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.

Do not use Pancuronium Bromide Solution for Injection
• if you have shown signs of hypersensitivity (severe allergy) to pancuronium or bromide in the past
• if you are using “depolarising” muscle relaxants, e.g. suxamethonium at the same time.

Tell your doctor if the above applies to you before this medicine is used.

Take special care with 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

Tell your doctor if any of the above applies to you before this medicine is used.

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.

Taking/using 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, hence, 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, neurolept 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 sulphate (used in the treatment of constipation, pre-eclampsia, abnormal heart rhythms)

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Pregnancy and breast-feeding**
Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will only use this medicine if the expected benefits outweigh any potential risk to your baby.

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

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

**Important information about one of the ingredients of Pancuronium Bromide Solution for Injection**
This medicinal product contains less than 1 mmol (23 mg) sodium per dose, i.e. 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 initial 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.

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

**If you are given too much or too little Pancuronium Bromide Solution for Injection**

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, pancuronium bromide 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

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 via:

**Ireland**

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: medsvetry@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PANCURONIUM BROMIDE SOLUTION FOR INJECTION

Keep out of the reach and sight 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
This medicine must not be used after the expiry date which is stated on the vial ampoule and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage
The ampoules should be kept in the outer carton, in order to protect from light, and stored in a refrigerator (2-8°C). They should not be frozen.

6. FURTHER 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.

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 and manufacturer
Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead
SL6 6RJ
UK

This leaflet was last revised in 11/2015
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.