PACKAGE LEAFLET: Information for the patient

MEBHIDROLINE

Sugar-coated tablets – 50 mg

(Mebhydrolin napadisilate)

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. 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 Mebhidroline is and what it is used for
2. Before you take Mebhidroline
3. How to take Mebhidroline
4. Possible side effects
5. How to store Mebhidroline
6. Other information

1. WHAT MEBHIDROLINE IS AND WHAT IT IS USED FOR

Mebhydrolin is a substance that is part of the group of antihistamines. The antihistamines reduce or inhibit the main actions of histamine in the organism through the reversible and competitive block of the histamine receptors; they do not disactivate histamine or do not prevent its synthesis or release. Mebhidroline presents antimuscarinic, serotonine antagonist properties and local anaesthetic effects. It is used for the symptomatic relief of hypersensitivity reactions, including urticaria and angioedema, rhinitis and conjunctivitis. It is considered as ineffective in asthma.

Mebhidroline sugar-coated tablet 50 mg is indicated in:

- hay fever;
- vasomotor rhinitis;
- bronchial asthma with an allergic origin;
- urticaria;
- exanthema by drugs;
- itching;
- eczema;
- allergic dermatitis and conjunctivitis;
- insect bites;
- Quincke oedema,
- food idiosyncrasias.

2. BEFORE YOU TAKE MEBHIDROLINE

Do not take Mebhidroline if:

- you are sensitive (allergic) to mebhydrolin napadisilate or to any of the excipients of Mebhidroline;
- you suffer from stomach and duodenal ulcer;
- you suffer from inflammatory diseases of the gastrointestinal tract;
- you suffer from porphyria.

Premature children and neonates should not take antihistamines.

Take special care with Mebhidroline

Ask your doctor before taking Mebhidroline if you:

- are pregnant or are planning to become pregnant;
- are breast - feeding;
- are sick with glaucoma;
- have a history of bronchial asthma;
- have hyperthyroidism;
- have cardiovascular disease or hypertension;
- have severe hypotension;

- have urine retention;
- are sick with prostate hypertrophy;
- suffer from liver or kidney diseases;
- suffer from epilepsy (high doses may enhance crysis in epileptics);
- are elderly;
- are taking antidepressants and / or alcohol.

In case extrapyramidal symptoms appear, the therapy with Mebhidroline should be withdrawn.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Mebhidroline. Please contact your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor about the treatment with Mebhidroline if you have been given any other drug during treatment.

It is especially important that your doctor knows that you are being treated with:

- anxiolytics and hypnotics (increase of the sedative effect);
- antipsychotics;
- opioid analgesics;
- barbiturates;
- tricyclic antidepressants (they increase the sedative and antimuscarinic effects);
- antimuscarinics (increase of the side effects of antimuscarinics);
- vasodilators and other antihypertensives (because mebhydrolin acts in a synergic way when combined with them);
- aminoglycosidic antibiotics (mebhydrolin may mask the warning signs of damage caused by ototoxic drugs).

Because of its antihistaminic effects, Mebhidroline may mask the positive reaction to the allergene extracts. As such, its use is recommended to be withdrawn 4 days before the skin test.

Taking Mebhidroline with food and drinks

The drug should not be taken with alcohol because it increases its sedative effects.

Pregnancy

Ask for the advice of the pharmacist or doctor before taking this drug.

It is recommended to avoid the use of Mebhidroline during pregnancy. Thus, always consult your doctor before using Mebhidroline during pregnancy.

Breastfeeding

Consult with your doctor before taking Mebhidroline during breastfeeding.

Driving and using machinery

Mebhidroline may cause drowsiness, especially at the beginning of treatment. Patients who are taking Mebhidroline should not drive and use machinery.

Important information about some of the excipients of Mebhidroline

This drug contains lactose and sucrose. If you have intolerance to some sugars, contact your doctor before taking this drug.

This drug contains also sodium benzoate and the azodye Sunset yellow FCF (E110) which may cause allergic reactions.

3. HOW TO TAKE MEBHIDROLINE

Always take Mebhidroline as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Mebhidroline are too strong or too weak, talk to your doctor or pharmacist.

The sugar - coated tablets of Mebhidroline are swallowed as whole, without chewing, during or immediately after food. For children who cannot swallow the sugar - coated tablets, these are powdered and mixed with food.

The dosage of Mebhidroline is given depending on age. A practical overview of its dosage is given as follows:

- *Children over 10 years old and adults*: 100 - 300 mg daily in divided doses;
- *Children 2 to 5 years old*: 50 - 150 mg daily;
- *Children up to 2 years old*: 50 - 100 mg daily.

If you have taken more Mebhidroline

If you have taken more Mebhidroline than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Mebhidroline

If you forget a dose (or more doses), take the next dose when it is time to take it usually.
Do not take a double dose (or higher) to make up for a forgotten dose (doses).
If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Mebhidroline may cause side effects, although not everybody manifests them. Sometimes they are serious, sometimes not. Do not get alarmed by this list of possible side effects. None of them may appear to you. The side effects that may appear are:

- drowsiness;
- psychomotor damage;
- headache;
- antimuscarinic effects, such as: urine retention, dry mouth, blurred vision, viscous secretions of the respiratory tract and gastrointestinal disorders;
- sometimes exanthema and photosensibility reactions may appear;
- rush, hypersensitivity reactions (like bronchospasm, angioedema, and anaphylaxis) and cross - sensitivity to the drugs of the same class;
- granulocytopenia and agranulocytosis have been noticed.

Other side effects that are reported during the use of antihistamines are: convulsions, sweating, myalgia, paraesthesia, extrapyramidal effects, tremor, sleep disorders, depression, confusion, tinnitus, hypotension and hair loss.
If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor of pharmacist.

5. HOW TO STORE MEBHIDROLINE

Keep out of the reach and sight of children!

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

Store below 25°C.

Store in the original packaging.

6. OTHER INFORMATION

What Mebhidroline contains

The active substance is mebhydrolin napadisilate.

Each sugar - coated tablet contains 50 mg mebhydrolin (as napadisilate).

The excipients are: starch, lactose monohydrate, gelatin, talc, magnesium stearate, povidone, calcium carbonate, titanium dioxide, sucrose, yellow iron oxide, red iron oxide, Sunset yellow FCF (E110), sodium benzoate, quinoline yellow, indigo carmine, shellac, carnauba wax, beeswax white.

Content of the pack:

Carton box with 30 sugar-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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