

## PATIENT INFORMATION LEAFLET

### **HYTRIN® 2mg TABLETS**

### **HYTRIN® 5mg TABLETS**

### **HYTRIN® 10mg TABLETS**

(terazosin)

Please read this leaflet carefully before you take these tablets. It gives a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

The name of your medicine is Hytrin 2mg tablets, Hytrin 5mg tablets or Hytrin 10mg tablets, but will be referred to as Hytrin tablets throughout the remainder of this leaflet.

#### **WHAT'S IN HYTRIN TABLETS?**

The name of your tablets is Hytrin tablets. The active ingredient in Hytrin tablets is terazosin.

Hytrin tablets contain 2mg, 5mg, or 10mg terazosin (as monohydrochloride dihydrate).

All Hytrin tablets contain other ingredients: lactose monohydrate, maize starch, purified talc, magnesium stearate, and either, quinoline yellow (E104), (2mg tablet), iron oxide burnt sienna (E172), (5mg tablet) or FD&C No.2 lake (E132), (10mg tablet).

The 2mg tablets are yellow, round, flat beveled edged tablets with the company logo  and triangular facets on one face and plain on the other.

The 5mg tablets are tan, round, flat beveled edged tablets with the company logo  and triangular facets on one face and plain on the other.

The 10mg tablets are blue, round, flat beveled edged tablets with the company logo  and triangular facets on one face and plain on the other.

The hypertension starter pack containing seven 1mg (white) and twenty-one 2mg (yellow) tablets (4 weeks treatment)

The BPH starter pack containing seven 1mg (white) tablets, fourteen 2mg (yellow) tablets and seven 5mg (tan) tablets (4 weeks treatment)

The 2mg, 5mg, and 10mg tablet packs each contain 28 tablets (4 weeks treatment).

Hytrin tablets are one of a group of medicines called alpha blockers.

**Manufactured by:** Amdipharm Plc, Regency House, Miles Gray Road, Basildon, Essex SS14 3AF, UK.

**Procured from within the EU and repackaged by the PPA holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK

**HYTRIN 2mg TABLETS - PPA No: 1328/95/1**

**HYTRIN 5mg TABLETS - PPA No: 1328/95/2**

**HYTRIN 10mg TABLETS – PPA No: 1328/95/3**

**POM**

#### **WHAT ARE HYTRIN TABLETS USED FOR?**

Hytrin tablets are used to treat patients suffering from high blood pressure. It helps reduce blood pressure.

Hytrin tablets are also used for the treatment of a condition called benign prostatic hyperplasia (BPH) which is common in older men. This condition is caused by the prostate gland growing too big and obstructing the flow of urine from the bladder. This leads to some unpleasant symptoms such as 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.

#### **BEFORE TAKING HYTRIN TABLETS**

Do not take Hytrin tablets if you know that you are allergic to terazosin, any of the following drugs: alfuzosin, indoramin, prazosin, tamsulosin, doxazosin, or any of the other ingredients in Hytrin tablets. (see: 'What's in Hytrin tablets?')

Before taking Hytrin tablets tell your doctor:

- If you are being treated for congestive heart failure, high blood pressure or if you are taking drugs to lower your blood pressure for any other reasons.
- If you are taking drugs for erectile dysfunction or drugs called ACE inhibitors or water tablets.
- If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as this product contains lactose.
- If you have ever fallen over or fainted while passing water.

If you are pregnant or breast-feeding do not take Hytrin tablets without consulting your doctor first, as the safety of Hytrin tablets in pregnancy and breast-feeding is not known.

#### **TAKING HYTRIN TABLETS FOR HYPERTENSION**

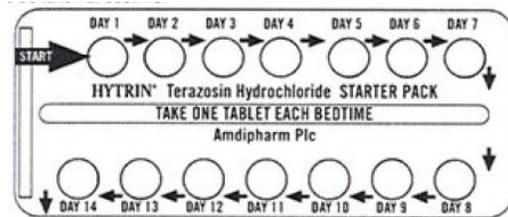
**1. Read this section if you are taking Hytrin tablets for the first time or if you have not taken Hytrin tablets in the last week. If you are continuing treatment without a break, please read section 2 below:**

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 Here**



**White tablets**

follow arrows

**Yellow tablets**

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.

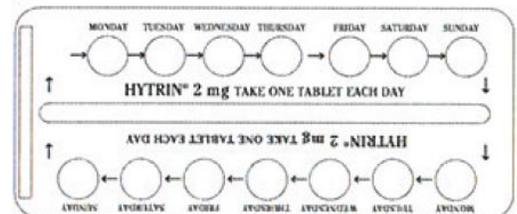
You will notice that from Day 8 onwards, the tablets are yellow. This is to show that the tablets contain a different dose of terazosin from the white tablets.

After taking the tablets on the 1<sup>st</sup> and 8<sup>th</sup> day, it is important that you **DO NOT** drive or undertake any hazardous tasks for 12 hours because dizziness, light-headedness or drowsiness occur with the first dose, a change in dose or after missing doses and restarting treatment.

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

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.

Follow the arrows



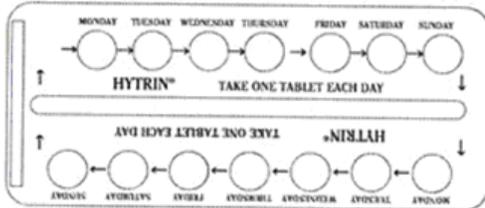
The strip is marked with the days of the week to help you remember if you have taken your tablet. For instance, if you start taking tablets from this strip on a Wednesday, take one tablet from a space marked Wednesday. Continue taking one tablet each day following the arrows on the strip until there are no tablets left.

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

## 2. Read this section 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 a prescription for 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 2mg (yellow tablets), 5mg (tan tablets) or 10mg (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 accidentally take an overdose (more than one tablet a day) call your doctor immediately.

**If you miss a dose take a tablet as soon as you remember. Do not take more than one tablet a day. If you have not taken a tablet for several days you should not continue using the same tablets. Return to your doctor for a new starter pack.**

### **TAKING HYTRIN TABLETS FOR BPH**

Your doctor will ask you to take one Hytrin tablet each day before bedtime.

At first you will be given a starter pack.

**It is important that you start with the strip marked STARTER PACK 1 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 4<sup>th</sup> week.

When you have finished your starter pack, your doctor will give you a prescription for 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 (one a day) unless your doctor tells you not to.

**You should avoid missing doses. If you miss a dose take a tablet as soon as you remember. Do not take more than one tablet a day. If you have not taken a tablet for several days you should NOT continue using the same tablets.** Return to your doctor for a new starter pack.

**Avoid driving or using machinery 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.**

If you accidentally take an overdose (more than one tablet in one day) call your doctor immediately.

### **WHAT PROBLEMS CAN HYTRIN TABLETS CAUSE?**

When taking Hytrin tablets for the first time or when starting to take higher dose tablets, some people may experience dizziness, light-headedness or fainting. These effects may also occur when standing up quickly from a lying or sitting position. If this occurs, you should lie down until you feel better then you should sit for a few minutes before standing up 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.

Hytrin tablets sometimes cause other side effects, the most common of which are weakness, a fast or uneven heartbeat, feeling sick, swelling, dizziness, sleepiness, blocked nose, and blurred vision.

Other, less frequent side effects may include: back pain, headache, weight gain, pain in extremities, decreased sex-drive, depression, nervousness, pins and needles, vertigo, difficulty breathing, and impotence.

In addition, the following effects have been reported in either clinical trials or during marketing experience. However, these may not necessarily have been caused by taking Hytrin tablets. fever, pain in neck, chest, shoulder, or abdomen, redness of the skin, constipation, diarrhoea, vomiting, flatulence, indigestion, dry mouth, gout, painful joints, anxiety, difficulty sleeping, bronchitis, flu, and cold symptoms, swollen or sore throat, nose bleed, itching/rash, sweating, conjunctivitis, noises, in the ear, such as ringing, or whistling. Urinary frequency/incontinence, and urinary tract infection occurs primarily in women who have gone through the menopause.

At least two cases of allergic reactions have been reported with the administration of Hytrin tablets. Some patients have experienced unexpected bruising and their blood taking longer than usual to clot after a cut to the skin. Permanent erection has also been reported. Some patients have experienced disturbances in their heartbeat whilst taking Hytrin tablets but this effect may not be due to the drug.

If you have any other unexpected or unusual symptoms, tell your doctor.

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

### **HOW SHOULD HYTRIN TABLETS BE STORED?**

Do not use these tablets after the expiry date which is printed on the blister and outer carton. If the tablets are out of date, return them to your pharmacist and, if necessary, get a new prescription from your doctor.

Do not store above 25°C.

### **KEEP OUT OF THE REACH AND SIGHT OF CHILDREN**

If your doctor decides to stop your treatment with Hytrin tablets return any remaining tablets to a pharmacist, for safe disposal.

**REMEMBER** these tablets are for **you**. **NEVER** give them to someone else. The tablets may harm them, even if their symptoms are the same as yours.

If you have any questions about your treatment which are not answered by this leaflet, ask your doctor or pharmacist.

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