104993 XX/19

Package leaflet: Information for the user

Murexal 10 mg/ml, solution for injection in pre-filled syringe

suxamethonium chloride anhydrous

AGUETTANT

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

What is in this leaflet

1. What Murexal is and what it is used for

Murexal belongs to a group of medicines called muscle relaxants.
Their effect is to block the connection between the nerves and certain muscles, which relaxes these muscles by temporarily paralysing them.
It is used in adults and paediatric population above 12 years of age in general anaesthesia or emergency situations.
Murexal is administered when inserting a tube into the windpipe (endotracheal intubation), if a person needs help to breathe. During this procedure, it is necessary for the muscles used for breathing to be paralysed.

2. What you need to know before you are given Murexal

You must not be given Murexal:
- if you are allergic to suxamethonium or any of the other ingredients of this medicine (listed in section 6);
- if you are a conscious patient;
- if you or any one in your family have reacted badly to an anaesthetic before such as a very high body temperature (malignant hyperthermia);
- if you have a deficiency of an enzyme called pseudocholinesterase that breaks down suxamethonium in the body;
- if you have high levels of potassium in your blood (hyperkalaemia);
- if you have had a major accident, operation or severe burns;
- if you have suffered a spinal cord injury, nerve injury or sudden muscle wasting;
- if you have not been able to move for a long time such as to allow a broken bone to mend or a long period of bed rest;
- if you have muscle weakness and wasting of muscle tissue (e.g. Duchenne muscular dystrophy);
- if you or any one in your family have a disease causing weakness of the muscles (myotonia congenita, dystrophia myotonica);
- if you have recently had any eye injuries;
- if you suffer from a problem caused by too much pressure in your eye (glaucoma), unless the potential benefit of its use outweighs the potential risk to the eye.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Murexal:
- if you ever had an allergic reaction to any muscle relaxant which was given as a part of an operation;
- if you suffer from myasthenia gravis a disease which causes severe weakness of the muscles or from any other disease of nerves or muscles;
- if you are pregnant or have given birth in the last six weeks;
- if you have tetanus, an infection which occurs through wound contamination;
- if you have tuberculosis or other severe or long standing bacterial infection;
- if you have any long standing illness which had left you weak;
- if you suffer from a blood disease known as anaemia;
- if you are undernourished or unable to absorb nutrients from food (malnutrition);
- if you suffer from liver or kidney problems;
- if you suffer from a disease caused by the body attacking itself (autoimmune disease) such as a disease of the thyroid gland (myxoedema);
- if you suffer from diseases that cause problems from the joints (collagen diseases);
- if you are having or have had treatment to your blood known as plasmapheresis therapy;
- if you have recently had a heart-lung by pass.

Children

This medicine is not recommended for children under 12 years of age because the sub-graduation of the pre-filled syringe does not allow an accurate administration of the product in this population.
Special care should be taken when this medicine is given to children above 12 years of age.

Other medicines and Murexal

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.
In particular, inform your doctor, pharmacist or nurse if you are taking / being treated with any of the following:
- psychiatric medicines (e.g. phenelzine, promazine);
- anti-cancer medicines (e.g. cyclophosphamide, thiotepa, irinotecan);
- anaesthetic medicines (e.g. ketamine, halothane, enflurane, desflurane, propofol);
- local anaesthetic medicines (e.g. lidocaine, procaine, procainamid);
- a medicine used to treat and prevent feeling or being sick (metoclopramide);
- medicines used for Alzheimer's disease or myasthenia gravis (anticholinesterase such as donezepil, edrophonium, galantamine, neostigmine, pyridostigmine, rivastigmine and tacrine);
- medicines for treating asthma or other breathing conditions (e.g bambuterol, terbutaline);
- organic substances containing phosphorus;
- a medicine used to reduce bleeding (aprotinin);
- oestrogens and oestrogen-containing oral contraceptives;
- a medicine to contract the womb (oxytocin);
- medicines used for inflammatory conditions (steroids such as rheumatism etc);
- medicines used to treat disturbances in heart beat rhythm (anti-arrhythmics such as e.g. quinidine, verapamil);
- some antibiotics used to treat bacterial infections (e.g. lincosamides, polymyxins, and aminoglycosides);
- antiepileptic medicines used to stop fits (e.g. carbamazepine and phenytoin);
- a beta-blocker medicine used to slow the heart beat (esmolol);
- a medicine to suppress the immune response (azathioprine);
- a medicine used to control over-excitement and/or depression (lithium);
- magnesium salts;
- medicines which increase heart muscle contraction (cardiac glycosides such as digoxin);
- a medicine used to treat high pressure in the eyes i.e. glaucoma (ecothiopate).

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.

The following information is intended for healthcare professionals only:

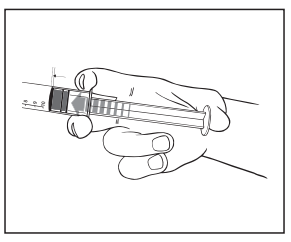
Instructions for use:

The pre-filled syringe is not suitable for use in a syringe driver.

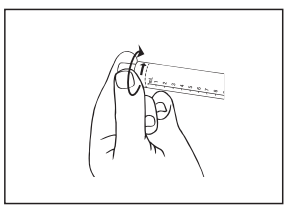
Please prepare the syringe carefully as follows.

The pre-filled syringe is for single patient use only. Discard the syringe after use. Do not reuse.
The medicine should be inspected visually for particles and discolouration prior to administration. Only clear colourless solution free from particles or precipitates should be used.
The medicine should not be used if the tamper evident seal on the syringe is broken.
The external surface of the syringe is sterile until the blister is opened. The blister must not be opened until use.
When handled using an aseptic method, this medicine can be placed on a sterile field once it has been removed from the blister.

1) Withdraw the sterile pre-filled syringe from the blister.



2) Push on the plunger to free the bung. The sterilisation process may have caused adhesion of the bung to the body of the syringe.



3) Twist off the end cap to break the seal. In order to avoid contamination, do not touch the exposed luer connection.

AGUETTANT
MÉDICAMENTS
ESSENTIELS

Murexal should only be used during pregnancy when your doctor decides the benefits to you are greater than any possible risk to the unborn baby.
Caution should be exercised following administration of suxamethonium to pregnant and puerperal patients.
It is not known whether suxamethonium passes into breast milk. However, because suxamethonium is rapidly metabolised to an inactive metabolite, no effects on the breastfed newborns/infants are anticipated.

Driving and using machines
It can be dangerous to drive or operate machinery too soon after having received this medicine. Your doctor will tell you how long to wait before you can drive or use machinery.

Murexal contains sodium.
This medicine contains 27.9 mg sodium (main component of cooking/table salt). This is equivalent to 1.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Murexal is given

You will never be expected to give yourself this medicine. It will always be given to you by a health care professional who is qualified to do so.
Your doctor will decide the dose you will receive. It will depend on your individual needs, body weight, the amount of muscular relaxation required.
Murexal will be given to you as an injection into your vein (intravenous use).
The pre-filled syringe is not suitable for use in a syringe driver.

If you are given more Murexal than you should
As this medicine will always be administered under carefully controlled conditions, it is unlikely that you will be given more than necessary. In case of an overdose, the muscle will stay relaxed for longer than required.

4. Possible side effects

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

Very common (may affect more than 1 in 10 people):
• visible twitching of muscle under the skin
• muscle pain after the operation - your doctor will monitor you for this.

Common (may affect up to 1 in 10 people)
• allergic reactions: itching, hives, collapse
• raised pressure of fluid in the eye which may cause headache or blurred vision
• raised stomach pressure
• speeding up or slowing down of your heart rate
• low blood pressure
• protein in the blood or urine due to muscle damage
• high level of potassium in your blood
• skin flushing
• skin rash

Rare (may affect up to 1 in 1,000 people)
• difficulty breathing
• high body temperature
• difficulty opening your mouth

Not known (frequency cannot be estimated from the available data)
• swelling (Quincke's edema)
• cardiac arrest
• high or low blood pressure
• excessive production of saliva
• excessive production of phlegm
• temporary loss of breath
• muscle damage

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
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 Murexal

Keep this medicine out of the sight and reach of children.
You should not be given this medicine after the expiry date which is stated on the pre-filled syringe label, blister and carton. The expiry date refers to the last day of that month.
Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Keep the pre-filled syringe in its unopened blister until use.
After opening, the medicinal product must be used immediately.
This medicine may be stored for a short period at temperatures not exceeding 25 °C. In all cases, once initially removed from refrigerated storage, the medicine should be discarded after 30 days.
Do not use this medicine if you notice visible signs of deterioration.
Any pre-filled syringe, even partially used, should be discarded appropriately after use. 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 Murexal contains
- The active substance is suxamethonium chloride.
  Each ml of solution for injection contains 10 mg of suxamethonium chloride anhydrous (as 11 mg of suxamethonium chloride dihydrate).
  Each 10 ml pre-filled syringe contains 100 mg of suxamethonium chloride anhydrous (as 110 mg of suxamethonium chloride dihydrate).
- The other ingredients are: sodium chloride, succinic acid, sodium hydroxide or hydrochloric acid (for pH adjustment), water for injection.

What Murexal looks like and contents of the pack
Murexal is a clear colourless solution for injection, in a 10 ml polypropylene pre-filled syringe, individually packed in a transparent blister pack. Cardboard boxes of 1 or 10 pre-filled syringes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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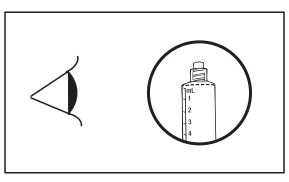
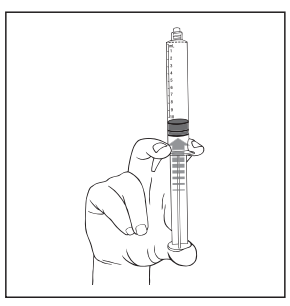


4) Check the syringe seal tip has been completely removed. If not, replace the cap and twist again.



5) Expel the air by gently pushing the plunger.

6) Connect the syringe to an access device or a needle. Push the plunger slowly to inject the required volume.