

**Patient Information Leaflet**  
**Doxapram Hydrochloride 2 mg/ml Solution for infusion**

**Read all of this leaflet carefully before you start using this medicine.**

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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

In this leaflet:

1. What Doxapram Hydrochloride 2 mg/ml Solution for infusion is and what it is used for
2. Before you are given Doxapram Hydrochloride 2 mg/ml Solution for infusion
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**1. WHAT DOXAPRAM HYDROCHLORIDE 2 MG/ML SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR BEFORE YOU**

Doxapram Hydrochloride 2 mg/ml Solution for infusion 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 2 mg/ml Solution for infusion can prevent this problem. Your doctor can also use Doxapram Hydrochloride 2 mg/ml Solution for infusion to speed up your recovery after an anaesthetic and also from associated sleepiness.

Doxapram Hydrochloride 2 mg/ml Solution for infusion works by increasing the amount of air that goes in and out of your lungs and increases your rate of breathing.

Doxapram Hydrochloride 2 mg/ml Solution for infusion is therefore useful in conditions where breathing properly may be difficult.

**2. BEFORE YOU ARE GIVEN DOXAPRAM HYDROCHLORIDE 2 MG/ML SOLUTION FOR INFUSION**

**You should not be given Doxapram Hydrochloride 2 mg/ml Solution for infusion if:**

- you know that you are allergic to any of the ingredients of Doxapram Hydrochloride 2 mg/ml Solution for infusion
- you have very high blood pressure
- you are suffering from a state of sudden severe wheezing known as status asthmaticus
- you have heart disease
- you suffer from epilepsy or a similar condition involving fits or convulsions
- you have what is called cerebral oedema, where there is build up of fluid in the brain
- you have suffered from a stroke
- 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)

- the airways in your lungs or the muscles in the chest wall that you use to breathe are severely blocked in any way
- you have a head injury
- you suffer from a blood clot in the lung (pulmonary embolism).

Make sure your doctor knows if you suffer from any of the above.

**Before you are given** Doxapram Hydrochloride 2 mg/ml Solution for infusion, 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 2 mg/ml Solution for infusion
- 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 2 mg/ml Solution for infusion. 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 2 mg/ml Solution for infusion 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.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines obtained without a prescription. 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 or think you may be pregnant, or are planning to become pregnant, or are breast feeding you should tell your doctor. This may affect his decision about whether to give you Doxapram Hydrochloride 2 mg/ml Solution for infusion or not.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Important information about some of the ingredients of Doxapram Hydrochloride 2 mg/ml Solution for infusion:**

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.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. HOW DOXAPRAM HYDROCHLORIDE 2 MG/ML SOLUTION FOR INFUSION IS GIVEN TO YOU**

Your doctor will give you Doxapram Hydrochloride 2 mg/ml Solution for infusion 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 2 mg/ml Solution for infusion per minute, up to periods of an hour or more.

Doxapram Hydrochloride 2 mg/ml Solution for infusion is not recommended for use in children.

#### **If you are given more Doxapram Hydrochloride 2 mg/ml Solution for infusion 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 Doxapram Hydrochloride 2 mg/ml Solution for infusion can sometimes 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:

- 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.

#### **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.

**You may also experience the below side effects with Doxapram:**

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) and premature contraction of heart (extrasystoles).

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie)

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE DOXAPRAM HYDROCHLORIDE 2 MG/ML SOLUTION FOR INFUSION**

Your doctor, pharmacist or nurse will know how to store Doxapram Hydrochloride 2 mg/ml Solution for infusion properly.

Do not use this medicine after the expiry date which is stated on the infusion bag. The expiry date refers to the last day of that month.

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

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. FURTHER INFORMATION**

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 used if it is clear and should not be used if particles, cloudiness or leaks are evident or if the container is damaged.

**What Doxapram Hydrochloride 2 mg/ml Solution for infusion looks like and contents of pack**

The name of your medicine is Doxapram Hydrochloride 2 mg/ml Solution for infusion 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**

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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