

i 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
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4. Possible side effects
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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, sugar-coated tablet 10 mg is indicated in:

- gastrointestinal or genito-urinary spasms;
 - Irritable Bowel Syndrome.
- Buskolamin, solution for injection 20 mg/ml 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 (nipagin), propyl hydroxybenzoate (nipazol) 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.

Take special care with Buskolamin

Ask your doctor before you take Buskolamin.

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;
- 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).

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 and MAOIs), antihistamines, antipsychotics (e.g. phenothiazines), quinidine, amantadine, disopyramide: 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, it may be used during pregnancy only if the potential benefit outweighs the risk for the fetus.

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

Breast - feeding

There have been no reports of any clinical effect on the infant associated with the use of hyoscine butylbromide by breast-feeding mothers. However, since the risk to the breastfed child cannot be excluded, Buskolamin is not recommended during lactation.

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 ingredients of Buskolamin

Buskolamin, solution for injection 20 mg/ml, contains methyl hydroxybenzoate (nipagin) and propyl hydroxybenzoate (nipazol). These two ingredients may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm. Buskolamin, sugar - coated tablets 10 mg contains 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.

Sugar-coated tablets 10 mg

> Adults and children over 12 years

For the treatment of gastrointestinal or genito-urinary 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

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 adequate water.

Solution for injection 20 mg/ml

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.

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 taking one dose (or more than one dose), take the next dose in its usual time. Do not take a double dose (or larger) 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.

Buskolamin may cause:

- > dry mouth, cessation of perspiration, tachycardia and eventually urinary retention and accommodation disorders (these symptoms are reversible and benign)
- > hypersensitivity reactions (including cutaneous reactions) and rarely cases of dyspnoea.

After parenteral administration of hyoscine butylbromide were observed rarely cases of vertigo and decreased blood pressure and very rarely cases of anaphylactoid reactions or anaphylactic shock.

The quaternary derivatives of hyoscine, such as butylbromide, do not readily cross the blood-brain barrier, so central effects 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 – Solution for injection 20 mg/ml 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 (nipagin), propyl

hydroxybenzoate (nipazol), water for injection.

What Buskolamin – Sugar-coated tablet 10 mg contains:

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 K-30, sucrose, calcium carbonate, titanium dioxide, Opaglos white 6000.

Contents of the pack:

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

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

Explanatory of the illustration icons on the packaging:



Ask your doctor or pharmacist.



Content.



Warning.



Tablet shape.



Solution for injection.

Marketing Authorisation Holder and Manufacturer:



PROFARMA Sh.a.
Rruga "Myslym Keta"
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Tirana - ALBANIA

This leaflet was formulated in June 2014.

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