

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

HYTRIN 5 MG TABLETS HYTRIN 10 MG TABLETS

Tablets

Each tablet contains:

Hytrin 5 mg Tablets:

Terazosin (as monohydrochloride dihydrate) 5 mg

Hytrin 10 mg Tablets:

Terazosin (as monohydrochloride dihydrate) 10 mg

Inactive and allergenic ingredients: see section 6 "Further Information" and in section 2 "Important information about some of the ingredients of the medicine".

Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1) WHAT IS THE MEDICINE INTENDED FOR?

Hytrin Tablets is used for the symptomatic treatment of urinary tract obstruction caused by benign enlargement of the prostate gland (benign prostatic hyperplasia - BPH) and for the treatment of mild to moderate hypertension.

Therapeutic group: Selective α -1 adrenergic receptor blocker.

2) BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to terazosin or to any of the additional ingredients contained in the medicine. For the list of inactive ingredients, see section 6 "Further Information". (Allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty swallowing or breathing).
- You are sensitive to any of the following medicines: alfuzosin, indoramin, prazosin, tamsulosin, doxazosin.
- You have ever fallen or fainted while passing water.

Special warnings regarding use of the medicine

Before taking the medicine, tell your doctor if you:

- Are taking other medicines for high blood pressure. If you start taking a medicine for high blood pressure while you are taking Hytrin Tablets, your doctor may need to adjust your dosage of Hytrin Tablets.
- Have any problems with your heart.
- Are taking medicines for impotence (e.g., Cialis, Viagra, Levitra).
- Are planning to undergo cataract-removal surgery.

Use Hytrin Tablets for benign prostate enlargement (benign prostatic hyperplasia – BPH) only after other reasons for abnormal/interrupted urinary flow within the urinary tract have been ruled out.

Hytrin Tablets can cause fainting or low blood pressure, usually after the first dose or the first few doses. These effects can also occur if you stop taking Hytrin Tablets and then resume (treatment).

Treatment should not be started in a new patient or re-started after stopping if a dosage of 1 mg and 2 mg cannot be attained.

Hytrin Tablets may also lead to decreases in certain laboratory values, such as red blood cells or white blood cells.

If any of the above conditions applies to you, or if you are not sure, please tell your doctor before taking Hytrin Tablets.

Children and adolescents

Hytrin Tablets is not recommended for use in children.

Drug interactions

If you are taking, if you have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking:

- Other medicines to treat high blood pressure including ACE inhibitors and diuretics;
- Medicines for impotence (e.g., Cialis, Viagra, Levitra, Stendra).

Some patients who take alpha blockers for the treatment of high blood pressure or prostate enlargement may experience dizziness or lightheadedness, which may be caused by low blood pressure upon sitting or standing up quickly.

The medicines which cause low blood pressure with alpha-blockers include:

- Medicines for the treatment of high blood pressure – adrenergic-neuron blockers (e.g., guanethidine),
- Alcohol,
- Cancer treating medicine (e.g., aldesleukin),
- Medicines for the treatment of high blood pressure (e.g., angiotensin-II receptor antagonists, beta blockers, calcium-channel blockers, clonidine, moxonidine, tizanidine, diazoxide, hydralazine, nitrates, sodium nitroprusside),
- Medicines for the treatment of schizophrenia (antipsychotics),
- Medicines for the treatment of muscle spasm (e.g., baclofen),
- Anti-inflammatory medicines such as corticosteroids,
- Medicines used for general anesthesia before surgery,
- Medicines for baldness (minoxidil),
- Medicines for the treatment of Parkinson's disease (e.g., levodopa and methyl dopa),
- Medicines for the treatment of depression (monoamine oxidase inhibitors),
- Medicines for chest pain (nitrates),
- Pain killers,
- Female sex hormone (estrogen).

Certain patients have experienced these symptoms when taking medicines for impotence with alpha-blockers. These medicines include alprostadil and moxisylyte. In order to make these

symptoms less likely to occur, you should be on a regular daily dose of your alpha-blockers before you start to take medicines for impotence.

If you are going to have a general anesthetic, you should tell the doctor or dentist in charge that you are taking Hytrin Tablets.

If you are undergoing eye surgery because of a cataract (cloudiness of the lens), please inform your eye specialist before the operation that you are taking or have previously taken Hytrin Tablets. This is because Hytrin Tablets may cause complications during the surgery, which can be managed if your eye specialist is prepared in advance.

Medicine use and food

Hytrin Tablets can be taken with or without food

Medicine use and alcohol consumption

Do not consume alcohol while on treatment with Hytrin as alcohol may increase the risk of dizziness, light-headedness or drowsiness.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult with your doctor or pharmacist before taking this medicine.

Pregnancy

Do not use Hytrin Tablets during pregnancy unless your doctor considers this to be appropriate.

Breast-feeding

It is not known whether Hytrin passes into breast milk.

Fertility

No data are available regarding human fertility. Decreased fertility and testicular atrophy were observed in rats with repeated administration of doses 20-30 times the maximum dose recommended for humans.

Driving and operating machinery

It is important to avoid driving, operating machinery or carrying out hazardous tasks for 12 hours after taking the first tablet of each different strength (e.g., terazosin 1 mg, 2 mg, 5 mg or 10 mg tablets), as dizziness, lightheadedness or drowsiness may occur.

Important information about some of the ingredients of the medicine

Hytrin Tablets contains lactose

If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to your doctor's or pharmacist's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Treatment should not be started in a new patient if a dosage of 1 mg and 2 mg cannot be attained.

If you are not sure when to take your tablets, consult with your doctor.

Do not exceed the recommended dose.

- **Duration of treatment**

Continue to take your tablets, unless your doctor tells you otherwise. **Do not stop** just because you are feeling better.

- **Method of administration**

Take the tablets by mouth, at the same time each day, at bedtime.
Do not halve, crush or chew the tablets, as there is no information.

If you accidentally took a higher dosage, contact your doctor immediately.

If you took an overdose (more than one tablet in one day), or if a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room, and bring the package of the medicine and all remaining tablets with you.

Signs of an overdose include low blood pressure, dizziness, lightheadedness, fainting, a rapid or irregular heartbeat and feeling sick.

If you forget to take the medicine at the required time

If you forgot to take a dose, simply take the next dose at the usual time. **Do not** take a double dose to make up for the forgotten dose. If you have not taken a tablet for several days, you **must not** continue using the same tablets, but rather return to your doctor, who will give you a prescription for an initial dosage of terazosin 1 mg tablets. Treatment should not be re-started in a patient if a dosage of 1 mg and 2 mg cannot be attained.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4) SIDE EFFECTS

As with any medicine, use of Hytrin Tablets may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking the medicine and seek medical advice immediately if you notice the following side effects (could be signs of an allergic reaction):

- Itching or skin rashes;
- Swelling of your face, lips or throat;
- Difficulty in breathing or wheeziness.

When taking Hytrin Tablets for the first time or when starting to take higher dose tablets, dizziness, lightheadedness or fainting may occur. These effects may also occur when standing up quickly from a lying or sitting position. If you are affected by this, you should lie down until you feel better, and then you should sit for a few minutes before standing up again, in order to prevent these effects from recurring. These side effects usually go away and should not recur once you have become used to taking your tablets.

Side effects of unknown frequency (frequency cannot be estimated from the available information):

- Low blood platelet count;
- Weakness, dizziness;

- A fast or uneven heartbeat;
- Feeling sick;
- Swelling of the hands and feet;
- Weakness (decrease in muscle strength);
- Sleepiness;
- Blocked nose;
- Blurred vision;
- Back pain, neck pain, shoulder pain;
- Pain in the hands and feet, “pins and needles” sensation;
- Headache;
- Increased heart rate, irregular heart rate;
- Low blood pressure which can cause dizziness or fainting on standing;
- Loss of consciousness;
- Dilatation of blood vessels;
- Weight gain;
- Irritability, depression, anxiety;
- Shortness of breath or difficulty breathing;
- Decreased sex-drive, impotence, persistent and painful erection;
- Vertigo (problems with balance that can result in feelings of dizziness or nausea – particularly on standing);
- Chest pain;
- Swollen face, flushing;
- Abdominal pain, indigestion;
- Nausea, constipation, diarrhea, flatulence;
- Dry mouth;
- Inflammation or pain in joints or muscles;
- Difficulty sleeping;
- Bronchitis (inflammation of the lungs);
- Sinusitis (inflammation of the nasal passages);
- Rhinitis (irritation and swelling of the mucous membrane in the nose);
- Nose bleeds;
- Flu-like symptoms, pain and irritation of the throat, sore throat, cough;
- Skin rashes and itching;
- Sweating;
- Vision problems and conjunctivitis;
- Ringing in the ears;
- Increased frequency of passing water, urinary tract infection, lack of bladder control;
- Low blood cell counts, abnormal laboratory tests.

Some patients experienced unexpected bruising, and their blood took a longer time than usual to clot after a cut in the skin.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

5) HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not dispose of medicines via wastewater or a household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help to protect the environment.

6) FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
Lactose, maize starch, pregelatinized starch, purified talc, magnesium stearate, dye iron oxide burnt sienna E172 (5 mg tablet) or dye blue FD&C No. 2 Al. lake E132 (10 mg tablet).
- What does the medicine look like and what are the contents of the package?
Hytrin 5 mg Tablets are: round, flat, pinkish-brown tablets, embossed with the company logo and triangles on one side and plain on the other side.
Hytrin 10 mg Tablets are: round, flat, blue tablets, embossed with the company logo and triangles on one side and plain on the other side.
Packages of Hytrin 5 mg and 10 mg contain 28 tablets.
- **Registration holder and address:**
Biotis Ltd., 22 Hamelacha St., Rosh Ha'ayin
- **Manufacturer and address: Amdipharm Sales and Mark. Ltd., England**
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:**
Hytrin 5 mg Tablets: 103 60 28682
Hytrin 10 mg Tablets: 103 61 28683

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