



AMDIPHARM

HYTRIN 1 mg, 2 mg, 5 mg and 10 mg TABLETS

Terazosin

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

- Please 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 symptoms 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:

1. What Hytrin Tablets are and what they are used for
2. What you need to know before you take Hytrin Tablets
3. How to use Hytrin Tablets
4. Possible Side Effects
5. How to Store Hytrin Tablets
6. Contents of the pack and other information

1. WHAT HYTRIN TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Hytrin 1 mg, 2 mg, 5 mg, or 10mg Tablets (called Hytrin Tablets in this leaflet). Hytrin Tablets contains the active ingredient terazosin. Terazosin belongs to a group of medicines called alpha-blockers. Hytrin Tablets are used in adults to treat high blood pressure. Hytrin Tablets are also used in adults 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 following drugs: alfuzosin, indoramin, prazosin, tamsulosin, doxazosin, or to any of the other ingredients contained in this medicine listed in section 6 (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 in swallowing or breathing);
- have ever fallen over or fainted while passing water.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hytrin Tablets if you:

- are taking other medication for high blood pressure. If a medicine for high blood pressure is started whilst you are taking Hytrin Tablets, then your doctor may need to adjust your dose of Hytrin Tablets;
- have any problems with your heart;
- are taking medicines for erectile dysfunction (e.g. Cialis, Viagra, Levitra);
- are planning cataract removal surgery.

Hytrin Tablets must be used for BPH only after excluding other possible reasons in urinary tract for abnormal/interrupted urinary flow.

Hytrin Tablets can cause fainting or low blood pressure, usually after the first or first few doses. These effects can also occur if you stop taking Hytrin Tablets and then re-start.

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

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

Children and adolescents

Hytrin Tablets are not recommended for use in children.

Other medicines and Hytrin Tablets

Please tell your doctor or pharmacist if you are taking or 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 and water tablets (diuretics);
- medicines for erectile dysfunction (e.g. Cialis, Viagra, Levitra, Stendra).

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness 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 treating high blood pressure - adrenergic neurone blockers (e.g. Guanithidine);
- alcohol;
- cancer treating medicine (e.g. aldesleukin);
- medicines for treating high blood pressure (e.g. Angiotensin – II receptor antagonists, Beta-blockers, Calcium-channel blockers, Clonidine, Moxinidine, Tizanidine Diazoxide, Hydralazine, Nitrate, Sodium nitroprusside);
- medicines for treating schizophrenia (antipsychotics);
- medicines for treating muscle spasm (e.g. baclofen);
- anti-inflammatory drugs like corticosteroids;
- medicines used for general anaesthesia before surgery;
- medicine used for baldness (Minoxidil);
- medicines for treating Parkinson's condition (e.g. levodopa and Methyl dopa) medicines for treating depression (MAO's).

Certain patients have experienced these symptoms when taking drugs for erectile dysfunction (impotence) with alpha-blockers. These medicines include alprostadil and Moxisylyte. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blockers before you start drugs for erectile dysfunction.

If you are going to have a general anaesthetic, you should tell the

doctor or dentist in charge that you are taking Hytrin Tablets.

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.

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. Hytrin Tablets should not be used during pregnancy unless considered appropriate by your doctor.

Driving and operating machinery

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 the hypertension 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 medicine.

Hytrin BPH 2 mg, 5 mg and 10 mg Tablets contain colouring agents Dye yellow E104 (2mg tablet), dye iron oxide burnt sienna E172 (5 mg tablet), dye blue E132 (10 mg tablet). May cause allergic reactions.

3. HOW TO USE HYTRIN TABLETS

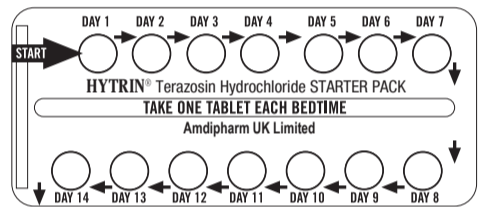
Always take Hytrin Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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 STARTER PACK**. All tablets from this strip should be taken at bedtime.

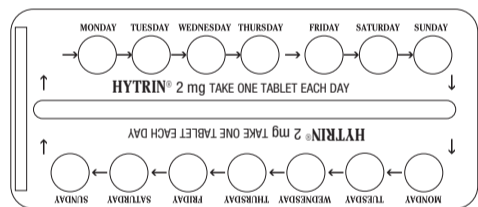


Start taking your Hytrin Tablets at Day 1 marked START on the strip. This is a white tablet, and you should take it by mouth just before going to bed.

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 from the white tablets.

Continue to take one tablet each day before you go to bed until you reach Day 14.

When you have finished the strip marked HYTRIN STARTER PACK, the next tablet that you take should come from the strip which is marked HYTRIN 2 mg 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.

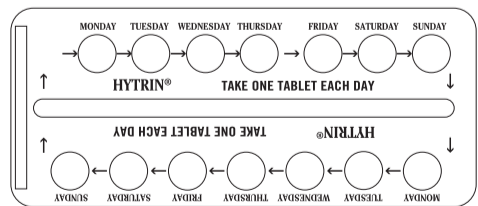
You should take your tablets at the same time each day at bedtime.

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

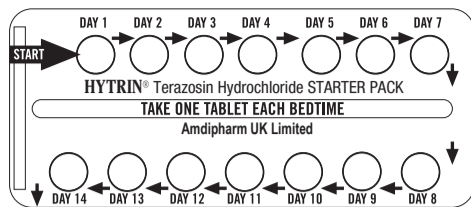
You should continue to take your tablets unless your doctor tells you not to. **Do not stop** just because you feel better.

For Benign Prostatic Hyperplasia (BPH)

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.

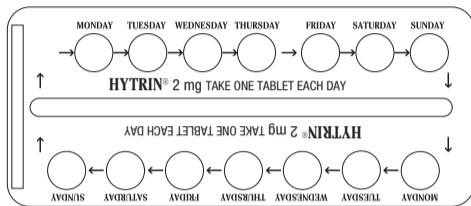
You should begin taking tablets from the strip marked HYTRIN STARTER PACK 1. All tablets from this strip should be taken at bedtime.



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 just before going to bed.

You will notice that from Day 8 to Day 14, the tablets are yellow. This is to show that the tablets contain a different dose of Hytrin from the white tablets.

When you have finished the strip marked HYTRIN STARTER PACK 1, the next tablet that you take should come from the strip, which is marked HYTRIN STARTER PACK 2. Start taking your Hytrin Tablets at Day 15 marked START on the strip. This is a yellow tablet. When you reach day 22, the tablets are tan. 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. See diagram below:

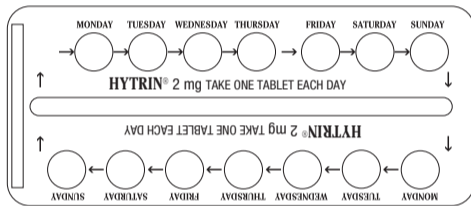


You should take your tablets at the same time each day at bedtime. If you are unsure about when to take your tablets, you should consult your doctor for advice.

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 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 2 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, e.g. bedtime. 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.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hytrin Tablets 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. 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.

The most common side effects of Hytrin Tablets are:

- weakness, dizziness;
- a fast or uneven heartbeat;
- feeling sick;
- swelling of the hands and feet;
- sleepiness;
- blocked nose;
- blurred vision.

Other, less frequent side-effects of Hytrin Tablets are:

- back pain, neck pain, shoulder pain;
- pains in hands and feet, pins and needles;
- headache;

- low blood pressure (hypotension) which can cause dizziness or faintness on standing;
- weight gain;
- nervousness, depression, anxiety;
- shortness of breath or difficulty breathing;
- decreased sex-drive, erectile dysfunction, persistent and painful erection;
- vertigo (problems with balance that can result in feelings of dizziness or sickness - particularly on standing);
- chest pains;
- facial swelling, flushing;
- stomach pain, indigestion;
- being sick, constipation, diarrhoea, wind;
- dry mouth;
- inflammation or pains in joints or muscles;
- difficulty sleeping;
- bronchitis (inflammation of the lungs);
- nose bleeds;
- flu-like symptoms, sore throat, cough;
- skin rashes and itching;
- sweating;
- vision problems and conjunctivitis;
- ringing in the ears; increased frequency of passing water, urinary infection, lack of bladder control;
- low blood cell counts, laboratory tests abnormal.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE HYTRIN TABLETS

Do not take Hytrin Tablets after the expiry date shown on the package. The expiry date refers to the last day of that month. Do not store above 25° C.

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.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Hytrin Tablets contains

Hytrin Tablets come in 4 strengths and colours containing either 1 mg (white), 2 mg (yellow), 5 mg (tan) or 10 mg (blue), of the active ingredient terazosin as terazosin monohydrochloride dihydrate. The other ingredients are: lactose, maize starch, purified talc, magnesium stearate, and either no colour (1mg tablet), dye yellow E104, (2mg tablet), dye iron oxide burnt sienna E172, (5 mg tablet) or dye blue E132 (10 mg tablet).

What Hytrin Tablets looks like and the contents of the packs

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 (1mg), yellow (2mg), tan (5mg) or blue (10mg)

They are available in 5 different packs;

- The hypertension Starter Pack containing seven 1 mg (white) tablets and twenty-one 2mg (yellow) tablets (4 weeks treatment).
- The BPH Starter Pack containing seven 1 mg (white) tablets, fourteen 2 mg (yellow) tablets and seven 5 mg (tan) tablets (4 weeks treatment).
- The 2 mg, 5 mg and 10 mg tablet packs each containing 28 tablets (4 weeks treatment).

Marketing Authorisation holder:

Amdipharm UK Limited,
Capital House, 85 King William Street,
London EC4N 7BL, UK

Manufacturer:

Aesica Queenborough Limited,
North road, Queenborough, Kent,
ME11 5EL, United Kingdom

This leaflet was last revised in June 2018.



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