

Package leaflet: Information for the patient

Hytrin® 1 mg and 2 mg Tablets (Starter Pack)

Hytrin® 2 mg Tablets

Hytrin® 5 mg Tablets

Hytrin® 10 mg Tablets

terazosin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Hytrin Tablets are and what they are used for

The name of your medicine is Hytrin Tablets. Hytrin Tablets contains the active ingredient terazosin. Terazosin belongs to a group of medicines called alpha blockers.

Hytrin Tablets are used to treat high blood pressure, either on its own or in combination with other medicines used to treat high blood pressure. Hytrin Tablets is also used for the treatment of a condition called benign prostatic hyperplasia (BPH) which affects the prostate and is common in older men.

This condition stops the flow of urine from the bladder and can lead to symptoms such as a weak or interrupted urine flow, a need to pass water more frequently and/or a sudden need to pass water.

Hytrin Tablets can relax the muscle of the prostate gland and bladder exit to help relieve these symptoms.

2. What you need to know before you take Hytrin Tablets

Do not take Hytrin Tablets:

- if you are allergic to terazosin or any of the other ingredients of this medicine (listed in section 6)
- if you have a history of syncope (fainting) during urination or after using the toilet
- if you have low blood pressure which can cause dizziness or feeling faint on standing

Warnings and precautions

Talk to your doctor or pharmacist before taking Hytrin Tablets if.

- you have ever fallen over or fainted while passing water;
- you are aged 65 years or older;
- you have any heart problems;
- you have any liver problems;
- you experience dizziness, fainting or light-headedness upon sitting or standing up quickly, as Hytrin Tablets may cause low blood pressure;
- you have been told by your doctor that you have a condition known as congestive heart failure.

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

If you are providing a blood or urine sample, always mention that you are being treated with Hytrin, as it may affect the test results.

Children and adolescents

Hytrin Tablets are not recommended for use in children under 12 years of age.

Other medicines and Hytrin Tablets

Tell your doctor or pharmacist if you are taking ,have recently taken or might take any other medicines, including medicines without a prescription.

It is especially important to tell your doctor if you are taking:

- other medicines to treat high blood pressure including ACE inhibitors (e.g. captopril, fosinopril, ramipril), water tablets (diuretics) (e.g. bendroflumethiazide, furosemide, spironolactone) and calcium channel blockers (e.g. amlodipine, verapamil, diltiazem);
- medicines for erectile dysfunction (e.g. sildenafil, tadalafil, vardenafil);
- non-steroidal anti-inflammatory medicines (NSAIDs) (e.g. aspirin, ibuprofen, diclofenac);
- medicines used to thin the blood (e.g. warfarin, heparin, acenocoumarol).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There is limited data available on the use of Terazosin in pregnant women. Hytrin Tablets must not be used during pregnancy.

Breast-feeding

Please consult your doctor if you are breast-feeding as it is not known whether Hytrin passes into breast milk.

Driving and using machines

It is important to avoid driving, using machinery or carrying out hazardous tasks for 12 hours after taking your first tablet of each different strength (i.e. the tablets taken on days 1, 8 and 22 of your starter pack), as dizziness, light-headedness or drowsiness may occur.

Hytrin Tablets contain Lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Hytrin Tablets

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

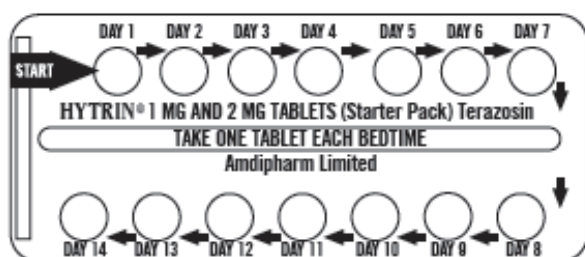
For high blood pressure (hypertension)

If you are taking Hytrin Tablets for the first time or if you have not taken Hytrin Tablets in the last week:

It is important that you take the correct Hytrin Tablet at the correct time.

You should begin taking tablets from the strip marked **HYTRIN® 1 MG AND 2 MG TABLETS (Starter Pack) Terazosin**.

All tablets from this strip should be taken one to two hours before going to bed.



Start taking your Hytrin Tablets at Day 1 marked START on the strip.

This is a white tablet and you should take it by mouth one to two hours before going to bed.

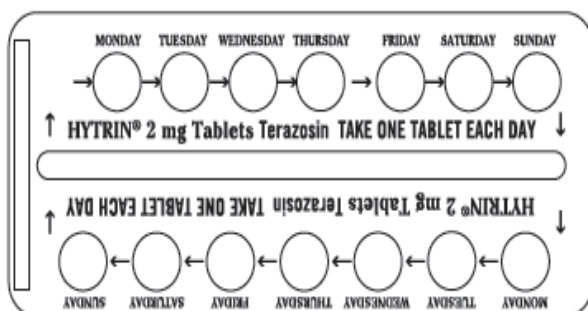
You will notice that from Day 8 onwards, the tablets are yellow.

This is to show that the tablets contain a different dose of Hytrin Tablets from the white tablets.

If no untoward effect has occurred continue to take one tablet per day (one to two hours before going to bed) until you reach Day 14, otherwise contact your doctor.

When you have finished the STARTER PACK, the next tablet that you take should come from the strip which is marked with the days of the week.

See diagram below:



This strip is marked with the days of the week to help you remember if you have taken your tablet.

For instance, if you start taking tablets from this strip on a Wednesday, take one tablet from a space marked Wednesday. Continue taking one tablet each day following the arrows on the strip until there are no tablets left.

You should take your tablets at the same time each day one to two hours before going to bed.

If you are unsure about when to take your tablets, you should consult your doctor for advice.

If you have taken Hytrin Tablets using a Starter Pack and you are continuing with your next pack:

When you have finished your starter pack, your doctor may give you more tablets.

Depending on your response to Hytrin Tablets, your doctor will decide which strength of tablet you need. You may be given a new pack of Hytrin Tablets.

Tablets containing either 2 mg (yellow tablets), 5 mg (tan tablets) or 10 mg (blue tablets). Whichever strength you have will be in a pack containing two strips of 14 tablets marked with the days of the week, as shown below:



Start the new strip by taking a tablet from the space marked with the correct day of the week e.g. If you are starting on a Wednesday, take your first tablet from a space marked Wednesday. Continue taking one tablet each day following the arrows on the strip until there are no tablets left.

You should take your tablets at the same time each day one to two hours before going to bed.

If you are unsure about when to take your tablets, you should consult your doctor for advice. You should continue to take your tablets unless your doctor tells you not to. **Do not stop** just because you feel better.

For Benign Prostatic Hyperplasia (BPH)

Your doctor will explain how to start your treatment, and you will usually be given a starter pack. If you are given a starter pack it is important that you start with the strip marked **HYTRIN® 1 MG AND 2 MG TABLETS (Starter Pack) Terazosin**, and that you take one tablet each day in the order shown on the strip. This is so that you take the weakest (white) tablets for the first week, stronger (yellow) tablets in weeks 2 and 3 and the strongest (tan) tablets in the 4th week.

You should take your tablets at the same time each day one to two hours before going to bed. When you have finished your starter pack, your doctor will give you more tablets. Depending on your response to Hytrin Tablets, your doctor will decide which strength of tablet is best for you.

You should continue to take your tablets unless your doctor tells you not to. **Do not stop** just because you feel better.

If you take more Hytrin tablets than you should

If you take more Hytrin Tablets than you should (more than one tablet in one day), contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you.

If you forget to take Hytrin Tablets

If you forget to take a dose, just take the next dose at the usual time, **DO NOT** take a double dose to make up for a forgotten tablet.

If you have not taken a tablet for several days you should **NOT** continue using the same tablets but return to your doctor for a new starter pack.

If you stop taking Hytrin Tablets

Do not stop taking Hytrin Tablets unless your doctor tells you to.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice:

- itching or skin rashes;
- swelling of your face, lips or throat;
- difficulty in breathing or wheeziness.

Stop taking the medicine and seek medical advice immediately.

These may be signs of an allergic reaction.

When taking Hytrin Tablets for the first time or when starting to take higher dose tablets dizziness, light-headedness or fainting may occur within 30 to 90 minutes of taking the tablet.

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 then you should sit for a few minutes before standing again to prevent these effects returning.

These side effects usually go away and should not return once you have become used to taking your tablets.

Side effects include:

Very common (may affect more than 1 in 10 people):

Dizziness

Common (may affect up to 1 in 10 people):

- weakness;
- a fast or uneven heartbeat;
- feeling sick (nausea);
- swelling of the hands and feet;
- sleepiness;
- blurred vision;
- headache;
- low blood pressure (hypotension) which can cause dizziness or faintness on standing;
- vertigo/ giddiness;
- loose motion (diarrhoea);
- chest pain;
- loss of consciousness;
- burning or prickling sensation;
- inability to get or keep an erection firm (erectile dysfunction)
- nasal blockage and/ or running nose;
- shortness of breath or difficulty in breathing;
- skin rashes and itching;
- weight gain.

Rare (may affect up to 1 in 1,000 people):

- low blood platelet count;
- abnormal heart rhythm;
- inability of body to control the evacuative functions of urination or defecation (mainly in post-menopausal women);
- persistent and painful erection (Priapism).

Not known (frequency cannot be estimated from the available data):

- back pain, neck pain, shoulder pain;
- pains in hands and feet,
- flushing;
- nervousness, depression, anxiety;
- decreased sex-drive
- facial swelling;
- stomach pain, indigestion;
- being sick (vomiting), constipation, wind;
- dry mouth;
- inflammation, stiffness or pains in joints or muscles;
- difficulty sleeping;
- bronchitis (inflammation of the lungs);
- nose bleeds, sore throat, blocked nose, fever;
- inflammation of the nasal passage (Sinusitis);
- cough;
- flu-like symptoms;
- sweating;
- conjunctivitis (a red and watery eye);
- ringing in the ears;
- increased frequency of passing water, urinary infection,
- gout;
- irregular heart beat;
- abnormal vision;
- inflammation of throat;
- swelling of skin and mucus membrane, itching.

Some patients have experienced unexpected bruising and their blood taking longer than usual to clot after a cut to the skin.

Taking Hytrin Tablets may affect the results of some laboratory tests including liver enzyme levels.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance.

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hytrin Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not store above 25° C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other Information

What Hytrin Tablets contains

-The active ingredient is terazosin as terazosin hydrochloride dihydrate. Hytrin Tablets come in 4 strengths and colours containing either 1 mg (white), 2 mg (yellow), 5 mg (tan) or 10 mg (blue).

-The other ingredients are: lactose monohydrate, maize starch, purified talc, pregelatinised maize starch, magnesium stearate, and either: no colour (1 mg tablet); dye yellow E104 (2 mg tablet); dye iron oxide burnt sienna E172 (5 mg tablet) or dye blue E132 (10 mg tablet).

What Hytrin Tablets look like and contents of the pack

Hytrin Tablets are round, flat bevelled tablets embossed with logo and triangular facets on one face and plain on the other and are either; white (1 mg), yellow (2 mg), tan (5 mg) or blue (10 mg).

The starter Pack containing seven 1mg tablets and seven 2mg tablets.

The 2mg, 5mg and 10mg tablet packs each containing 28 tablets.

Marketing Authorisation holder:

Amdipharm Limited, Temple Chambers,
3 Burlington Road, Dublin 4, Ireland.

Manufacturer:

Famar Italia S.P.A.
Via Zambelletti, 25,
Baranzate, 20021,
Italy

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