LEAFLET: INFORMATION FOR THE USER

Gutron 2,5 mg Tablet

Midodrine hydrochloride

Read this leaflet carefully before taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your physician or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others, the medicine may harm them, even if they have the same symptoms.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your physician or pharmacist.

In this leaflet:

1. WHAT IS GUTRON AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Group 3.3 Cardiovascular. Sympathomimetic.

ATC code: C01CA17

Your physician has prescribed you this medication because **Gutron** is a selective peripherally acting sympathomimetic that:
- Increases blood pressure, when it is reduced, improving the symptoms of low blood pressure.
- In the urological system you normally see, increase of urethral pressure, which leads to an improvement in some cases of urinary incontinence.

So **Gutron** is indicated in cases of:

Hypotension:
- Orthostatic hypotension;
- Reduction of blood pressure due to treatment with neuroleptics and antidepressants;
- Hypersensitivity to changing weather conditions;
- Hypotension after anaesthesia, infections and haemodialysis.

Urological indications:
Females:
- Effort Urinary Incontinence type III (Blaivas, McGuire) (sphincter dysfunction).

- As an adjunct in the remaining stress urinary incontinence with mild or moderate urethral hypermobility.
Males:
- Retrograde ejaculation.
- In the involuntary loss of urine resulting from sphincter hypotonia, namely postoperative.

2. BEFORE TAKING GUTRON

Don´t take Gutron

- If you are allergic to the active substance (midodrine) or any other component of **Gutron**.

- If you have hypertension, pheochromocytome, acute nephritis, severe perturbation of renal function, narrow-angle glaucoma, prostatic hypertrophy with significant residue, mechanical obstruction to the bladder emptying or hyperthyroidism.

Gutron should be administered with caution in patients with heart and renal failure.

Patients with renal impairment: In general, **Gutron** is contraindicated in patients with severe acute renal failure.

Patients with hepatic impairment: No specific experience in the management of **Gutron** in this group of patients.

Elderly: No specific studies have been conducted in the elderly that allow the need for dose reduction in this patient group.

Take special care with Gutron

- Talk to your physician about any health problems you may have now or have had, and about any allergies.

- If you are in a prolonged treatment with **Gutron** is advised monitoring the renal function and blood pressure.

- Concomitant administration of **Gutron** and other drugs which have an effect on blood pressure or heart rate (guanethidine β-1 agonists, non-selective β blockers) requires frequent monitoring of blood pressure and heart rate.

.

Taking Gutron with other medicines

Tell your physician or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

You should also inform any other physician who prescribes new medication that you are taking **Gutron**.

α *and* β Blockers: The activity of **Gutron** can be inhibited by direct α-blocking agents (prazosin, phentolamine) or indirect α-blockers agents (reserpine).

Digitalics: Concurrent use of digitalics is not recommended due the possible increase in bradycardia or intracardiac conduction defects caused by these agents.

Take Gutron with food and drinks

Administration of **Gutron** tablets should be done with a glass of water.

Pregnancy and lactation

Before taking any medicine consult your physician or pharmacist.

The administration of **Gutron** during pregnancy should only be considered when the benefits to the mother outweigh the risks to the foetus.

Gutron should be used with caution and the new-born should be carefully monitoring during lactation.

Driving and using machines

Not described.

Important information about some components of Gutron

Not apply.

3. HOW TO TAKE GUTRON

Take **Gutron** always according to the instructions of the physician. If you have questions talk to your physician or pharmacist.

Children: Considering the lack of experience in treating children, it is not recommended to use **Gutron** in patients under 12 years of age.

The usual dose is:

Orthostatic hypotension: 1 tablet 2 to 3 times a day. This dose should be adjusted gradually after about 3 days of treatment depending on the patient response, and may be decreased to 1/2 tablet 2 to 3 times daily, increased to 2 tablets for 2 to 3 times a day

The maintenance dose: should be chosen individually for each patient in order to obtain the optimum therapeutic effect together with a minimum of side effects.

Maximum daily dose: 30 mg

The administration of **Gutron** must be done during the day when the patient is in operation. It is suggested the administration Interval 3-4 hours immediately after rising in the morning, at midday and in the evening, at least 4 hours before bedtime.

Urologic indications: 1 to 2 tablets 2 to 3 times a day (the last dose should be taken at least 4 hours before bedtime).

If you take Gutron more than you should

Please contact your physician or pharmacist if you take **Gutron** more than you should.

Overdose produces skin reactions, dose-related, especially in the posterior neck and scalp, feeling cold, reflex bradycardia, increase in blood pressure with cephalic congestion and urinary urgency or urinary retention.

Antidote:
α-receptor blockers such as competitive antagonists, e.g., Phentolamine. Bradycardia and conduction defects may be antagonized by atropine.

If you forgot to take Gutron

Do not take a double dose to make up the dose that you missed.

In case of failure of one or more doses, you should continue treatment as prescribed by your physician, without taking the previous doses.

If you stop taking Gutron

If you have further questions about using this medicine, ask your physician or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your physician or pharmacist.

In some cases could appear some complaints like angina, cardiac arrhythmias and rashes.

Higher doses can lead to the appearance of skin reactions, especially in the posterior neck and scalp, feeling cold, urinary urgency or urinary retention.

Can appear a decrease in the heart rate reflex that can be treated with atropine.

5. HOW TO STORE GUTRON

Store below 25 ° C.

Keep out of the reach and sight of children.

Do not take **Gutron** after the expiry date printed on the blister and the carton after EXP.:. The expiry date refers to the last day of that month indicated.

Do not take **Gutron** if you notice any visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. OTHER INFORMATION

Which is the composition of Gutron

- The active substance is midodrine hydrochloride.

- The other componentes are: Magnesium stearate, talc, colloidal anhydrous silica, microcrystalline cellulose and corn starch.

What is the aspect of Gutron and the contents of pack

Gutron has the pharmaceutical form of tablets for oral administration, is packed in PVC / aluminium, and comes in packs of 20, 60 and 100 tablets.

MARKETING AUTHORISATION HOLDER AND MANUFACTUR

MARKETING AUTHORISATION HOLDER:

BLUEMED Unipessoal, Lda.
Rua Poeta Adriano Correia de Oliveira, 233
4510-698 Fânzeres – Portugal

Manufacture:

Labialfarma – Laboratórios de Produtos Farmacêuticos e Nutracêuticos, S.A.
Felgueira
3450-336 Sobral Mortágua

For any information about this medicinal product, please contact the Marketing Authorisation Holder.

Medicinal product subject to medical prescription.

Your physician has more complete information about **Gutron**, so it can ensure that you use the medicine properly.

This leaflet was last approved on 28/06/12