

Package leaflet: Information for the user

Bysimin 20mg/ml solution for injection

Hyoscine butylbromide

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

What is in this leaflet

1. What Bysimin is and what it is used for
2. What you need to know before you use Bysimin
3. How to use Bysimin
4. Possible side effects
5. How to store Bysimin
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1. What Bysimin is and what it is used for

Bysimin contains the active substance hyoscine butylbromide. This belongs to a group of medicines called antispasmodics.

Bysimin is used to relieve cramps of your:

- Gastrointestinal tract
- Biliary tract
- Pancreas
- Urogenital tract

Bysimin can also be used in diagnostic medical procedures.

2. What you need to know before you use Bysimin

Do not use Bysimin:

- If you are allergic to hyoscine butylbromide or any of the other ingredients of this medicine (listed in section 6).
- If you have glaucoma (eye disease).
- If you have megacolon (abnormally enlarged bowel).
- If you have myasthenia gravis (muscle weakness).
- If you have tachycardia (abnormally rapid heartbeats).
- If you have difficulty or pain passing water (urine) such as men with prostate problems.
- If you have gut blockage problems or a totally inactive gut.

Warnings and precautions

Talk to your doctor or pharmacist before using Bysimin if:

- You are being treated with anticoagulant drugs, intramuscular injection should not be given since intramuscular haematoma may occur. You can receive slow subcutaneous or intravenous injection.
- You have unexplained abdominal pain which persists or worsens or occurs with: fever, feeling sick, being sick, changes in your bowel movements, abdominal tenderness, low blood pressure, feeling faint or blood in stool..You have heart problems such as: tachycardia, cardiac insufficiency or failure and in cardiac surgery where it may further accelerate the heart rate.
- You have fever, because anticholinergics such as hyoscine butylbromide may reduce sweating.
- You develop a painful, red eye with loss of vision after the injection of hyoscine butylbromide. Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as hyoscine butylbromide in patients with undiagnosed and therefore untreated narrow angle glaucoma.

Other medicines and Bysimin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because hyoscine butylbromide can affect the way some other medicines work. Also some other medicines can affect the way hyoscine butylbromide work.

In particular tell your doctor or pharmacist if you are taking any of the following:

- Medicines for depression called 'tetracyclic antidepressants' or 'tricyclic antidepressants' such as doxepin.
- Medicines for allergies and travel sickness called antihistamines.
- Medicines to control your heart beat such as quinidine or disopyramide.
- Medicines for severe mental illness such as haloperidol or fluphenazine.
- Medicines usually used for breathing problems such as salbutamol, ipratropium, tiotropium or atropine-like medicines.
- Amantadine - for Parkinson's disease and flu.
- Metoclopramide - for feeling sick (nausea).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before receiving Bysimin.

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.

You should not be given Bysimin if you are pregnant, likely to get pregnant or are breast-feeding.

Driving and using machines

Some people may have sight problems or feel dizzy while taking this medicine. If this happens to you, wait until your sight returns to normal or you stop feeling dizzy before driving or using any tools or machines.

Bysimin contains sodium chloride.

The amount of sodium in a 1 ml ampoule is less than 1 mmol (23 mg), the total amount of sodium if you are given five ampoules in 24 hours is less than 1 mmol (23 mg) this means that your medicine is essentially sodium free.

3. How to use Bysimin

Bysimin will be given by a doctor or nurse and the dosage will be determined by a doctor.

Use in children

Bysimin is not recommended for children.

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

4. Possible side effects

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

Stop taking your medicine and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

- Allergic reactions such as skin rash, nettle rash, redness of the skin and itching.
- Severe allergic reactions (anaphylaxis) such as difficulty breathing, feeling faint or dizzy (shock).
- Painful red eye with loss of vision.

Common side effects (may affect up to 1 in 10 people)

- Dry mouth.
- Constipation
- Dizziness.
- Blurred vision.
- Increased heart rate.

Other side effects (not known frequency which cannot be estimated from the available data)

- Small blisters on hands and feet.
- Being unable to pass water (urine).
- Low blood pressure, for example feeling faint.
- Flushing.
- Dilated pupils.
- Increased fluid pressure inside the eye.

Pain at the place you had the injection may occur if you have been given Bysimin into a muscle.

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 the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bysimin

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

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

This medicinal product does not require any special storage conditions.

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 Bysimin contains

- The active substance is hyoscine butylbromide. Each ampoule contains 20 mg of the active ingredient hyoscine butylbromide.
- The other excipients are: sodium chloride, sodium hydroxide, hydrochloric acid concentrated, water for injection.

What Bysimin looks like and contents of the pack

Clear, colourless or almost colourless solution free from visible particles.

Box containing 5 x 1 ml or 10 x 1 ml or 50 x 1 ml type I clear glass ampoules in PVC trays sealed with PE transparent foil.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Medochemie Ltd.
1-10 Constantinoupoleos street,
3011 Limassol, Cyprus

Manufacturer

Medochemie Ltd.
Ampoule Injectable Facility
48 Iapetou Street, Agios Athanassios Industrial Area,
4101 Agios Athanassios, Limassol, Cyprus

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden	Bysimin
Bulgaria	BUSCOPAMINE
Cyprus	BYSIMIN
Croatia	BYSIMIN
Estonia	BYSIMIN
Malta	BYSIMIN
Romania	BYSIMIN
Spain	BYSIMIN
Portugal	BYSIMIN

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