

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number 75-140**

**FINAL PRINTED LABELING**

# PATIENT INFORMATION ABOUT TERAZOSIN (ter-A-zo-sin) Hydrochloride Capsules

When used to treat HYPERTENSION or  
BENIGN PROSTATIC HYPERPLASIA (BPH)

Please read this leaflet before you start taking terazosin hydrochloride capsules. Also, read it each time you get a new prescription. This is a summary and should NOT take the place of a full discussion with your doctor who has additional information about terazosin hydrochloride. You and your doctor should discuss terazosin hydrochloride and your condition before you start taking it and at your regular check-ups.

Terazosin hydrochloride capsules are used to treat high blood pressure (hypertension). Terazosin hydrochloride capsules are also used to treat benign prostatic hyperplasia (BPH) in men. This leaflet describes terazosin hydrochloride as a treatment for hypertension or BPH.

**What is Hypertension (High Blood Pressure)?** Blood pressure is the tension of the blood within the blood vessels. If blood is pumped too forcefully, or if the blood vessels are too narrow, the pressure of the blood against the walls of the vessels rises.

If high blood pressure is not treated, over time, the increased pressure can damage blood vessels or it can cause the heart to work too hard and may decrease the flow of blood to the heart, brain, and kidneys. As a result, these organs may become damaged and not function correctly. If high blood pressure is controlled, this damage is less likely to happen.

**Treatment Options for Hypertension:** Non-drug treatments are sometimes effective in controlling mild hypertension. The most important lifestyle changes to lower blood pressure are to lose weight, reduce salt, fat, and alcohol in the diet, quit smoking, and exercise regularly. However, many hypertensive patients require one or more ongoing medications to control their blood pressure. There are different kinds of medications used to treat hypertension. Your doctor has prescribed terazosin hydrochloride for you.

**What Terazosin Hydrochloride Does to Treat Hypertension:** Terazosin hydrochloride works by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

**What is BPH?** The prostate is a gland located below the bladder of men. It surrounds the urethra (you-REETH-rah), which is a tube that drains urine from the bladder. BPH is an enlargement of the prostate gland. The symptoms of BPH, however, can be caused by an increase in the tightness of muscles in the prostate. If the muscles inside the prostate tighten, they can squeeze the urethra and slow the flow of urine. This can lead to symptoms such as:

- a weak or interrupted stream when urinating
- a feeling that you cannot empty your bladder completely
- a feeling of delay when you start to urinate
- a need to urinate often, especially at night, or
- a feeling that you must urinate right away.

**Treatment Options for BPH:** There are three main treatment options for BPH:

- Program of monitoring or "Watchful Waiting". Some men have an enlarged prostate gland, but no symptoms, or symptoms that are not bothersome. If this applies, you and your doctor may decide on a program of monitoring including regular checkups, instead of medication or surgery.
- Medication. There are different kinds of medication used to treat BPH. Your doctor has prescribed terazosin hydrochloride for you. See "What Terazosin Hydrochloride Does to Treat BPH" below.
- Surgery. Some patients may need surgery. Your doctor can describe several different surgical procedures to treat BPH. Which procedure is best depends on your symptoms and medical condition.

**What Terazosin Hydrochloride Does to Treat BPH:** Terazosin hydrochloride relaxes the tightness of a certain type of muscle in the prostate and at the opening of the bladder. This may increase the rate of urine flow and/or decrease the symptoms you are having.

- Terazosin hydrochloride helps relieve the symptoms of BPH. It does NOT change the size of the prostate, which may continue to grow. However, a larger prostate does not necessarily cause more or worse symptoms.
- If terazosin hydrochloride is helping you, you should notice an effect on your particular symptoms in 2 to 4 weeks of starting to take the medication.
- Even though you take terazosin hydrochloride and it may help you, terazosin hydrochloride may not prevent the need for surgery in the future.

## Other Important Facts About Terazosin Hydrochloride for BPH:

- You should see an effect on your symptoms in 2 to 4 weeks. So, you will need to continue seeing your doctor to check your progress regarding your BPH and to monitor your blood pressure in addition to your other regular check-ups.
- Your doctor has prescribed terazosin hydrochloride for your BPH and not for prostate cancer. However, a man can have BPH and prostate cancer at the same time. Doctors usually recommend that men be checked for prostate cancer once a year when they turn 50 (or 40 if a family member has had prostate cancer). These checks should continue even if you are taking terazosin hydrochloride. Terazosin hydrochloride is not a treatment for prostate cancer.
- About Prostate Specific Antigen (PSA) Your doctor may have done a blood test called PSA. Your doctor is aware that terazosin hydrochloride does not affect PSA levels. You may want to ask your doctor more about this if you have had a PSA test done.

**What You Should Know While Taking Terazosin Hydrochloride for Hypertension or BPH: WARNINGS:** Terazosin Hydrochloride Can Cause a Sudden Drop in Blood Pressure After the VERY FIRST DOSE. You may feel dizzy, faint, or "lightheaded" particularly after you get up from bed or from a chair. This is more likely to occur after you've taken the first few doses, but can occur at any time while you are taking the drug. It can also occur if you stop taking the drug and then re-start treatment.

Because of this effect, your doctor may have told you to take terazosin hydrochloride at bedtime. If you take terazosin hydrochloride at bedtime but need to get up from bed to go to the bathroom, get up slowly and cautiously until you are sure how the medicine affects you. It is also important to get up slowly from a chair or bed at any time until you learn how you react to terazosin hydrochloride. You should not drive or do any hazardous tasks until you are used to the effects of the medication. If you begin to feel dizzy, sit or lie down until you feel better.

- You will start with a 1 mg dose of terazosin hydrochloride. Then the dose will be increased as your body gets used to the effect of the medication.
- Other side effects you could have while taking terazosin hydrochloride include drowsiness, blurred or hazy vision, nausea, or "puffiness" of the feet or hands. Discuss any unexpected effects you notice with your doctor.

Extremely rarely, terazosin hydrochloride and similar medications have caused painful erection of the penis, sustained for hours and unrelieved by sexual intercourse or masturbation. This condition is serious, and if untreated it can be followed by permanent inability to have an erection. If you have a prolonged abnormal erection, call your doctor or go to emergency room as soon as possible.

**How to Take Terazosin Hydrochloride Capsules:** Follow your doctor's instructions about how to take terazosin hydrochloride capsules. You must take it every day at the dose prescribed. Talk with your doctor if you don't take it for a few days, you may have to re-start it at a 1 mg dose and be cautious about possible dizziness. Do not share terazosin hydrochloride capsules with anyone else; it was prescribed only for you.

Keep terazosin hydrochloride capsules and all medicines out of the reach of children.

Store capsules at 15° - 30°C (59° - 86°F).

Protect from light and moisture.

**FOR MORE INFORMATION ABOUT TERAZOSIN HYDROCHLORIDE CAPSULES AND HYPERTENSION OR BPH, TALK WITH YOUR DOCTOR, NURSE, PHARMACIST OR OTHER HEALTH CARE PROVIDER.**



Mylan Pharmaceuticals Inc.  
Morgantown, WV 26505

REVISED JUNE 1998  
PL.TERZ.R1A

N 0378-1570-10 7



10 mg\*

\*Each capsule contains 10 mg of terazosin as terazosin hydrochloride anhydrous



NDC 0378-1570-10

MYLAN®

# TERAZOSIN HYDROCHLORIDE CAPSULES 10 mg\*

1000 CAPSULES



Dispense in a light, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

**STORE AT CONTROLLED ROOM TEMPERATURE 15° to 30°C (59° to 86°F). PROTECT FROM LIGHT AND MOISTURE.**

Usual Dosage: See accompanying prescribing information.

This is a bulk container and not intended for dispensing for household use.

Mylan Pharmaceuticals Inc.  
Bergantown, WV 26005

001570C

N 0378-2268-01 0



5 mg\*

\*Each capsule contains 5 mg of terazosin as terazosin hydrochloride anhydrous



NDC 0378-2268-01

MYLAN®

# TERAZOSIN HYDROCHLORIDE CAPSULES 5 mg\*

100 CAPSULES



Dispense in a light, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

**STORE AT CONTROLLED ROOM TEMPERATURE 15° to 30°C (59° to 86°F).**

**PROTECT FROM LIGHT AND MOISTURE.**

Usual Dosage: See accompanying prescribing information.

Mylan Pharmaceuticals Inc.  
Bergantown, WV 26005

N 0378-1570-01 5



10 mg\*

\*Each capsule contains 10 mg of terazosin as terazosin hydrochloride anhydrous



NDC 0378-1570-01

MYLAN®

# TERAZOSIN HYDROCHLORIDE CAPSULES 10 mg\*

100 CAPSULES



Dispense in a light, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

**STORE AT CONTROLLED ROOM TEMPERATURE 15° to 30°C (59° to 86°F).**

**PROTECT FROM LIGHT AND MOISTURE.**

Usual Dosage: See accompanying prescribing information.

Mylan Pharmaceuticals Inc.  
Bergantown, WV 26005

001570C


Each capsule contains 2 mg of terazosin as terazosin hydrochloride anhydrous

3 0378-2264-01 2

2 mg\*

MYLAN®

**TERAZOSIN HYDROCHLORIDE CAPSULES**  
2 mg\*

100 CAPSULES 

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

STORE AT CONTROLLED ROOM TEMPERATURE 20° to 25°C (68° to 77°F).

PROTECT FROM LIGHT AND MOISTURE.

Usual Dosage: See accompanying prescribing information.

This is a bulk container and not intended for dispensing for household use.

Mylan Pharmaceuticals Inc.  
Morgantown, WV 26505


Each capsule contains 5 mg of terazosin as terazosin hydrochloride anhydrous

N 0378-2268-10 2

5 mg\*

MYLAN®

**TERAZOSIN HYDROCHLORIDE CAPSULES**  
5 mg\*

1000 CAPSULES 

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

STORE AT CONTROLLED ROOM TEMPERATURE 15° to 30°C (59° to 86°F).

PROTECT FROM LIGHT AND MOISTURE.

Usual Dosage: See accompanying prescribing information.

This is a bulk container and not intended for dispensing for household use.

Mylan Pharmaceuticals Inc.  
Morgantown, WV 26505


Each capsule contains 2 mg of terazosin as terazosin hydrochloride anhydrous

N 0378-2264-10 4

2 mg\*

MYLAN®

**TERAZOSIN HYDROCHLORIDE CAPSULES**  
2 mg\*

1000 CAPSULES 

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

STORE AT CONTROLLED ROOM TEMPERATURE 15° to 30°C (59° to 86°F).

PROTECT FROM LIGHT AND MOISTURE.

Usual Dosage: See accompanying prescribing information.

This is a bulk container and not intended for dispensing for household use.


Mylan Pharmaceuticals Inc.  
Morgantown, WV 26505

Each capsule contains 1 mg of terazosin as terazosin hydrochloride anhydrous

N 0378-2260-01

MYLAN®

**TERAZOSIN  
HYDROCHLORIDE  
CAPSULES**  
1 mg\*

100 CAPSULES 

NDC 0378-2260-01

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

STORE AT CONTROLLED ROOM TEMPERATURE 15° to 30°C (59° to 86°F).

PROTECT FROM LIGHT AND MOISTURE.

Usual Dosage: See accompanying prescribing information.


Mylan Pharmaceuticals Inc.  
Morgantown, WV 26505

Each capsule contains 1 mg of terazosin as terazosin hydrochloride anhydrous

N 0378-2260-10

MYLAN®

**TERAZOSIN  
HYDROCHLORIDE  
CAPSULES**  
1 mg\*

1000 CAPSULES 

NDC 0378-2260-10

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

STORE AT CONTROLLED ROOM TEMPERATURE 15° to 30°C (59° to 86°F).

PROTECT FROM LIGHT AND MOISTURE.

Usual Dosage: See accompanying prescribing information.

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