PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

HYTRIN 1 mg, 2 mg, 5 mg tablets

Terazosin

Contains sugar (lactose monohydrate):

128,56 mg per HYTRIN 1 mg tablet

127,28 mg per HYTRIN 2 mg tablet

123,07 mg per HYTRIN 5 mg tablet.

Read all of this leaflet carefully before you start taking HYTRIN.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.
- HYTRIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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
3. How to take HYTRIN
4. Possible side effects
5. How to store HYTRIN
6. Contents of the pack and other information.

1. What HYTRIN is and what it is used for

HYTRIN tablets contain the active ingredient terazosin.

HYRTIN is used to treat patients suffering from high blood pressure. It is prescribed for use either alone or in a combination with other high blood pressure medicines.

HYTRIN is also used for the treatment of a condition called benign prostatic hyperplasia. 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 sudden need to pass water. HYTRIN can relax the muscle of the prostate gland and bladder exit to help relieve these symptoms.

HYTRIN is one of a group of medicines called alpha blockers.

2. What you need to know before you take HYTRIN

Do not take HYTRIN tablets:

- if you are hypersensitive (allergic) to terazosin or any of the other ingredients of HYTRIN (see section 6 for other ingredients)
- if you have a heart disease.

Warnings and precautions

Take special care with HYTRIN:

- if you are 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 again to prevent these effects returning

- if you have any problems with your heart
- if you are taking medicines which may influence hepatic metabolism
- if you are taking medicines for erectile dysfunction (phosphodiesterase type 5 (PDE5) inhibitors e.g. sildenafil)
- if you 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 may also lead to decreases of certain laboratory values, such as red blood cells or white blood cells.

Children and adolescents

HYTRIN should not be administered to children younger than 12 years of age.

Other medicines and HYTRIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Before taking HYTRIN 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. Viagra).

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, Nitrates, 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 Methyldopa)

• 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.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking HYTRIN.

Pregnancy

HYTRIN tablets is not recommended during pregnancy.

Driving and using machines

Avoid driving or hazardous tasks for approximately the first 12 hours after the first dose or when the dose is increased.

HYTRIN contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking HYTRIN tablets.

3. How to take HYTRIN

Do not share medicines prescribed for you with any other person. These tablets may harm them even if their symptoms are the same.

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

1. If you are taking HYTRIN for the first time

Take one tablet each day before you go to bed. You should take your tablets at the same time each day. Do not alter the daily dose without consulting with your doctor.

2. If you are continuing taking HYTRIN tablets

Your doctor will ask you to take one HYTRIN tablet each day before you go to bed. 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, one each day before you go to bed, unless your doctor tells you not to.

If you take more HYTRIN tablets than you should

In the event of overdosage, consult your doctor or pharmacist.

If neither is available, contact the nearest hospital or poison centre.

If you forget to take HYTRIN tablets

You should avoid missing doses. If you miss a dose, take the missed dose as soon as you remember. However, do not take more than one tablet a day.

If you have not taken a tablet for several days, you should not continue the same tablets. Consult your doctor.

4. Possible side effects

HYTRIN can have side effects.

Not all side effects reported for HYTRIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HYTRIN, please consult your health care provider for advice.

If any of the following happens, stop taking HYTRIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to HYTRIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- palpitations, tachycardia (heart beating too hard or too fast, skipping a beat, or fluttering)
- abnormal heart rhythm (dysrhythmia)
- chest pain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown:

- thrombocytopenia (a lower than normal number of platelets in the blood, characterised by easy or excessive bruising)
- depression, nervousness, anxiety, difficulty in sleep (insomnia)
- sleepiness (somnolence), headache, tingling, “pins and needles” sensation (paraesthesia)
- a feeling of spinning dizziness (vertigo)
- blurred vision, a problem with visual acuity, or eyesight (amblyopia), abnormal vision, infection of the eye (conjunctivitis)
- ringing noises in your ear (tinnitus)
- dizziness or light-headedness when standing after sitting or lying down (postural hypotension), low blood pressure (hypotension), a widening of blood vessels, leading to increased blood flow with flushing or warmth (vasodilatation)
- blocked nose (nasal congestion), runny nose (rhinitis), inflammation of the sinuses (sinusitis), inflammation in bronchial tubes (bronchitis), cold symptoms, nose bleeds (epistaxis), flu symptoms, increased cough, sore throat (pharyngitis)
- feeling sick (nausea), stomach pain, constipation, diarrhoea, dry mouth, indigestion

(dyspepsia), passing wind (flatulence), being sick (vomiting)

- sweating
- pain in back, arms and legs, neck pain, shoulder pain
- inflammatory arthritis that results from an excess of uric acid in the blood (gout)
- inflammation or pain that comes from inside a joint (arthralgia), swelling of the joints (arthritis), joint disorder, muscle pain (myalgia)
- urinary frequency, urinary tract infection and urinary incontinence (primarily reported in postmenopausal women)
- low sex drive (decreased libido), difficulty getting and keeping an erection (impotence)
- lack of energy (asthenia)
- increase in body mass (weight gain)
- fever
- intraoperative floppy iris syndrome (IFIS), a complication during cataract surgery.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of HYTRIN.

5. How to store HYTRIN

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from moisture.

Keep tablets in original container until required for use.

Do not use after the expiry date printed on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HYTRIN contains

The active substance is terazosin.

Other ingredients are lactose monohydrate, maize starch, pregelatinised starch, talc, magnesium stearate, Quinoline Yellow (E104) aluminium lake in HYTRIN 2 mg and Iron oxide (E172) burnt sienna in HYTRIN 5 mg.

What HYTRIN looks like and contents of the pack

HYTRIN 1 mg	White, round, flat, bevelled-edge tablet, 7 mm in diameter and approximately 3 mm thick, with Abbott logo and triangular facets on one side, plain on reverse side.
HYTRIN 2 mg	Yellow, round, flat, bevelled-edge tablet, 7 mm in diameter and approximately 3 mm thick, with Abbott logo and triangular facets on one side, plain on reverse side.
HYTRIN 5 mg	Tan, round, flat, bevelled-edge tablet, 7 mm in diameter and approximately 3 mm thick, with Abbott logo and triangular facets on one side, plain on reverse side.

PVC/PVDC aluminium foil blister strip, packed in an outer carton.

HYTRIN 1 mg is supplied in packs containing 10 tablets.

HYTRIN 2 mg and 5 mg are supplied in packs containing 28 tablets.

Holder of Certificate of Registration

Abbott Laboratories S.A. (Pty) Ltd

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HYTRIN 1 mg 30 January 2023

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Registration numbers

HYTRIN 1 mg A27/7.1/0519

HYTRIN 2 mg A27/7.1/0520

HYTRIN 5 mg A27/7.1/0521

NAME AND ADDRESS OF MANUFACTURER

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Country	Product	Registration number	Scheduling status
Zimbabwe	HYTRIN 1 mg	2001/12.3.1/3987	PP
	HYTRIN 2 mg	2001/12.3.1/3988	PP
	HYTRIN 5 mg	2001/12.3.1/3989	PP

Namibia	HYTRIN 1 mg	04/7.1/1259	NS2
	HYTRIN 2 mg	04/7.1/1260	NS2
	HYTRIN 5 mg	04/7.1/1261	NS2
	HYTRIN 10 mg	04/7.1/1262	NS2