

You should not be given Doxapram Hydrochloride:

- if you are allergic to Doxapram Hydrochloride or any of the ingredients of this medicine (listed in section 6).
- if you have very high blood pressure
- if you are suffering from a state of sudden severe wheezing known as status asthmaticus
- if you have heart disease
- if you suffer from epilepsy or a similar condition involving fits or convulsions
- if you have what is called cerebral oedema, where there is build up of fluid in the brain
- if you have suffered from a stroke

- if you suffer from the condition known as hyperthyroidism/ thyrotoxicosis. (when you have an overactive thyroid gland and your body produces too much of the hormone thyroxine)
 - if the airways in your lungs or the muscles in the chest wall that you use to breathe are severely blocked in any way
 - if you have a head injury
 - if you suffer from a blood clot in the lung (pulmonary embolism).
- Make sure your doctor knows if you suffer from any of the above.

Warnings and precautions

Before you are given Doxapram Hydrochloride, your doctor will take special care if any of the following situations apply to you.

Make sure your doctor is aware of these situations if it is not already obvious:

- If you are wheezing or have problems with your breathing, your doctor will probably give you another drug or oxygen to control this while you are taking Doxapram Hydrochloride
- If you suffer from any liver problems
- You have been under anaesthetic, the type of anaesthetic used will affect the way your doctor gives you Doxapram Hydrochloride. Your doctor will monitor you closely after having an anaesthetic, as the effects of other drugs used during an operation must be considered when Doxapram Hydrochloride is being given
- If you have a tumour of the adrenal glands called a phaeochromocytoma
- If you have high blood pressure.

Tell your doctor if any of these apply to you.

Other medicines and Doxapram Hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is extremely important because some medicines can strengthen or weaken the effects of others.

In particular, tell your doctor if you are taking any of the following as it may alter their effect:

- Drugs that stimulate certain nerves known as sympathomimetics. These are often used in the treatment of asthma, eg salbutamol and terbutaline
- A Monoamine oxidase inhibitor (MAOI) which is a drug used to treat depression (eg. phenelzine, tranylcypromine)
- Certain anaesthetics such as halothane, cyclopropane and enflurane
- A drug called aminophylline/theophylline which may be used in the treatment of asthma
- curare-type medicines used as muscle relaxants.

Pregnancy and breast feeding

If you are pregnant or breast feeding, think you may become pregnant or are planning to have a baby, you should tell your doctor. This may affect his decision about whether to give you Doxapram Hydrochloride or not.

Doxapram Hydrochloride contains glucose:

Contains 0.05 g (50 mg) glucose per ml. This should be taken into account in patients with diabetes mellitus when doses more than 100 ml are administered.

3. How Doxapram Hydrochloride is given to you

Your doctor will give you Doxapram Hydrochloride through a drip into one of your veins. The amount you are given will depend on your condition and on how well you are responding to the medicine.

Adults and the elderly:

Normally you will be given between 1.5 and 4 mg of Doxapram Hydrochloride per minute, up to periods of an hour or more.

Use in children

Doxapram Hydrochloride is not recommended for use in children.

If you are given more Doxapram Hydrochloride than you should

If your doctor accidentally gives you too much of this medicine you may feel the following, your heartbeat becomes irregular, you develop some shortness of breath and your muscle movements become more difficult. Tell your doctor immediately if you feel any of these symptoms.

If you have any further questions on the use of this product ask your doctor or pharmacist.

4. Possible side effects

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

All medicines can cause allergic reactions although serious allergic reactions are very rare. **Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.**

If you develop sudden and severe increase in blood pressure or difficulty in breathing your doctor will stop Doxapram.

The following side effects have also been reported with frequency of not known (they cannot be estimated from the available data).

- feeling feverish, flushed and possibly sweating
- headache
- coughing
- dizziness
- shortness of breath
- feeling hyperactive
- tightening of the chest and throat\
- feeling confused
- increased blood pressure
- having hallucinations (see, hear, smell, taste, or feel something quicker or slower heartbeat than usual that is not there)
- feeling sick and perhaps being sick
- warmth at the base of the tummy

- vomiting
- salivation
- irregular heart beat
- muscle twitches
- slight decrease in blood supply to the brain
- inability to pass urine or sudden passing of urine
- fits
- chest pain or chest tightness.
- Increase in muscle tone and sustained muscle contractions (Muscle spasticity),
- series of involuntary muscular contractions (Clonus),
- reflex of toe in response to foot stroke (bilateral Babinski),
- increased reflexes in brain function (increased deep tendon reflexes)
- premature contraction of heart (extrasystoles).

Additional side effects in children, infants and pre-term newborns:

Although doxapram is not recommended for use in children, its use in children is known to cause the following side effects:

Prolonged use of Doxapram in premature infants may cause neurodevelopmental delay (some parts of the brain are late in maturing)

- Doxapram use in pre-term neonates may cause cardiac problems (significant lengthening of QTc interval on Electrocardiogram, sometimes associated with heart block)
- Blood in stools, painful swelling of abdominal cavity (abdominal distension), death of tissues in the portions of bowel (necrotizing enterocolitis), multiple gastric perforations (penetration of wall of the stomach)
- Early teeth eruption.

If any of the side effects persist or become more serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Doxapram Hydrochloride

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

Your doctor, pharmacist or nurse will know how to store Doxapram Hydrochloride properly.

Do not use this medicine after the expiry date which is stated on the infusion bag after 'EXP'.

The expiry date refers to the last day of that month.

Keep bag in its outer pouch until ready to use.

Do not store above 25°C.
For single use only. Discard any unused contents. Once opened use immediately.

6. Contents of the pack and other information

What Doxapram Hydrochloride contains

The active substance is doxapram hydrochloride. There is 2 mg of doxapram hydrochloride in 1 ml of the infusion solution.

There is 1000 mg (1 g) of doxapram Hydrochloride in 500 ml of infusion solution. (2 mg in 1 ml infusion solution).

The other ingredient is 5% glucose and water for injections.

The product should only be given if it is clear and should not be given if particles, cloudiness or leaks are evident or if the container is damaged.

What Doxapram Hydrochloride looks like and contents of pack

The name of your medicine is Doxapram Hydrochloride and is supplied in flexible plastic bags inside a protective plastic overpouch.

Each Infusion bag contains 500 ml of a clear colourless sterile solution for infusion.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

MercuryPharm Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer

Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk, IP24 3SE United Kingdom.

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