PACKAGE LEAFLET: Information for the patient

PANCURON

Solution for injection – 4 mg / 2 ml

(Pancuronium bromide)

Read this leaflet carefully before you start taking 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Pancuron is and what it is used for
2. Before you take Pancuron
3. How to take Pancuron
4. Possible side effects
5. How to store Pancuron
6. Other information

1. WHAT PANCURON IS AND WHAT IT IS USED FOR

Pancuron contains the active substance pancuronium bromide.

Pancuron is a long-acting non-depolarising muscle relaxant, also known as non-depolarising neuromuscular blocking agent.

Pancuron solution for injection is used for muscle relaxation in general anaesthesia.

2. BEFORE YOU TAKE PANCURON

Do not use Pancuron:

- if you are hypersensitive (allergic) to pancuronium, bromide ion or any of the ingredients of Pancuron;
- in patients who cannot have artificial respiration;
- in patients with pre-existing tachycardia or in patients in whom even a minor elevation in heart rate is undesirable.

Take special care with Pancuron

Competitive neuromuscular blockers can severely compromise respiratory function and cause respiratory paralysis.

Competitive neuromuscular blockers should be used only by individuals who are experienced in their use and in the maintenance of an adequate airway and respiratory support.

Patients who have received a neuromuscular blocker should always have their respiration assisted or controlled until the drug has been inactivated or antagonised.

Competitive neuromuscular blockers should be used with great care, if at all, in respiratory insufficiency or pulmonary disease and in the dehydrated or severely ill patient.

Pancuronium paralyses the respiratory and skeletal musculature, without affecting consciousness. Pancuronium must therefore only be administered after sleep-inducing drugs have been given. An antidote should be immediately available.

Competitive neuromuscular blockers should be used with caution in patients with hepatic impairment and in geriatric or debilitated patients.

The response to neuromuscular blockers is often unpredictable in patients with neuromuscular disorders and they should be used with great care in these patients.

Care is also required in patients with a history of hypersensitivity to any neuromuscular blocker because high rates of cross-sensitivity have been reported.

Resistance to the effects of competitive neuromuscular blockers may occur in patients with burns. The dose requirements of competitive neuromuscular blockers are increased in patients with burns.

Competitive neuromuscular blockers excreted mainly in the urine should be used with caution in renal impairment; a reduction in dosage may be necessary.

Competitive neuromuscular blockers should be used with extreme caution, if at all, in patients with myasthenia gravis.

The effects of competitive neuromuscular blockers are increased by metabolic or respiratory acidosis, hypokalaemia, hypermagnesaemia, hypocalcaemia, hypophosphataemia and dehydration.

Pancuronium should be used with caution in patients with raised catecholamine concentrations, or in those who are receiving drugs with sympathomimetic effects, as cardiovascular adverse effects are more likely in these patients.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Combinations of competitive neuromuscular blockers may have additive or synergistic effects and the sequence of administration may also affect the interaction. The effects of a competitive blocker may be increased if it is given after a depolarizing blocker.
The effect of pancuronium is increased when inhalation narcotics (e.g. halothane, isoflurane, enflurane, sevoflurane, desflurane) are given.

The aminoglycoside antibacterials possess neuromuscular blocking activity. Appropriate measures should be taken to accommodate the increased neuromuscular blockade and the prolonged and potentially fatal respiratory depression that can occur if these antibacterials are used with conventional neuromuscular blocking drugs.

The effects of pancuronium can be opposed by aminophylline. Supraventricular tachycardia has occurred in patients taking aminophylline when pancuronium was given.

The effects of many competitive neuromuscular blockers are reduced and shortened if carbamazepine or phenytoin are given for longer than one week, but they appear to be increased if phenytoin, and possibly carbamazepine, are given acutely (e.g. during surgery).

Colistin, colistimethate sodium, polymyxin B, clindamycin, lincomycin, some penicillins (apalcillin, azlocillin, mezlocillin, piperacillin) and vancomycin possess some neuromuscular blocking activity. Increased and prolonged neuromuscular blockade is possible if these antibacterials are used with neuromuscular blocking drugs.

The neuromuscular blocking effect of pancuronium is antagonised by high-dose of prednisone, or prednisolone and hydrocortisone. However, prolonged coadministration of high-dose corticosteroids and neuromuscular blockers may increase the risk of myopathy, resulting in prolonged paralysis following the discontinuation of the neuromuscular blocker.

Serious cardiac arrhythmias can develop in patients receiving digitalis glycosides who are given pancuronium.

Calcium-channel blockers can increase the neuromuscular blocking effects of competitive neuromuscular blockers.

The effects of the neuromuscular blockers have been both increased and decreased by furosemide.

Tricyclic antidepressants may increase the risk of arrhythmias and hypotension during anaesthesia. Tachyarrhythmias have been seen in patients taking imipramine who were given halothane and pancuronium.

In patients taking lithium, prolonged blockade and respiratory difficulties after receiving standard doses of pancuronium may occur.

The effects of pancuronium can be increased and prolonged by magnesium sulfate given parenterally.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Competitive neuromuscular blocking drugs are highly ionised at physiological pH and are therefore unlikely to cross the placenta in significant amounts. However, Pancuron should be used during pregnancy only when the administering doctor decides that the potential benefits outweigh the possible risks on the fetus.

Neuromuscular blocking agents should be used with caution and dosage reduced as necessary in pregnant women receiving magnesium sulfate during delivery, since the neuromuscular blockade may be potentiated and its reversal impeded.

Breastfeeding

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.
Competitive neuromuscular blocking drugs are unlikely to be present in milk in significant amounts, because they are ionised at physiological pH. Breastfeeding may be resumed once the mother has recovered from neuromuscular block. However Pancuron should only be administered to breastfeeding women when the administering doctor decides that the potential benefits outweigh the risks.

Driving and using machines

Do not drive or use machines within 24 hours after full recovery from the neuromuscular blocking action of pancuronium.

Important information about some of the ingredients of Pancuron

This medicinal product contains less than 1 mmol sodium (23 mg) per one ampoule.

3. HOW TO TAKE PANCURON

Always take Pancuron exactly as your doctor has told you.

This drug should be administered by or under the supervision of experienced clinicians, familiar with the use of neuromuscular blocking agents.

The basic rule is that the lowest possible dose must be given, which produces the required degree of muscle relaxation.

There is a large degree of variability between individuals regarding neuromuscular sensitivity to pancuronium bromide. Peripheral nerve stimulators can be used for monitoring neuromuscular block and recovery. If it is not possible to do this, then the following dosage recommendations may be used as a general guideline for adults:

Intubation and subsequent operation:

After intravenous injection of 0.1 mg / kg bodyweight, clinically sufficient conditions for intubation develop in 90 to 120 seconds; at 0.08 mg/kg bodyweight, this takes 120 to 180 seconds. A complete neuromuscular block can be expected after 2 – 4 or 4 – 6 minutes.

Repetition dosage:

Administering 0.01 to 0.02 mg / kg bodyweight at intervals of 30 – 45 minutes allows a complete neuromuscular blockade to be maintained.

A reduced dose may be needed:

- in patients with renal function disorders;
- in patients with neuromuscular diseases;
- in adipose and very elderly patients;

- with simultaneous use of inhalation anaesthetics;
- for operative intervention in hypothermia.

Allow for an increased requirement for Pancuron:
- in patients with burns, hypergammaglobulinaemia or liver diseases.

Children:
The anaesthetist will decide on the most appropriate dose.

Elderly patients:
Longer duration of the effect may happen for very elderly patients. This is due to the increased elimination half-life as a result of the reduced kidney function at more advanced ages.

Pancuron solution for injection is for intravenous use only.

Doses of neuromuscular blockers need to be carefully titrated for individual patients according to response, and may vary with the procedure, the other drugs given, and the state of the patient; monitoring of the degree of block is recommended in order to reduce the risk of overdosage.

If it is used more Pancuron than it should
If a higher dose of pancuronium is used, this can cause longer-lasting peripheral respiratory insufficiency. Artificial respiration is needed until sufficient spontaneous breathing returns. Additionally, a cholinesterase inhibitor, such as neostigmin (together with atropine) may be used as an antidote, provided that the first motor indicators of beginning spontaneous respiration are recognisable.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Pancuron can cause side effects, although not everybody gets them.
The adverse effects of competitive neuromuscular blockers are generally similar although they differ in their propensity to cause histamine release and associated cardiovascular effects. Pancuronium has little histamine-releasing effect. Hypersensitivity reactions are relatively rare

but severe anaphylactoid reactions, bradycardia, bronchospasm, hypotension, and cardiovascular collapse have been reported.
Occasionally, transient rashes and wheezing have been reported and a burning sensation along the vein has occurred in conscious patients who received pancuronium.
Pancuronium has vagolytic and sympathomimetic action, which may cause tachycardia and hypertension, but does not produce ganglionic blockade.
Pancuronium has been associated with excessive salivation in some patients.
Because of its prolonged duration of action, pancuronium may be more likely than other neuromuscular blockers to produce residual neuromuscular block; such residual block is associated with an increased incidence of postoperative respiratory complications.
Malignant hyperthermia has been associated rarely with pancuronium.
Pancuronium can cause a decrease in the partial thromboplastin time and prothrombin time.
Pancuronium can cause miosis.
Muscle weakness has been reported but the frequency of this side effect is not known.
Inform your doctor or pharmacist if you get these side effects or any other side effects not mentioned in this leaflet.

5. HOW TO STORE PANCURON

Keep out of the sight and reach of children!
Do not use Pancuron after the expiry date which is stated on the package.
Store at 2°C to 8°C (in a refrigerator).
Do not freeze.
Keep in the original package to protect from light.

6. OTHER INFORMATION

What Pancuron 4 mg/2 ml solution for injection contains

The active substance is pancuronium bromide.
Each 2 ml ampoule contains 4 mg of pancuronium bromide.
Other ingredients: sodium chloride, sodium acetate trihydrate, glacial acetic acid and water for injections.

Contents of the pack:

Box with 10 ampoules (2 ml).

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in January 2024.