

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
Doxapram Hydrochloride 20mg/ml Solution for Injection
Doxapram Hydrochloride

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU ARE GIVEN 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.

The name of your medicine is Doxapram Hydrochloride 20mg/ml Solution for Injection. It will be referred to as Doxapram Injection for ease hereafter.

What is in this leaflet

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

1. WHAT DOXAPRAM INJECTION IS AND WHAT IT IS USED FOR

Doxapram Injection contains the active substance doxapram hydrochloride. It 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 painkillers used in anaesthesia have the side effect of decreasing your breathing and this medicine can prevent this problem. Your doctor can also use this medicine to speed up your recovery after an anaesthetic and also from associated sleepiness.

Doxapram Injection works by increasing the amount of air that goes in and out of your lungs and increases your rate of breathing.

This medicine is therefore useful in conditions where breathing properly may be difficult.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN DOXAPRAM INJECTION

You should not be given Doxapram Injection:

- if you know that you are allergic to Doxapram Hydrochloride or any of the other ingredients of Doxapram Injection
- 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 an injury to the head
- 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

Talk to your doctor or nurse before you are given Doxapram Injection:

- 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 Injection
- 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 Injection. Your doctor will monitor you closely after having an anaesthetic, as the effects of other drugs used during an operation must be considered when this medicine is being given
- If you have a tumour of the adrenal glands called phaeochromocytoma
- If you have high blood pressure.

Tell your doctor if any of these apply to you.

Other medicines and Doxapram Injection

Tell your doctor if you are taking, have recently taken, or might take any other medicines, including 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 muscle relaxant drugs (which decrease the muscle tone).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine. This may affect his decision about whether to give you Doxapram Injection or not.

3. HOW DOXAPRAM INJECTION IS GIVEN TO YOU

Your doctor will give you Doxapram Injection by injecting it 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:

The recommended dose that you would be given is between 1.0 and 1.5mg of this medicine for each kilogram that you weigh (e.g. if you weigh 70 kilograms you will probably receive between 70mg and 105mg of this medicine). This dose may be repeated hourly if necessary.

Use in children and adolescents:

Doxapram Injection is not recommended for use in children.

If you are given more Doxapram Injection 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 medicine ask your doctor or nurse.

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 Injection.

The following side effects have also been reported:

Not known (frequency cannot be estimated from available data)

- feeling feverish, flushed and possibly sweating
- coughing
- shortness of breath
- tightening of the chest and throat
- increased blood pressure
- quicker or slower heartbeat than usual
- warmth at the base of the tummy
- muscle twitches
- chest pain or chest tightness
- increased muscle tone/stiffness (Muscle spasticity)
- reflex of toe in response to foot stroke (bilateral Babinski)
- weakness in the limbs, slurred speech or visual disturbances which may be caused by reduced blood supply to the brain
- slight decrease in blood supply to brain
- premature contraction of heart (extrasystoles)

- fits
- headache
- dizziness
- feeling hyperactive
- feeling confused
- having hallucinations (see, hear, smell, taste, or feel something that is not there)
- nausea (feeling sick) and vomiting (being sick)
- salivation
- series of involuntary muscular contractions (Clonus)
- increased reflexes in brain function (increased deep tendon reflexes)
- irregular heart beat
- inability to pass urine or sudden passing of urine.

Children, infants and pre-term newborns

Although Doxapram Injection 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.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly. (See details below)

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance,

Earlsfort Terrace,

IRL - Dublin 2;

Tel: +353 1 6764971;

Fax: +353 1 6762517.

Website: www.hpra.ie

E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOXAPRAM INJECTION

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

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

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate.

Once opened use immediately.

For single use only. Discard any unused contents.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Doxapram Injection contains

The active substance is doxapram hydrochloride. There is 100mg of Doxapram hydrochloride in 5ml of the injection (20mg in each ml of the injection).

The other ingredient is Water for Injections.

What Doxapram Injection looks like and contents of pack

The name of your medicine is Doxapram Hydrochloride 20mg/ml Solution for Injection and is supplied in glass ampoules packed in a cardboard carton.

Each ampoule contains 5ml of a clear colourless sterile solution for injection.

Five ampoules are supplied in a carton.

Marketing Authorisation holder

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

Manufacturer

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

This leaflet was last revised in June 2017.

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for medical or healthcare professionals only.

Incompatibilities:

Doxapram Injection is incompatible with alkaline solutions such as aminophylline, furosemide and thiopental sodium.