PACKAGE LEAFLET: Information for the patient

BUSKOLAMIN

Sugar-coated tablets – 10 mg

Solution for injection – 20 mg/ml

(Hyoscine butylbromide)

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 BUSKOLAMIN IS AND WHAT IT IS USED FOR

Buskolamin contains as active substance hyoscine butylbromide. Hyoscine butylbromide is a quaternary ammonium salt. This drug, due to its anticholinergic action, possesses antispasmodic properties and it is used to relieve smooth muscle spasms.

Buskolamin 10 mg sugar-coated tablets are indicated in:

- gastrointestinal or genitourinary spasms;
- Irritable Bowel Syndrome.

Buskolamin 20 mg/ml solution for injection is indicated:

- in acute spasm (spasm of the gastrointestinal tract and renal/biliary colic);
- during diagnostic procedures (radiography or endoscopy).

Your doctor may have given Buskolamin for another purpose. Ask your doctor if you want to know why you were given this drug.

2. BEFORE YOU TAKE BUSKOLAMIN

Do not take Buskolamin if you:

- are hypersensitive (allergic) to hyoscine butylbromide, methyl hydroxybenzoate (only for the solution for injection), propyl hydroxybenzoate (only for the solution for injection) or to any of the excipients of Buskolamin;
- suffer from *Myasthenia gravis*, megacolon, closed-angle glaucoma, tachycardia, prostatic enlargement with urinary retention, mechanical stenoses of the gastrointestinal tract or paralytic ileus.

Buskolamin ampoules should not be given to you by intramuscular injection if you are being treated with anticoagulant drugs since intramuscular haematoma may occur.

Take special care with Buskolamin

Ask your doctor before you take Buskolamin.

If you experience severe, unexplained abdominal pain which persists or worsens, or occurs together with symptoms like fever, nausea, vomiting, changes in bowel movements, abdominal tenderness, decreased blood pressure, fainting, or blood in stool, contact immediately your doctor or pharmacist.

Take special care if you:

- suffer from tachycardia (caused by hyperthyroidism or heart failure) and in cardiac surgery where it may further accelerate the heart rate; when Buskolamin injection is used, special care is required in other cardiac diseases as well;

- suffer from undiagnosed and therefore untreated closed-angle glaucoma since elevation of intraocular pressure may be produced; in case you develop painful, red eye with loss of vision, you should seek urgent ophthalmological advice;
- have pyrexia (this drug may reduce sweating).

Allergic reactions have been observed after injection of hyoscine butylbromide (see section 4). Therefore, you will be monitored after injection of hyoscine butylbromide and treated appropriately in case such reactions occur.

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.

Inform your doctor, especially if you are taking the following medicines:

- antidepressants (tricyclics, tetracyclics and MAOIs), antihistamines, antipsychotics (e.g. phenothiazines), quinidine, amantadine, disopyramide, other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds): consequently their anticholinergic effects may be intensified;
- metoclopramide and other dopamine antagonists: consequently may result in diminution of the effects of both drugs;
- β-adrenergic agents: consequently the tachycardic effects of these drugs may be enhanced.

Taking Buskolamin with food and drinks

No data.

Pregnancy

There are no sufficient data on the use of this drug during pregnancy.

In these conditions, avoid the use of Buskolamin during pregnancy.

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

Breastfeeding

There have been no reports of any clinical effect on the infant associated with the use of hyoscine butylbromide by breastfeeding mothers.

However, since the risk to the breastfed child cannot be excluded, Buskolamin is not recommended during breastfeeding.

Driving and using machines

The patient may experience undesirable effects such as dizziness or accommodation disorders during treatment. If these symptoms occur, avoid driving and using machines until the vision is clarified.

Important information about some of the excipients of Buskolamin

Buskolamin 20 mg/ml solution for injection contains methyl hydroxybenzoate (nipagin) and propyl hydroxybenzoate (nipazol). These two ingredients may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

This medicine also contains less than 1 mmol sodium (23 mg) in 1 ml solution, that is to say essentially 'sodium-free'.

Buskolamin 10 mg sugar-coated tablets contain sucrose. If you have been told by your doctor that you have an intolerance to some type of sugars, contact your doctor before taking this drug.

3. HOW TO TAKE BUSKOLAMIN

Always take Buskolamin exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

10 mg sugar-coated tablets

- Adults and children over 12 years

For the treatment of gastrointestinal or genitourinary spasms a dose of 10 – 20 mg (1-2 sugar-coated tablets) may be given. When necessary, this dose may be repeated up to 3 times daily. Treatment should not be continued for more than 3 days without medical supervision.

In Irritable Bowel Syndrome the starting dose is 10 mg (1 sugar-coated tablet) three times daily which may be increased to 20 mg four times daily, if necessary.

- Children 6 to 12 years

It may be used only with medical recommendation.
A dose of 10 mg (1 sugar-coated tablet) three times daily may be given.

- Children under 6 years

Due to the high content of the active substance, this medicine is not recommended for children under 6 years.

The tablets should be swallowed whole with an adequate amount of water.

20 mg/ml solution for injection
The recommended dose is 20 mg (1 ampoule), repeated after 30 minutes if necessary (may be repeated more frequently in endoscopy).
The maximum daily dose is 100 mg.
This medicine is not recommended in children.
The solution is given by intramuscular or slow intravenous injection.
Hyoscine butylbromide injection should not be used on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

If you take more Buskolamin than you should
If you take more Buskolamin than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures. In these cases the following symptoms may occur: urinary retention, dry mouth, reddening of the skin, tachycardia, inhibition of gastrointestinal motility and transient visual disturbances.
Symptoms of overdose respond to parasympathomimetics.
For patients with glaucoma, pilocarpine should be given locally.
Cardiovascular complications should be treated according to usual therapeutic principles.

Respiratory paralysis may require intubation and artificial respiration.
Catheterisation may be required for urinary retention.
In addition, appropriate supportive measures may be used.

If you forget to take Buskolamin

If you forget to take one dose (or more than one dose), take the next dose in its usual time. Do not take a double dose (or higher) to make up a forgotten dose(s).
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Buskolamin can cause side effects, although not everybody gets them.
Many of the undesirable effects can be assigned to the anticholinergic properties of Buskolamin.
Stop taking this medicine and immediately contact your doctor if you notice any of the following serious adverse effects, because you may need urgent medical treatment:

- severe allergic reactions (anaphylaxis) such as: difficulty in breathing, syncope feeling or dizziness (shock);
- cutaneous allergic reactions such as: urticaria, itching, rash, erythema;
- eye pain and eye redness associated with vision loss.

Other side effects: dry mouth, cessation of perspiration, tachycardia and eventually urinary retention and accommodation disorders (these symptoms are reversible and benign).
Buskolamin injection can cause serious adverse effects including tachycardia, hypotension, and anaphylaxis. These effects are more likely to be fatal in patients with underlying heart disease, such as heart failure, coronary heart disease, arrhythmia or hypotension.
The quaternary derivatives of hyoscine, such as butylbromide, do not readily cross the blood-brain barrier, so central effects (i.e. confusion) are rare.

Inform your doctor or pharmacist if you get these side effects or any side effect not listed in this leaflet.

5. HOW TO STORE BUSKOLAMIN

Keep out of the sight and reach of children!

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

Do not store above 25°C!

Keep in the original package to protect from light.

6. OTHER INFORMATION

What Buskolamin 20 mg/ml solution for injection contains:

The active substance is hyoscine butylbromide.

1 ampoule of 1 ml contains 20 mg hyoscine butylbromide.

The other ingredients are: sodium chloride, trisodium citrate, citric acid monohydrate, methyl hydroxybenzoate, propyl hydroxybenzoate, water for injection.

What Buskolamin 10 mg sugar-coated tablets contain

The active substance is hyoscine butylbromide.

1 sugar-coated tablet contains 10 mg hyoscine butylbromide.

The other ingredients are: pregelatinised starch, microcrystalline cellulose, hydroxypropyl cellulose, magnesium stearate, colloidal anhydrous silica, stearic acid, talc, gelatin, povidone, sucrose, calcium carbonate, titanium dioxide, Opaglos® white (containing: ethanol, shellac, carnauba wax, white bees wax).

Contents of the pack:

Sugar-coated tablets: box with 20 sugar-coated tablets.

Solution for injection: box with 10 ampoules of 1 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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