

Package leaflet: Information for the user

Pancuronium Bromide 2 mg/ml Solution for Injection pancuronium bromide

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

What is in this leaflet

1. What Pancuronium Bromide Solution for Injection is and what it is used for
2. What you need to know before you use Pancuronium Bromide Solution for Injection
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1. What Pancuronium Bromide Solution for Injection is and what it is used for

Pancuronium bromide is one of a group of medicines called ‘non-depolarising’ muscle relaxants.

Pancuronium Bromide Solution for Injection is used to relax muscles during surgery, including caesarean section and in intensive care.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Pancuronium Bromide Solution for Injection

Do not use Pancuronium Bromide Solution for Injection

- if you are allergic to pancuronium bromide or any of the ingredients of this medicine (listed in section 6).
- if you are using “depolarising” muscle relaxants, e.g. suxamethonium at the same time.

Warning and precautions

Talk to your doctor or pharmacist or nurse before using Pancuronium bromide solution for injection

- if you have kidney, liver, lung or heart disease
- if you have high blood pressure
- if you have cancer, particularly lung cancer
- if you suffer from any of the following conditions: muscular dystrophy, myasthenia gravis, myasthenic syndrome (other neuromuscular diseases) or poliomyelitis
- if you have fluid retention (you may have swelling around the ankles)
- if you have jaundice

Children and elderly

Special care will also be taken in the elderly, newborn babies, patients who are dehydrated or in general poor health and patients who have blood abnormalities, such as altered calcium, magnesium, potassium and protein levels (the doctor may do blood tests to check for such abnormalities).

If you are passing a lot of urine (hyperdiuresis) or have a very low body temperature (hypothermia), this medicine may not work as well.

Other medicines and Pancuronium Bromide Solution for Injection

Tell your doctor, pharmacist or nurse if you are taking or have recently taken or might take any other medicines. Pancuronium bromide must not be administered along with a “depolarising” muscle relaxant, e.g. suxamethonium.

Other medicines used/taken at the same time as pancuronium bromide may interact, special care may be needed, for example:

- other muscle relaxants of the ‘non-depolarising’ type (e.g. mivacurium)
- some anaesthetic/analgesic agents (e.g. halothane, ether, enflurane, isoflurane, methoxyflurane, cyclopropane, thiopentone, methohexitone, ketamine, gammahydroxybutyrate, etomidate, propanidid, neuroleptic analgesia (e.g. droperidol/fentanyl))
- anticancer medicines belonging to a group called ‘alkylating agents’ (including medicines known as ‘nitrogen mustards’)
- some antibiotics (e.g. aminoglycosides, polypeptide antibiotics and metronidazole) and antifungal medicines (e.g. imidazoles)
- medicines affecting the heart or blood pressure (glyceryl trinitrate (“nitroglycerin”), propranolol, adrenaline, noradrenaline, alpha blockers, beta blockers, quinidine)
- water tablets (diuretics)
- medicines used to control anxiety (diazepam)
- antidepressants (e.g. tricyclic antidepressants, monoamine oxidase inhibitors)
- strong pain-killers (e.g. narcotics)
- steroid medicines
- medicines used to treat a disease affecting the muscles called ‘myasthenia gravis’ (neostigmine, pyridostigmine, edrophonium)
- phenytoin (antiepilepsy medicine)
- heparin and protamine (medicines used to control the ease with which the blood will clot)
- azathioprine (a medicine used to prevent transplant rejection)
- theophylline (a medicine used to treat some breathing disorders)
- medicines used to increase the level of some salts in the blood (potassium chloride, sodium chloride, calcium chloride)
- vitamin B1 (thiamine) if taken in high doses
- magnesium sulfate (used in the treatment of constipation, pre-eclampsia, abnormal heart rhythms)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will only use this medicine if the expected benefits outweigh any potential risk to your baby.

Driving and using machines

Do not drive or use machines for 24 hours after full recovery from the muscle relaxant effects of pancuronium bromide.

Pancuronium Bromide Solution for Injection contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per ampoule, that is to say essentially ‘sodium free’.

3. How to use Pancuronium Bromide Solution for Injection

This medicine will be given to you as an injection into a vein.

Dose

The dose of medicine given to you will depend upon your age, your weight, expected duration of surgery, drugs that have been given to you previously and how well your kidneys and liver are working.

The recommended dose range in adults is typically between 50 and 100 micrograms/kg bodyweight. Smaller doses of 10 to 20 micrograms/kg bodyweight may follow.

For children, the initial dosage range of medicine given to you may be between 60 – 100 micrograms/kg bodyweight. Smaller doses of 10 to 20 micrograms/kg bodyweight may follow.

Use in children

For neonates, the dosage may vary but may be between 30 – 40 micrograms/kg bodyweight.

If you are given more Pancuronium Bromide Solution for Injection than you should

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

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

During use of Pancuronium Bromide Solution for Injection your doctor will be observing you for:

- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint

If this serious side effect occurs, urgent medical attention will be needed.

After you have come round, if any of the following happen, tell your doctor as soon as possible:

- breathing difficulties
- unusually rapid heartbeat, palpitations or irregular heart beat
- pain, itching, local skin reaction or irritation particularly around the injection site
- problems with your vision
- skin rash
- excess production of saliva

Muscle weakness has been reported however its frequency cannot be estimated from the available data.

After pancuronium bromide administration, a small to moderate rise in blood pressure may occur. Increased heart rate and force are also frequently reported. These side-effects are generally considered to be positive. Your doctor may monitor for these changes.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance.

Website: www.hpra.ie.

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Pancuronium Bromide Solution for Injection

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

For single use only. Discard any unused contents.

Do not use pancuronium bromide solution for injection if you notice that it shows evidence of precipitation or any other particulate matter.

Expiry

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

Storage

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the ampoule in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pancuronium Bromide Solution for Injection contains

The active substance is pancuronium bromide. Each millilitre (ml) of solution contains 2 milligrams (mg) of pancuronium bromide.

The other ingredients are sodium chloride, sodium acetate trihydrate, water for injections and glacial acetic acid (see section 2 **Pancuronium Bromide Solution for Injection contains Sodium**).

What Pancuronium Bromide Solution for Injection looks like and contents of the pack

Pancuronium Bromide Solution for Injection is a clear, sterile, colourless solution for injection which comes in glass containers called ampoules.

It may be supplied in packs containing:

- 5 x 4 mg/2 ml ampoules
- 10 x 4 mg/2 ml ampoules
- 50 x 4 mg/2 ml ampoules

Not all packs may be marketed.

Marketing Authorisation Holder

Pfizer Healthcare Ireland
9 Riverwalk, National Digital Park
Citywest Business Campus
Dublin 24, Ireland

Manufacturers

Pfizer Service Company BVBA
Hoge Wei 10

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Belgium

This leaflet was last revised in 12/2020

Ref: gxPU 9_0

Pancuronium Bromide 2 mg/ml Solution for Injection

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3 of the package leaflet, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities

Do not mix other solutions in the same syringe as a change in pH can cause precipitation.

Instructions for use and handling

For single use only.

Any unused solution should be discarded.

It is not recommended to give this product by infusion.