

PATIENT INFORMATION LEAFLET

Hytrin® 2mg, 5mg & 10mg 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Hytrin is and what it is used for
2. What you need to know before you take Hytrin Tablets
3. How to take Hytrin Tablets
4. Possible side effects
5. How to Store Hytrin Tablets
6. Contents of the pack and other information

1. WHAT HYTRIN IS AND WHAT IT IS USED FOR

The name of your medicine is Hytrin Tablets.

Hytrin Tablets contain the active ingredient terazosin.

Terazosin belongs to a group of medicines called alpha blockers.

Hytrin is used to treat high blood pressure, either on its own or in combination with other medicines used to treat high blood pressure.

Hytrin 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 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 if you:

- Are **allergic** to
 - **Terazosin** or any of the other ingredients of this medicine (listed in section 6),
 - any of the following drugs: alfuzosin, indoramin, prazosin, tamsulosin, doxazosin
 - or to any of the other ingredients contained in this medicine, detailed in section 6 of this leaflet (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);
- suffer from a condition called congestive heart failure;
- are a child under 12 years of age

Warnings and precautions

Talk to your doctor before taking Hytrin tablets if you:

- have ever fallen over or fainted while passing water;
- are aged 65 years or older;
- have any heart problems;
- have any liver problems;
- if you experience dizziness, fainting, or light-headedness upon sitting or standing up quickly, as Hytrin may cause low blood pressure.

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

Other medicines and Hytrin

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 (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).

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

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.

This is because Hytrin may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Pregnancy, breast-feeding and fertility

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

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 your starter pack), as dizziness, light-headedness or drowsiness may occur.

Hytrin Tablets contain Lactose, a type of sugar

Tell your doctor before taking this medicine if you have been told that you have an **intolerance to some sugars**. This is because Hytrin tablets contain lactose, a type of sugar.

3. HOW TO TAKE 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)

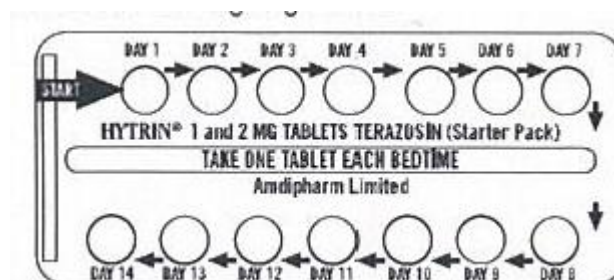
If you are taking Hytrin for the first time or if you have not taken Hytrin in the last week:

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 AND 2 mg Terazosin (Starter pack)

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.

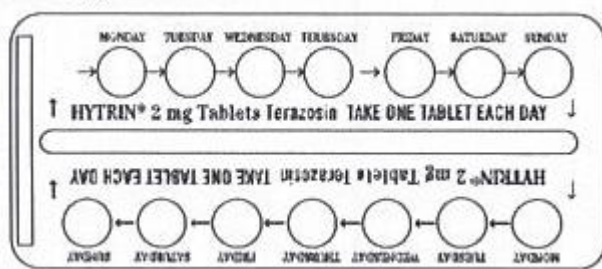
This is a white tablet and you should take it by mouth one to two hours before going to bed.

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 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.

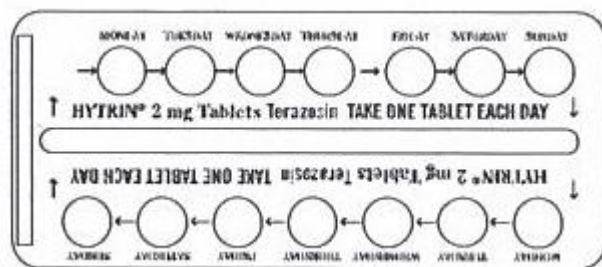
If you are unsure about when to take your tablets, you should consult your doctor for advice.

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, 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 two strips of 14 tablets marked with the days of the week, as shown below.



Start with 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 AND 2 mg TERAZOSIN (Starter Pack)**, 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, your doctor will decide which strength of tablet is best for you.

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

If you take more tablets than you should

If you take more Hytrin 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

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 the 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hytrin 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
- Persistent and painful erection
- 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

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

- Back pain, neck pain, shoulder pain
- Pains in hands and feet, pins and needles
- 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
- Cough
- Flu-like symptoms
- Sweating
- Conjunctivitis (a red and watery eye)
- Ringing in the ears
- Increased frequency of passing water, urinary infection, lack of bladder control
- Gout
- Irregular heart beat
- Abnormal vision
- Indigestion
- Swelling in face
- 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, Earlsfort Terrace, Dublin 2, Ireland; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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 the tablets if they are past the expiry date which is clearly marked on the carton, label and blister foil. 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 SIGHT AND REACH OF CHILDREN.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Hytrin contains**

Each Hytrin 2mg Tablet contains 2mg terazosin (as hydrochloride dihydrate).

Each Hytrin 5mg Tablet contains 5mg terazosin (as hydrochloride dihydrate).

Each Hytrin 10mg Tablet contains 10mg terazosin (as hydrochloride dihydrate).

Hytrin 2mg Tablets are yellow, round flat, bevel edged tablets embossed with the 'Abbott' logo and triangular facets on one face and plain on the other.

Hytrin 5mg Tablets are tan, round flat, bevel edged tablets embossed with the 'Abbott' logo and triangular facets on one face and plain on the other.

Hytrin 10mg Tablets are blue, round flat, bevel edged tablets embossed with the 'Abbott' logo and triangular facets on one face and plain on the other.

They also contain the following excipients:

Lactose monohydrate, maize starch, purified talc and magnesium stearate.

Hytrin 2mg Tablets also contain dye yellow (quinoline yellow, E104); Hytrin 5mg Tablets also contain dye (iron oxide burnt sienna, E172); Hytrin 10mg Tablets contain dye blue E132 (FD&C No. 2 lake).

Pack sizes: Hytrin Tablets are available in a blister pack of 28 tablets, contained in an outer cardboard carton.

MANUFACTURER

Aesica Queensborough Limited, Queensborough, Kent, ME11 5EL, UK or Amdipharm Plc, Regency House, Miles Gray Road, Basildon, Essex SS14 3AF, UK.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Product Authorisation Number:

Hytrin 2mg Tablets	PPA 465/161/1
Hytrin 5mg Tablets	PPA 465/161/2
Hytrin 10mg Tablets	PPA 465/161/3

Hytrin is a registered trademark of Abbott Laboratoires.

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