

 PACKAGE LEAFLET:  
Information for the patient

# PROSERINE

Solution for injection – 0.5 mg / 1 ml  
(Neostigmine bromide)

**Read all of 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

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

## 1. WHAT PROSERINE IS AND WHAT IT IS USED FOR

Proserine is a compound that inhibits cholinesterase activity and thus prolongs and intensifies the physiological actions of acetylcholine. It probably also has direct effects on skeletal muscle fibres. The anticholinesterase actions of neostigmine are reversible.

After parenteral doses, Proserine is excreted in the urine both as unchanged drug and metabolites. Neostigmine undergoes hydrolysis by cholinesterases and is also metabolised in the liver.

Proserine is indicated in:

- diagnosis of *Myasthenia gravis*;
- symptomatic control of *Myasthenia gravis*;
- as an antidote for non-depolarising neuromuscular blockers after surgery;
- prevention and treatment of postoperative urinary retention.

Your doctor may have given you Proserine for another reason. Ask your doctor if you want to know why you are given this drug.

## 2. BEFORE YOU TAKE PROSERINE

**Do not take Proserine if you:**

- are hypersensitive to neostigmine;
- have mechanical gastrointestinal or urinary-tract obstruction;
- have peritonitis.

**Take special care with Proserine**

Ask your doctor before taking Proserine. It should be used with caution in patients with bronchial asthma, arrhythmia, bradycardia, recent acute myocardial infarction, hypotension, peptic ulcer, vagotonia, epilepsy, hyperthyroidism, parkinsonism,

renal impairment, and during pregnancy and lactation. This drug should be used with extreme caution in patients who have undergone recent intestinal or bladder surgery.

Neostigmine should not be used during anesthesia with cyclopropane or halothane; it can be used after anesthesia has passed.

When neostigmine is given by injection, atropine should always be available to counteract any excessive muscarinic reactions; atropine may also be given before, or with neostigmine to prevent or minimise muscarinic adverse effects but this may mask the initial symptoms of overdosage and lead to cholinergic crisis.

## Taking other medicines

Concomitant treatment with other drugs, may affect or be affected by Proserine. Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those without a prescription. Remember to inform your doctor that you are taking Proserine if you are given another drug during treatment.

Drugs with neuromuscular blocking activity, such as the aminoglycosides, clindamycin, colistin, cyclopropane, and the halogenated inhalation anaesthetics, may antagonise the effects of neostigmine.

Those such as quinine, chloroquine, hydroxychloroquine, quinidine, procainamide, propafenone, lithium, and the beta blockers, that have the potential to aggravate myasthenia gravis, can reduce the effectiveness of treatment with parasymphomimetics.

Anticholinesterases, such as neostigmine, can inhibit the metabolism of suxamethonium and enhance and prolong its action; combined use is not recommended. Antimuscarinics such as atropine antagonise the muscarinic effects of neostigmine.

Corticosteroids may antagonise the effect of anticholinesterases in *Myasthenia gravis*, and causing deep muscular depression.

Neuromuscular blockade caused by succinylcholine may be prolonged or antagonised by neostigmine.

## Pregnancy

**Ask your doctor or pharmacist for advice before taking this drug!**

Category C.

This drug should be avoided in pregnancy and may be used only if the benefit outweighs the risk to which the fetus is exposed.

## Breast-feeding

Neostigmine is distributed in breastmilk in small amounts.

Use during breast-feeding should be avoided.

## 3. HOW TO TAKE PROSERINE

Always take Proserine exactly as your doctor has told you. If you feel that the effect of Proserine is too strong or too weak, talk to your doctor or pharmacist. Injections may be given intravenously, intramuscularly or subcutaneously.

Proserine may be used as described below:

*In Myasthenia gravis*: subcutaneous or intramuscular injection

*adults*: 1 – 2.5 mg in suitable intervals (total daily dose 5 – 20 mg);

*children*: 0.2 – 0.5 mg as necessary;

*neonates*: 0.05 – 0.25 mg every 4 hours, 30 minutes before feeding.

*As an antagonist of non-depolarising neuromuscular blockade*

0.05 – 0.07 mg / kg (maximum 5 mg) injected slowly in the vein (over one minute), after or with 0.6 – 1.2 mg atropine sulfate.

## If you take more Proserine than you should

If you take more Proserine than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital, or call the emergency to get an opinion of the risk and advice on the actions to be taken.

## If you forget to take Proserine

If you forget a dose, take the next dose when it is the normal time to take it.

Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

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

During treatment with Proserine some side effects may appear which include: nausea and vomiting, increased salivation, abdominal cramps, and diarrhea (which appear more with high doses).

Some overdosage symptoms: increase of gastrointestinal disturbances, increased bronchial secretion, excessive sweating, involuntary defaecation, miosis, nystagmus, bradycardia, hypotension, agitation, weakness till paralysis. Atropine may be used as antidote for muscarinic effects.

## 5. HOW TO STORE PROSERINE

Keep out of the reach and sight of children.

Do not use Proserine after the expiry date which is stated on the package.

Do not store above 25°C.

Store in the original package to protect it from light and humidity!

## 6. FURTHER INFORMATION

**What Proserine – solution for injection contains**

**The active substance** is neostigmine bromide.

Each ampoule 1 ml contains 0.5 mg (0.05%) neostigmine bromide.

The other ingredient is water for injection.

**Content of the pack**

Box with 10 ampoules

Box with 100 ampoules (hospital use).

**Explanatory of the illustration icons on the packaging:**



According to medical prescription.



Content.



Warning.



Solution for injection.

**Marketing Authorisation Holder and Manufacturer:**



**PROFARMA Sh.a.**

Rruga "Myslym Keta"

Tel.Fax. 00355 4 23 62 800

Tirana - ALBANIA

**This leaflet was last revised in December 2011.**

**PAY ATTENTION**, all the layers are visible.

If you have to print this document please check or uncheck the specific layers.

