CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

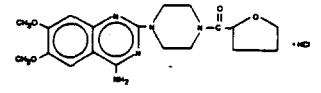
74530

DRAFT FINAL PRINTED LABELING

TERAZOSIN HYDROCHLORIDE TABLETS
Rx only

DESCRIPTION

Terazosin hydrochloride, an alpha-1-selective adrenoceptor blocking agent, is a quinazoline derivative. The chemical name for terazosin hydrochloride is 1-(4-Amino-6,7-dimethoxy-2-quinazolinyl)-4-(tetrahydro-2-furoyl)piperazine monohydrochloride dihydrate. It has the following structural formula:



$C_{19}H_{25}N_5O_4 \cdot HCl$ M. W. 423.89

Terazosin hydrochloride is a white, crystalline substance, freely soluble in water and isotonic saline. Each tablet for oral administration contains terazosin hydrochloride equivalent to 1 mg, 2 mg, 5 mg or 10 mg terazosin. In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, corn starch, crospovidone, lactose monohydrate, magnesium stearate and talc, with the following colorants: 2 mg (Pink Titanium Lake Blend [titanium dioxide and FD&C Red #40 Aluminum Lake]); 5 mg (Yellow Pigment Blend [yellow iron oxide and red iron oxide]); 10 mg (FD&C Blue #2 Aluminum Lake).

CLINICAL PHARMACOLOGY

Pharmacodynamics

A. Benign Prostatic Hyperplasia (BPH)

The symptoms associated with BPH are related to bladder outlet obstruction, which is comprised of two underlying components: a static component and a dynamic component. The static component is a consequence of an increase in prostate size. Over time, the prostate will continue to enlarge. However, clinical studies have demonstrated that the size of the prostate does not correlate with the severity of BPH symptoms or the degree of urinary obstruction [1]. The dynamic component is a function of an increase in smooth muscle tone in the prostate and bladder neck, leading to constriction of the bladder outlet. Smooth muscle tone is mediated by sympathetic nervous stimulation of alpha-1 adrenoceptors, which are abundant in the prostatic, prostatic capsule and bladder neck. The reduction in symptoms and improvement in urine flow rates following administration of terazosin is related to relaxation of smooth muscle produced by blockade of alpha-1 adrenoceptors in the bladder neck and prostate. Because there are relatively few alpha-1 adrenoceptors in the bladder body, terazosin is able to reduce the bladder outlet obstruction without affecting bladder contractility.

Terazosin has been extensively studied in 1222 men with symptomatic BPH. In three placebo-controlled studies, symptom evaluation and urodynamic measurements were performed approximately 24 hours following dosing. Symptoms were systematically quantified using the Boyarsky Index. The questionnaire evaluated both obstructive (hesitancy, intermittency, terminal dribbling, impairment of size and force of stream, sensation of incomplete bladder emptying) an irritative (nocturia, daytime frequency, urgency, dysuria) symptoms by rating each of the 9 symptoms from 0-3, for a total score of 27 points. Results from these studies indicated that terazosin statistically significantly improved symptoms and peak urine flow rates over placebo as follows:

		Symptom Score (Range 0-27)			Peak Flow Rate (mL/sec)		
	n	Mean Baseline	Mean Change (%)	n	Mean Baseline	Mean Change (%)
Study 1 (10 mg)[a]							
Titration to fixed dose (12 wks)							
Placebo	55	9.7	-2.3 (24)	54	10.1	+1.0 (10)
Terazosin	54	10.1	-4.5 (45)*	52	9.8	+3.0 (34)*
Study 2 (2, 5, 10, 20 mg)[b]							
Titration to response (24 wks)							
Placebo	89	12.5	-3.8 (30)	88	8.8	+1.4 (16)
Terazosin	85	12.2	-5.3 (43)*	84	9.4	+2.9 (35)*
Study 3 (1, 2, 5, 10 mg)[c]							
Titration to response (24 wks)							
Placebo	74	10.4	-1.1 (11)	74	8.8	+1.2 (14)
Terazosin	73	10.9	-4.6 (42)*	73	8.6	+2.6 (30)*

[a] Highest dose 10 mg stratum.
[b] 23% of patients on 10 mg, 41% of patients on 20 mg.
[c] 67% of patients on 10 mg.
* Significantly ($p \leq 0.05$) more improvement than placebo.

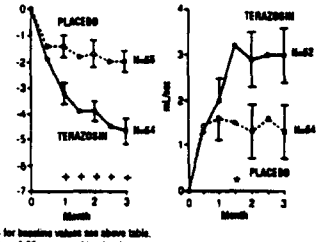
In all three studies, both symptom scores and peak urine flow rates showed statistically significant improvement from baseline in patients treated with terazosin from week 2 (or the first clinic visit) and throughout the study duration.

Analysis of the effect of terazosin on individual urinary symptoms demonstrated that compared to placebo, terazosin significantly improved the symptoms of hesitancy, intermittency, impairment in size and force of urinary stream, sensation of incomplete emptying, terminal dribbling, daytime frequency and nocturia.

Global assessments of overall urinary function and symptoms were also performed by investigators who were blinded to patient treatment assignment. In studies 1 and 3, patients treated with terazosin had a significantly ($p \leq 0.001$) greater overall improvement compared to placebo treated patients.

In a short term study (Study 1), patients were randomized to either 2, 5 or 10 mg of terazosin or placebo. Patients randomized to the 10 mg group achieved a statistically significant response in both symptoms and peak flow rate compared to placebo (Figure 1).

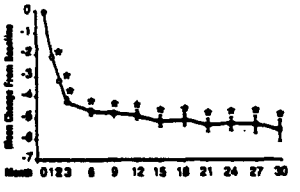
Figure 1
Study 1
Mean Change in Total Symptom Score from Baseline* | Mean Increase in Peak Flow Rate (mL/sec) from Baseline*



+ for baseline values see above table.
*$p \leq 0.05$, compared to placebo group.

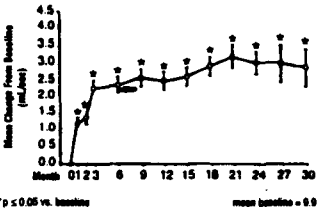
In a long-term, open-label, non-placebo controlled clinical trial, 181 men were followed for 2 years and 58 of these men were followed for 30 months. The effect of terazosin on urinary symptom scores and peak flow rates was maintained throughout the study duration (Figures 2 and 3):

Figure 2
Mean Change in Total Symptom Score from Baseline
Long-Term, Open-Label, Non-Placebo Controlled Study (N=464)



*$p \leq 0.05$ vs. baseline mean baseline = 10.7

Figure 3
Mean Change in Total Symptom Score from Baseline
Long-Term, Open-Label, Non-Placebo Controlled Study (N=464)



*$p \leq 0.05$ vs. baseline mean baseline = 8.9

In this long-term trial, both symptom scores and peak urinary flow rates showed statistically significant improvement suggesting a relaxation of smooth muscle cells.

Although blockade of alpha-1 adrenoceptors also lowers blood pressure in hypertensive patients with increased peripheral vascular resistance, terazosin treatment of normotensive men with BPH did not result in a clinically significant blood pressure lowering effect:

Mean Changes in Blood Pressure from Baseline to Final Visit in all Double-Blind, Placebo-Controlled Studies

		Normotensive Patients SBP ≤ 90 mm Hg		Hypertensive Patients SBP > 90 mm Hg	
	Group	n	Mean Change	n	Mean Change
SBP (mm Hg)	Placebo	293	-0.1	45	-5.8
	Terazosin	519	-3.3*	65	-14.4*
DBP (mm Hg)	Placebo	293	+0.4	45	-7.1
	Terazosin	519	-2.2*	65	-15.1

*$p \leq 0.05$ vs. placebo

B. Hypertension

In animals, terazosin causes a decrease in blood pressure by decreasing total peripheral vascular resistance. The vasodilatory hypotensive action of terazosin appears to be produced mainly by blockade of alpha-1-adrenoceptors. Terazosin decreases blood pressure gradually within 15 minutes following oral administration.

Patients in clinical trials of terazosin were administered once daily (the great majority) and twice daily regimens with total doses usually in the range of 5-20 mg/day, and had mild (about 77%, diastolic pressure 90-105 mmHg) or moderate (23%, diastolic pressure 105-115 mmHg) hypertension. Because terazosin, like all alpha antagonists, can cause eventually large falls in blood pressure after the first dose or first few doses, the initial dose was 1 mg in virtually all trials with subsequent titration to a specified fixed dose or titration to some specified blood pressure end point (usually a supine diastolic pressure of 90 mmHg).

Blood pressure responses were measured at the end of the dosing interval (usually 24 hours) and effects were shown to persist throughout the interval with the usual supine responses 5-10 mmHg systolic and 3.5-8 mmHg diastolic greater than placebo. The responses in the standing position tended to be somewhat larger, by 1-3 mmHg, although this was not true in all studies. The magnitude of the blood pressure responses was similar to prazosin and less than hydrochlorothiazide [in a single study of hypertensive patients]. In measurements 24 hours after dosing heart rate was unchanged.

Limited measurements of peak responses (2-3 hours after dosing) during chronic terazosin administration indicate that it is greater than about twice the trough (24 hour) response, suggesting some attenuation of responses at 24 hours, presumably due to a fall in blood terazosin concentrations at the end of the dose interval. This explanation is not established with certainty, however, and is not consistent with the sensitivity of blood pressure response to once daily and twice daily dosing and with the absence of an observed dose-response relationship over a range of 5-20 mg i.d., if blood concentrations had fallen to the point of providing less than full effect at 24 hours, a shorter dosing interval or larger dose should have led to increased response.

Further dose response and dose duration studies are being carried out. Blood pressure should be measured at the end of the dose interval: if response is not satisfactory, patients may be tried on a larger dose or twice daily dosing regimen. The latter should also be considered if possibly blood pressure-related side effects, such as dizziness, palpitations, or orthostatic complaints, are seen within a few hours after dosing.

The general blood pressure effect associated with peak plasma concentrations (first few hours after dosing) appears somewhat more postural-dependent (greater in the erect position) than the effect of terazosin at 24 hours and in the erect position there is also a 6-10 beat per minute increase in heart rate in the first few hours after dosing. During the first 3 hours after dosing 12.5% of patients had a systolic pressure fall of 30 mmHg or more from supine to standing, or standing systolic pressure below 90 mmHg with a fall of at least 20 mmHg, compared to 4% of a placebo group.

There was a tendency for patients to gain weight during terazosin therapy. In placebo-controlled monotherapy trials, male and female patients receiving terazosin gained a mean of 1.7 and 2.2 pounds respectively, compared to losses of 0.2 and 1.2 pounds respectively in the placebo group. Both differences were statistically significant.

During controlled clinical trials, patients receiving terazosin monotherapy had a small but statistically significant decrease (a 3% fall) compared to placebo in total cholesterol and the combined low-density and very-low-density lipoprotein fractions. No significant changes were observed in high-density lipoprotein fractions and triglycerides compared to placebo.

Analysis of clinical laboratory data following administration of terazosin suggested the possibility of hemodilution based on decreases in hematocrit, hemoglobin, white blood cells, total protein and albumin. Decreases in hematocrit and total protein have been observed with alpha-blockade and are attributed to hemodilution.

Pharmacokinetics

Relative to solution, terazosin hydrochloride administered as terazosin tablets is essentially completely absorbed in man. Food had little or no effect on the extent of absorption but food delayed the time to peak concentration by about 1 hour. Terazosin has been shown to undergo minimal hepatic first-pass metabolism and nearly all of the circulating dose is in the form of parent drug. The plasma levels peak about one hour after dosing, and then decline with a half-life of approximately 12 hours. In a study that evaluated the effect of age on terazosin pharmacokinetics, the mean plasma half-lives were 14.0 and 11.4 hours for the age group ≥70 years and the age group of 20-39 years, respectively. After oral administration the plasma clearance was decreased by 31.7% in patients 70 years of age or older compared to that in patients 20-39 years of age.

The drug is highly bound to plasma proteins and binding is consistent over the clinically observed concentration range. Approximately 10% of an orally administered dose is excreted as parent drug in the urine and approximately 20% is excreted in the feces. The remainder is eliminated as metabolites. Impaired renal function had no significant effect on the elimination of terazosin, and dosage adjustment of terazosin to compensate for the drug removal during hemodialysis (approximately 10%) does not appear to be necessary. Overall, approximately 40% of the administered dose is excreted in the urine and approximately 60% in the feces. The disposition of the compound in animals is qualitatively similar to that in man.

INDICATIONS AND USAGE

Terazosin hydrochloride tablets are indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH). There is a rapid response with approximately 70% of patients experiencing an increase in urinary flow and improvement in symptoms of BPH when treated with terazosin hydrochloride. The long-term effects of terazosin hydrochloride on the incidence of surgery, acute urinary obstruction or other complications of BPH are yet to be determined.

Terazosin hydrochloride tablets are indicated for the treatment of hypertension. They can be used alone or in combination with other antihypertensive agents such as diuretics or beta-adrenergic blocking agents.

CONTRAINDICATIONS

Terazosin hydrochloride tablets are contraindicated in patients known to be hypersensitive to terazosin hydrochloride.

WARNINGS

Syncope and "First-dose" Effect

Terazosin tablets, like other alpha-adrenergic blocking agents, can cause marked lowering of blood pressure, especially postural hypotension, and syncope in association with the first dose or first few days of therapy. A similar effect can be anticipated if therapy is interrupted for several days and then continued, Syncope has also been reported with other alpha-adrenergic blocking agents in association with rapid dosage increases or the initiation of another antihypertensive drug. Syncope is believed to be due to an excessive postural hypotensive effect, although occasionally the syncopal episode has been preceded by a bout of severe supraventricular tachycardia with heart rates of 150-160 beats per minute. Additionally, the possibility of the contribution of hemodilution to the symptoms of postural hypotension should be considered.

To decrease the likelihood of syncope or excessive hypotension, treatment should always be initiated with a 1 mg dose of terazosin, taken at bedtime. The 2 mg, 5 mg and 10 mg tablets are not indicated as initial therapy. Dosage should then be increased slowly, according to recommendations in the Dosage and Administration section and additional antihypertensive agents should be added with caution. The patient should be cautioned to avoid situations, such as driving or hazardous tasks, where injury could result should syncope occur during initiation of therapy.

In early unsupervised studies, where patients using single doses up to 7.5 mg were given at 3 day intervals, tolerance to the first dose phenomenon did not necessarily develop and the "first dose" effect could be observed at all doses. Syncopal episodes occurred in 3 of the 14 subjects given terazosin tablets at doses of 2.5, 5 and 7.5 mg, which are higher than the recommended initial dose; in addition, severe orthostatic hypotension (blood pressure falling to 50/0 mmHg) was seen in two others and dizziness, tachycardia, and lightheadedness occurred in most subjects. These adverse effects all occurred within 90 minutes of dosing.

In three placebo-controlled BPH studies 1, 2, and 3 (see CLINICAL PHARMACOLOGY), the incidence of postural hypotension in the terazosin treated patients was 5.1%, 5.2%, and 3.7% respectively.

In multiple dose clinical trials involving nearly 2000 hypertensive patients treated with terazosin tablets, syncope was reported in about 1% of patients. Syncope was not necessarily associated only with the first dose.

If syncope occurs, the patient should be placed in a recumbent position and treated supportively as necessary. There is evidence that the orthostatic effect of terazosin tablets is greater, even as chronic use, shortly after dosing. The risk of the events is greatest during the initial seven days of treatment, but continues at still time intervals.

Priapism:

Rarely, (probably less than once in every several thousand patients), terazosin and other α_1-antagonists have been associated with priapism (painful penile erection, sustained for hours and unrelieved by sexual intercourse or masturbation). Two or three dozen cases have been reported. Because this condition can lead to permanent impotence if inappropriately treated, patients must be advised about the seriousness of the condition (see PRECAUTIONS: Information for Patients).

PRECAUTIONS

General

Prostatic Cancer

Carcinoma of the prostate and BPH cause many of the same symptoms. These two diseases frequently co-exist. Therefore, patients thought to have BPH should be examined prior to starting terazosin therapy to rule out the presence of carcinoma of the prostate.

Orthostatic Hypotension

While syncope is the most severe orthostatic effect of terazosin tablets (see WARNINGS), other symptoms of lowered blood pressure, such as dizziness, lightheadedness and palpitations, were more common and occurred in some 28% of patients in clinical trials of hypertension. In BPH clinical trials, 21% of the patients experienced one or more of the following: dizziness, hypotension, postural hypotension, syncope, and vertigo. Patients with occupations in which such events represent potential problems should be treated with particular caution.

Information for Patients (see Patient Package Insert):

Patients should be made aware of the possibility of syncopal and orthostatic symptoms, especially at the initiation of therapy, and to avoid driving or hazardous tasks for 12 hours after the first dose, after a dosage increase and after interruption of therapy when treatment is resumed. They should be cautioned to avoid situations where injury could result should syncope occur during initiation of terazosin therapy. They should also be advised of the need to sit or lie down when symptoms of lowered blood pressure occur, although these symptoms are not always orthostatic, and to be careful when rising from a sitting or lying position. If dizziness, lightheadedness, or palpitations are bothersome they should be reported to the physician, so that dose adjustment can be considered.

Patients should also be told that drowsiness or somnolence can occur with terazosin tablets, requiring caution in people who must drive or operate heavy machinery.

Patients should be advised about the possibility of priapism as a result of treatment with terazosin and other similar medications. Patients should know that this reaction to terazosin is extremely rare, but that if it is not brought to immediate medical attention, it can lead to permanent erectile dysfunction (impotence).

Laboratory Tests

Small but statistically significant decreases in hematocrit, hemoglobin, white blood cells, total protein and albumin were observed in controlled clinical trials. These laboratory findings suggested the possibility of hemodilution. Treatment with terazosin for up to 24 months had no significant effect on prostate specific antigen (PSA) levels.

Drug Interactions

In controlled trials, terazosin tablets have been added to diuretics, and several beta-adrenergic blockers; no unexpected interactions were observed. Terazosin tablets have also been used in patients on a variety of concomitant therapies; while these were not formal interaction studies, no interactions were observed. Terazosin tablets have been used concomitantly in at least 50 patients on the following drugs or drug classes: 1) analgesics/anti-inflammatories, (e.g., acetaminophen, aspirin, codeine, ibuprofen, indomethacin); 2) antibiotics (e.g., erythromycin, trimethoprim and sulfamethoxazole); 3) anticholinergics/sympathomimetics (e.g., phenylephrine hydrochloride, phenylpropanolamine hydrochloride, pseudoephedrine hydrochloride); 4) antigout (e.g., allopurinol); 5) antihistamines (e.g., chlorpheniramine); 6) cardiovascular agents (e.g., atenolol, hydrochlorothiazide, methyldopa/zide, propranolol); 7) corticosteroids; 8) gastrointestinal agents (e.g., antacids); 9) hypoglycemics; 10) sedatives and tranquilizers (e.g., diazepam).

Use with Other Drugs

In a study (n=24) where terazosin and verapamil were administered concomitantly, terazosin's mean AUC_{0-24} increased 11% after the first verapamil dose and after 3 weeks of verapamil treatment it increased by 24% with associated increases in C_{max} (25%) and C_{min}

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(32%) means. Terazosin mean T_{max} decreased from 1.3 hours to 0.8 hours after 3 weeks of verapamil treatment. Statistically significant differences were not found in the verapamil level with and without terazosin. In a study (n=6) where terazosin and captopril were administered concomitantly, plasma disposition of captopril was not influenced by concomitant administration of terazosin and terazosin metabolites concentrations increased linearly with dose at steady-state after administration of terazosin plus captopril (see DOSAGE AND ADMINISTRATION).

Carcinogenesis, Mutagenesis, Impairment of Fertility

Terazosin was devoid of mutagenic potential when evaluated *in vivo* and *in vitro* (the Ames test, *in vivo* cytogenetics, the dominant lethal test in mice, *in vivo* Chinese hamster chromosome aberration test and V79 forward mutation assay).

Terazosin, administered in the feed to rats at doses of 8, 40, and 250 mg/kg/day (70, 350, and 2100 mg/m²/day), for two years, was associated with a statistically significant increase in benign adrenal medullary tumors of male rats exposed to the 250 mg/kg dose. This dose is 175 times the maximum recommended human dose of 20 mg (12 mg/m²). Female rats were unaffected. Terazosin was not oncogenic in mice when administered in feed for 2 years at a maximum tolerated dose of 32 mg/kg/day (110 mg/m²: 9 times the maximum recommended human dose). The absence of mutagenicity in a battery of tests, of tumorigenicity of any cell type in the two-year carcinogenicity assay, of increased total tumor incidence in either species, and of proliferative adrenal lesions in female rats, suggests a mode not species-specific for terazosin. Numerous other diverse pharmacological and chemical compounds have also been associated with benign adrenal medullary tumors in male rats without supporting evidence for carcinogenicity in man.

The effect of terazosin on fertility was assessed in a standard fertility/reproductive performance study in which male and female rats were administered oral doses of 8, 30 and 120 mg/kg/day. Four of 20 male rats given 30 mg/kg (240 mg/m²: 20 times the maximum recommended human dose), and five of 19 male rats given 120 mg/kg (960 mg/m²: 80 times the maximum recommended human dose), failed to sire a litter. Testicular weights and morphology were unaffected by treatment. Vaginal smears at 30 and 120 mg/kg/day, however, appeared to contain less sperm than smears from control matings and good correlation was reported between sperm count and subsequent pregnancy.

Oral administration of terazosin for one or two years elicited a statistically significant increase in the incidence of testicular atrophy in rats exposed to 40 and 250 mg/kg/day (29 and 175 times the maximum recommended human dose), but not in rats exposed to 8 mg/kg/day (<6 times the maximum recommended human dose). Testicular atrophy was also observed in dogs dosed with 300 mg/kg/day (>500 times the maximum recommended human dose) for three months but not after one year when dosed with 20 mg/kg/day (36 times the maximum recommended human dose). This lesion has also been seen with prazosin hydrochloride, another (marketed) selective alpha-1 blocking agent.

Pregnancy

Teratogenic effects: Pregnancy Category C

Terazosin was not teratogenic in either rats or rabbits when administered at oral doses up to 280 and 68 times, respectively, the maximum recommended human dose. Fetal resorptions occurred in rats dosed with 480 mg/kg/day, approximately 280 times the maximum recommended human dose. Increased fetal resorptions, decreased fetal weight and an increased number of supernumerary ribs were observed in offspring of rabbits dosed with 90 times the maximum recommended human dose. These findings (as both species) were most likely secondary to maternal toxicity. There are no adequate and well-controlled studies in pregnant women and the safety of terazosin in pregnancy has not been established. Terazosin is not recommended during pregnancy unless the potential benefit justifies the potential risk to the mother and fetus.

Nonteratogenic effects

In a peri- and post-natal development study in rats, significantly more pups died in the group dosed with 120 mg/kg/day (>75 times the maximum recommended human dose) than in the control group during the three-week postpartum period.

Nursing Mothers

It is not known whether terazosin is excreted in breast milk. Because many drugs are excreted in breast milk, caution should be exercised when terazosin is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been determined.

ADVERSE REACTIONS

Benign Prostatic Hyperplasia

The incidence of treatment-emergent adverse events has been ascertained from clinical trials conducted worldwide. All adverse events reported during these trials were recorded as adverse reactions. The incidence rates presented below are based on combined data from six placebo-controlled trials involving once-a-day administration of terazosin at doses ranging from 1 to 20 mg. Table 1 summarizes those adverse events reported for patients in these trials when the incidence rate in the terazosin group was at least 1% and was greater than that for the placebo group, or where the reaction is of clinical interest. Asthenia, postural hypotension, dizziness, somnolence, nasal congestion/rhinitis, and impotence were the only events that were significantly ($p \leq 0.05$) more common in patients receiving terazosin than in patients receiving placebo. The incidence of urinary tract infection was significantly lower in the patients receiving terazosin than in patients receiving placebo. An analysis of the incidence rate of hypotensive adverse events (see PRECAUTIONS) adjusted for the length of drug treatment has shown that the risk of the events is greatest during the initial seven days of treatment, but continues at all time intervals.

TABLE 1
ADVERSE REACTIONS DURING PLACEBO-CONTROLLED TRIALS
BENIGN PROSTATIC HYPERPLASIA

BODY SYSTEM	TERAZOSIN (N = 690)	PLACEBO (N = 349)
BODY AS A WHOLE		
Asthenia	7.4%*	3.5%
Flu Syndrome	2.4%	1.7%
Headache	4.9%	5.8%
CARDIOVASCULAR SYSTEM		
Hypotension	0.6%	0.6%
Palpitations	0.9%	1.1%
Postural Hypotension	3.9%*	0.9%
Syncope	0.6%	0.0%
DIGESTIVE SYSTEM		
Nausea	1.7%	1.1%
METABOLIC AND NUTRITIONAL DISORDERS		
Peripheral Edema	0.9%	0.3%
Weight Gain	0.5%	0.0%
NERVOUS SYSTEM		
Dizziness	9.1%*	4.2%
Somnolence	3.6%*	1.9%
Vertigo	1.4%	0.3%
RESPIRATORY SYSTEM		
Dyspnea	1.7%	0.8%
Nasal Congestion/Rhinitis	1.9%*	0.0%
SPECIAL SENSES		
Blurred Vision/Amblyopia	1.3%	0.6%
UROGENITAL SYSTEM		
Impotence	1.9%*	0.6%
Urinary Tract Infection	1.3%	3.9%*

+Includes weakness, tiredness, lassitude and fatigue.
* $p \leq 0.05$ comparison between groups.

Additional adverse events have been reported, but these are, in general, not distinguishable from symptoms that might have occurred in the absence of exposure to terazosin. The safety profile of patients treated in the long-term open-label study was similar to that observed in the controlled studies.

The adverse events were usually transient and mild or moderate in intensity, but sometimes were serious enough to interrupt treatment. In the placebo-controlled clinical trials, the rates of premature termination due to adverse events were not statistically different between the placebo and terazosin groups. The adverse events that were bothersome, as judged by their being reported as reasons for discontinuation of therapy by at least 0.5% of the terazosin group and being reported more often than in the placebo group, are shown in Table 2.

TABLE 2
DISCONTINUATIONS DURING PLACEBO-CONTROLLED TRIALS
BENIGN PROSTATIC HYPERPLASIA

BODY SYSTEM	TERAZOSIN (N = 690)	PLACEBO (N = 349)
BODY AS A WHOLE		
Fever	0.9%	0.0%
Headache	1.1%	0.9%
CARDIOVASCULAR SYSTEM		
Postural Hypotension	0.5%	0.0%
Syncope	0.5%	0.0%
DIGESTIVE SYSTEM		
Nausea	0.5%	0.3%
NERVOUS SYSTEM		
Dizziness	2.0%	1.1%
Vertigo	0.5%	0.0%
RESPIRATORY SYSTEM		
Dyspnea	0.5%	0.3%
SPECIAL SENSES		
Blurred Vision/Amblyopia	0.6%	0.0%
UROGENITAL SYSTEM		
Urinary Tract Infection	0.5%	0.3%

Hypertension

The prevalence of adverse reactions has been ascertained from clinical trials conducted primarily in the United States. All adverse experiences (events) reported during these trials were recorded as adverse reactions. The prevalence rates presented below are based on combined data from fourteen placebo-controlled trials involving once-a-day administration of terazosin, as monotherapy or in combination with other antihypertensive agents, at doses ranging from 1 to 40 mg. Table 3 summarizes those adverse experiences reported for patients in these trials where the prevalence rate in the terazosin group was at least 5%, where the prevalence rate for the terazosin group was at least 2% and was greater than the prevalence rate for the placebo group, or where the reaction is of particular interest.

Asthenia, blurred vision, dizziness, nasal congestion, nausea, peripheral edema, palpitations and somnolence were the only symptoms that were significantly ($p < 0.05$) more common in patients receiving terazosin than in patients receiving placebo. Similar adverse reaction rates were observed in placebo controlled monotherapy trials.

TABLE 3
ADVERSE REACTIONS DURING PLACEBO-CONTROLLED TRIALS
HYPERTENSION

BODY SYSTEM	TERAZOSIN (N = 890)	PLACEBO (N = 548)
BODY AS A WHOLE		
Asthenia	11.3%*	4.3%
Back Pain	2.4%	1.3%
Headache	16.2%	15.9%
CARDIOVASCULAR SYSTEM		
Palpitations	4.3%*	1.3%
Postural Hypotension	1.3%	0.2%
Tachycardia	1.9%	1.3%
DIGESTIVE SYSTEM		
Nausea	4.4%*	1.4%
METABOLIC AND NUTRITIONAL DISORDERS		
Edema	0.9%	0.6%
Peripheral Edema	5.5%*	2.4%
Weight Gain	0.5%	0.2%
MUSCULOSKELETAL SYSTEM		
Pain-Extremities	3.5%	3.0%
NERVOUS SYSTEM		
Depression	0.3%	0.2%
Dizziness	19.3%*	7.5%
Libido Decreased	0.6%	0.2%
Somnolence	2.3%	1.9%
Paresthesia	2.9%	1.4%
Somnolence	5.4%*	2.6%
RESPIRATORY SYSTEM		
Dyspnea	3.1%	2.4%
Nasal Congestion	5.8%*	3.4%
Sinusitis	2.6%	1.4%
SPECIAL SENSES		
Blurred Vision	1.6%*	0.0%
UROGENITAL SYSTEM		
Impotence	1.2%	1.4%

+Includes weakness, tiredness, lassitude and fatigue
* Statistically significant at $p = 0.05$ level

Additional adverse reactions have been reported, but these are, in general, not distinguishable from symptoms that might have occurred in the absence of exposure to terazosin. The following additional adverse reactions were reported by at least 1% of 1087 patients who received terazosin in controlled or open, short- or long-term clinical trials or have been reported during marketing experience:

Body as a Whole: chest pain, facial edema, fever, abdominal pain, neck pain, shoulder pain.

Cardiovascular System: arrhythmia, vasodilation.

Digestive System: constipation, diarrhea, dry mouth, dyspepsia, flatulence, vomiting.

Metabolic/Nutritional Disorders: gout.

Musculoskeletal System: arthralgia, arthritis, joint disorder, myalgia.

Nervous System: anxiety, insomnia.

Respiratory System: bronchitis, cold symptoms, epistaxis, flu symptoms, increased cough, pharyngitis, rhinitis.

Skin and Appendages: pruritus, rash, sweating.

Special Senses: abnormal vision, conjunctivitis, tinnitus.

Urogenital System: urinary frequency, urinary incontinence primarily reported in postmenopausal women, urinary tract infection.

Post-marketing experience indicates that in rare instances patients may develop allergic reactions, including anaphylaxis, following administration of terazosin tablets. There have been rare reports of priapism during post-marketing surveillance.

The adverse reactions were usually mild or moderate in intensity but sometimes were serious enough to interrupt treatment. The adverse reactions that were most bothersome, as judged by their being reported as reasons for discontinuation of therapy by at least 0.5% of the terazosin group and being reported more often than in the placebo group, are shown in Table 4.

TABLE 4
DISCONTINUATIONS DURING PLACEBO-CONTROLLED TRIALS
HYPERTENSION

BODY SYSTEM	TERAZOSIN (N = 890)	PLACEBO (N = 548)
BODY AS A WHOLE		
Asthenia	1.6%	0.0%
Headache	1.3%	1.0%
CARDIOVASCULAR SYSTEM		
Palpitations	1.4%	0.2%
Postural Hypotension	0.5%	0.0%
Syncope	0.5%	0.2%
Tachycardia	0.6%	0.0%
DIGESTIVE SYSTEM		
Nausea	0.8%	0.0%
METABOLIC AND NUTRITIONAL DISORDERS		
Peripheral Edema	0.6%	0.0%
NERVOUS SYSTEM		
Dizziness	3.1%	0.4%
Paresthesia	0.8%	0.2%
Somnolence	0.6%	0.2%
RESPIRATORY SYSTEM		
Dyspnea	0.9%	0.6%
Nasal Congestion	0.6%	0.0%
SPECIAL SENSES		
Blurred Vision	0.6%	0.0%

OVERDOSAGE

Should overdosage of terazosin lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, shock should first be treated with volume expanders. If necessary, vasopressors should then be used and renal function should be monitored and supported as needed. Laboratory data indicate that terazosin is highly protein bound; therefore, dialysis may not be of benefit.

DOSAGE AND ADMINISTRATION

If terazosin administration is discontinued for several days, therapy should be reinitiated using the usual dosing regimen.

Benign Prostatic Hyperplasia

Initial Dose

1 mg at bedtime is the starting dose for all patients, and this dose should not be exceeded as an initial dose. Patients should be closely followed during initial administration in order to minimize the risk of severe hypotensive response.

Subsequent Dosing

The dose should be increased in a stepwise fashion to 2 mg, 5 mg, or 10 mg once daily to achieve the desired improvement of symptoms and/or flow rates. Doses of 10 mg once daily are generally required for the clinical response. Therefore, treatment with 10 mg for a minimum of 4-6 weeks may be required to assess whether a beneficial response has been achieved. Some patients may not achieve a clinical response despite appropriate titration. Although some additional patients responded at a 20 mg daily dose, there was an insufficient number of patients studied to draw definitive conclusions about this dose. There are insufficient data to support the use of higher doses for those patients who show inadequate or no response to 20 mg daily.

Use with Other Drugs

Caution should be observed when terazosin tablets are administered concomitantly with other antihypertensive agents, especially the calcium channel blocker verapamil, to avoid the possibility of developing significant hypotension. When using terazosin tablets and other antihypertensive agents concomitantly, dosage reduction and restriction of either agent may be necessary (see PRECAUTIONS).

Hypertension

The dose of terazosin and the dose interval (12 or 24 hours) should be adjusted according to the patient's individual blood pressure response. The following is a guide to its administration:

Initial Dose

1 mg at bedtime is the starting dose for all patients, and this dose should not be exceeded. This initial dosing regimen should be strictly observed to minimize the potential for severe hypotensive effects.

Subsequent Doses

The dose may be slowly increased to achieve the desired blood pressure response. The usual recommended dose range is 1 mg to 5 mg administered once a day; however, some patients may benefit from doses as high as 20 mg per day. Doses over 20 mg do not appear to provide further blood pressure effect and doses over 40 mg have not been studied. Blood pressure should be monitored at the end of the dosing interval to be sure control is maintained throughout the interval. It may also be helpful to measure blood pressure 2-3 hours after dosing to see if the maximum and minimum responses are similar, and to evaluate symptoms such as dizziness or palpitations which can result from excessive hypotensive response. If response is substantially diminished at 24 hours an increased dose or use of a twice daily regimen can be considered. If terazosin administration is discontinued for several days or longer, therapy should be reinitiated using the initial dosing regimen. In clinical trials, except for the initial dose, the dose was given in the morning.

Use with other drugs: (see above).

HOW SUPPLIED

Terazosin hydrochloride tablets are available as white, round, unscored, flat-faced, beveled-edge tablets, debossed "Z4360" on one side and "1" on the other side containing terazosin hydrochloride, equivalent to 1 mg terazosin, packaged in bottles of 100, 500 and 1000 tablets.

Terazosin hydrochloride tablets are available as pink, round, unscored, flat-faced, beveled-edge tablets, debossed "Z4361" on one side and "2" on the other side containing terazosin hydrochloride, equivalent to 2 mg terazosin, packaged in bottles of 100, 500 and 1000 tablets.

Terazosin hydrochloride tablets are available as light gold, round, unscored, flat-faced, beveled-edge tablets, debossed "Z4362" on one side and "5" on the other side containing terazosin hydrochloride, equivalent to 5 mg terazosin, packaged in bottles of 100, 500 and 1000 tablets.

Terazosin hydrochloride tablets are available as light blue, round, unscored, flat-faced, beveled-edge tablets, debossed "Z4363" on one side and "10" on the other side containing terazosin hydrochloride equivalent to 10 mg terazosin, packaged in bottles of 100, 500 and 1000 tablets.

PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).

Store at controlled room temperature 15°-30°C (59°-86°F).

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TERAZOSIN HYDROCHLORIDE TABLETS

TERAZOSIN HYDROCHLORIDE TABLETS PATIENT INFORMATION

PATIENT INFORMATION ABOUT TERAZOSIN HYDROCHLORIDE When used to treat HYPERTENSION or BENIGN PROSTATIC HYPERPLASIA (BPH)

Please read this leaflet before you start taking terazosin. 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. You and your doctor should discuss terazosin and your condition before you start taking it and at your regular check-ups.

Terazosin is used to treat high blood pressure (hypertension). Terazosin is also used to treat benign prostatic hyperplasia (BPH) in men. This leaflet describes terazosin 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 for you.

What terazosin does to treat hypertension
Terazosin 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 can not 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 for you. See "What terazosin 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.

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What terazosin does to treat BPH
Terazosin 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 helps to 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 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 and it may help you, terazosin may not prevent the need for surgery in the future.

Other important facts about terazosin for BPH

- You should see an effect on your symptoms in 2 to 4 week. 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 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. Terazosin 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 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 for hypertension or BPH

WARNINGS
Terazosin 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 at bedtime. If you take terazosin 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. 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. 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 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 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 an emergency room as soon as possible.

How to take terazosin
Follow your doctor's instructions about how to take terazosin. 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 restart it at a 1 mg dose and be cautious about possible dizziness. Do not share terazosin with anyone else; it was prescribed only for you.

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

Store at controlled room temperature 15°-30°C (59°-86°F).

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

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TERAZOSIN HYDROCHLORIDE TABLETS
PATIENT INFORMATION

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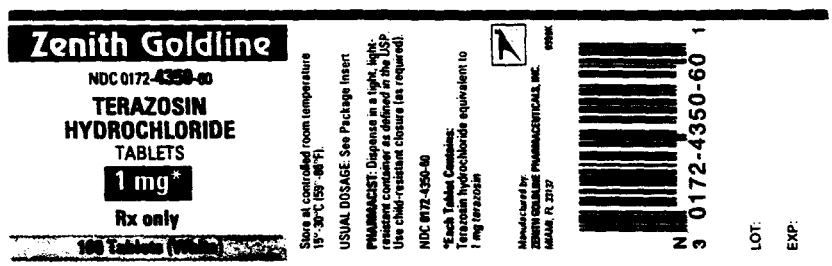
Zenith Goldline
NDC 0172-4350-60
TERAZOSIN HYDROCHLORIDE
TABLETS
1 mg*
Rx only
100 Tablets (White)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
NDC 0172-4350-60
*Each Tablet Contains: Terazosin hydrochloride equivalent to 1 mg terazosin
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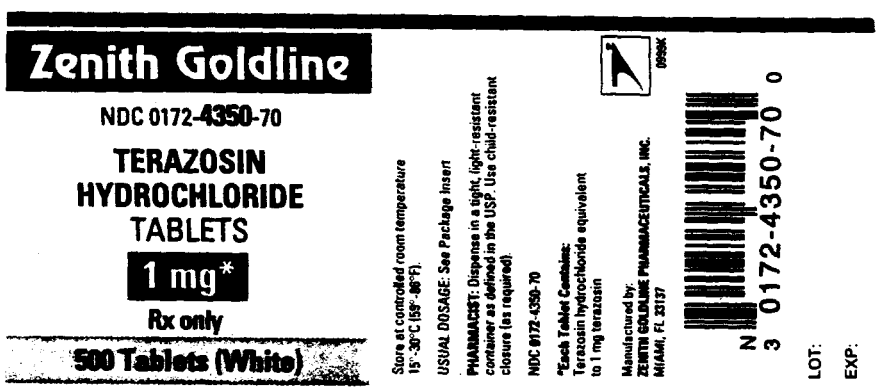
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NDC 0172-4350-70
TERAZOSIN HYDROCHLORIDE
TABLETS
1 mg*
Rx only
500 Tablets (White)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
NDC 0172-4350-70
*Each Tablet Contains: Terazosin hydrochloride equivalent to 1 mg terazosin
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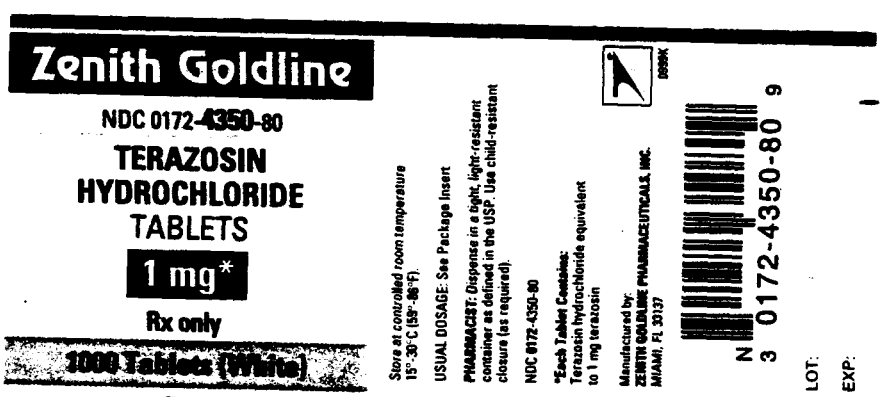
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NDC 0172-4350-80
TERAZOSIN HYDROCHLORIDE
TABLETS
1 mg*
Rx only
1000 Tablets (White)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
NDC 0172-4350-80
*Each Tablet Contains: Terazosin hydrochloride equivalent to 1 mg terazosin
Manufactured by: ZENITH GOLDLINE PHARMACEUTICALS, INC. MIAMI, FL 33137
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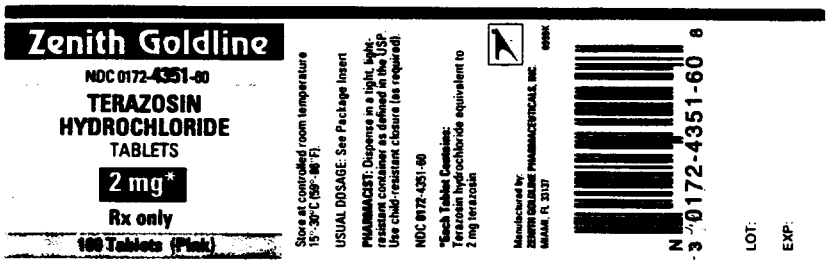
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NDC 0172-4351-60
TERAZOSIN
HYDROCHLORIDE
TABLETS
2 mg*
Rx only
100 Tablets (Pink)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
NDC 0172-4351-60
*Each Tablet Contains: Terazosin hydrochloride equivalent to 2 mg terazosin
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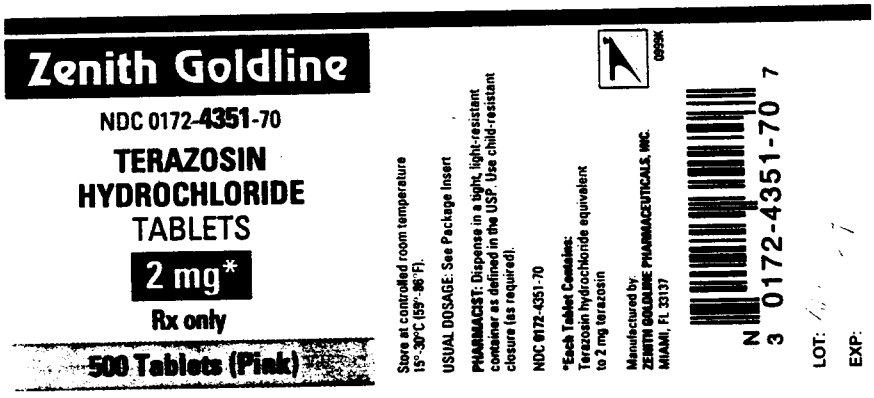
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TERAZOSIN
HYDROCHLORIDE
TABLETS
2 mg*
Rx only
500 Tablets (Pink)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
NDC 0172-4351-70
*Each Tablet Contains: Terazosin hydrochloride equivalent to 2 mg terazosin
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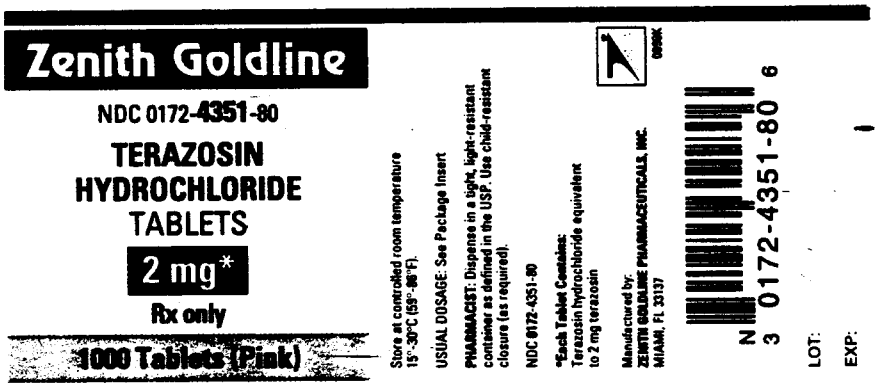
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NDC 0172-4351-80
TERAZOSIN
HYDROCHLORIDE
TABLETS
2 mg*
Rx only
1000 Tablets (Pink)
Store at controlled room temperature 15°-30°C (59°-86°F).
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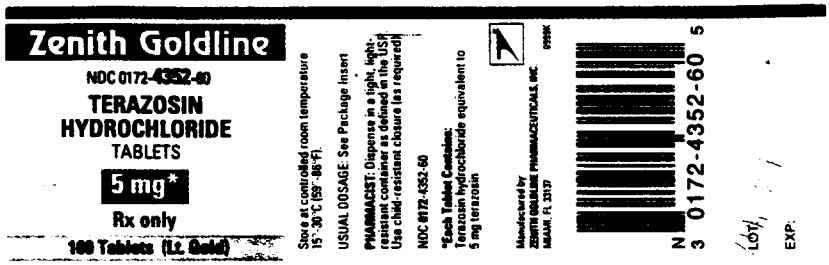
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NDC 0172-4352-60
TERAZOSIN
HYDROCHLORIDE
TABLETS
5 mg*
Rx only
100 Tablets (Lt. Gold)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
NDC 0172-4352-60
*Each Tablet Contains: Terazosin hydrochloride equivalent to 5 mg terazosin
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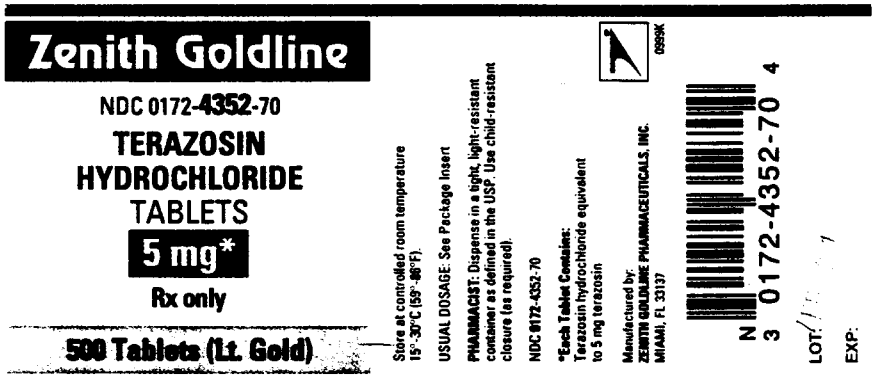
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NDC 0172-4352-70
TERAZOSIN
HYDROCHLORIDE
TABLETS
5 mg*
Rx only
500 Tablets (Lt. Gold)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
NDC 0172-4352-70
*Each Tablet Contains: Terazosin hydrochloride equivalent to 5 mg terazosin
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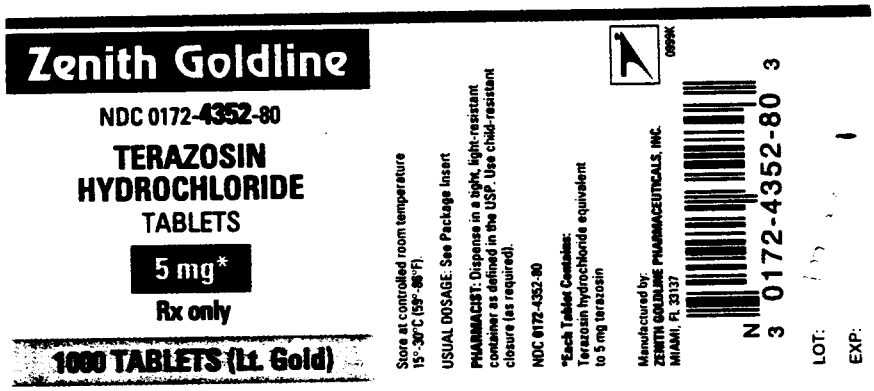
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TERAZOSIN
HYDROCHLORIDE
TABLETS
5 mg*
Rx only
1000 TABLETS (Lt. Gold)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
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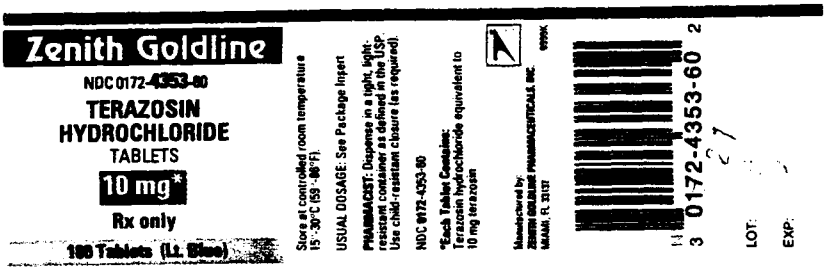
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TERAZOSIN
HYDROCHLORIDE
TABLETS
10 mg*
Rx only
100 Tablets (Lt. Blue)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
NDC 0172-4353-60
*Each Tablet Contains: Terazosin hydrochloride equivalent to 10 mg terazosin
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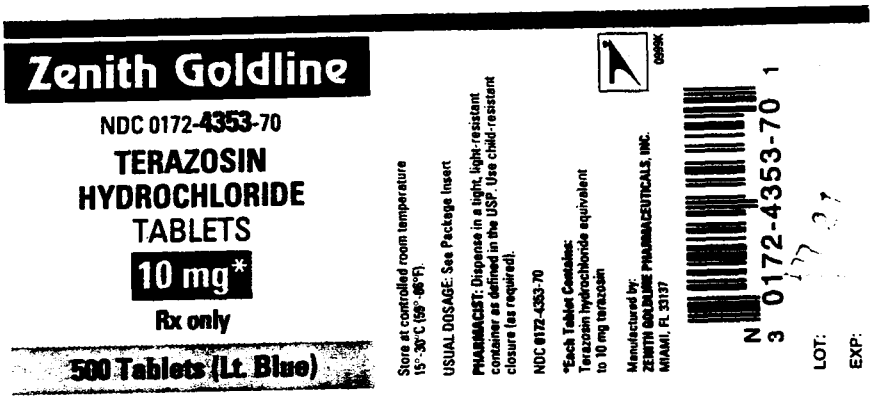
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NDC 0172-4353-70
TERAZOSIN
HYDROCHLORIDE
TABLETS
10 mg*
Rx only
500 Tablets (Lt. Blue)
Store at controlled room temperature 15°-30°C (59°-86°F).
USUAL DOSAGE: See Package Insert
PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP. Use child-resistant closure (as required).
NDC 0172-4353-70
*Each Tablet Contains: Terazosin hydrochloride equivalent to 10 mg terazosin
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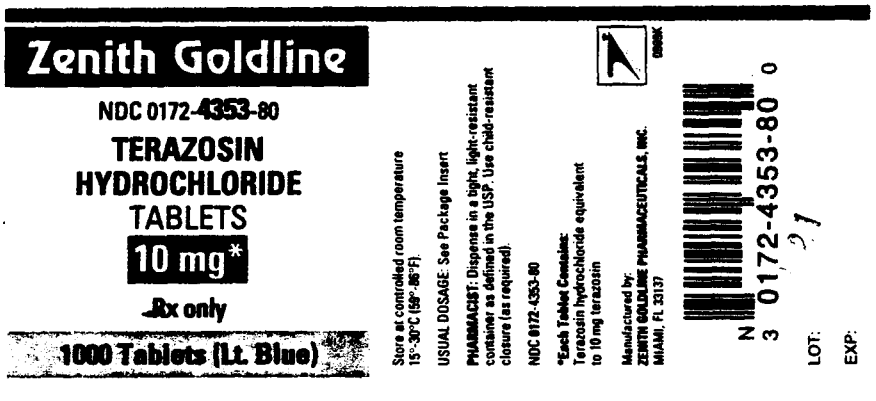
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NDC 0172-4353-80
TERAZOSIN
HYDROCHLORIDE
TABLETS
10 mg*
Rx only
1000 Tablets (Lt. Blue)
Store at controlled room temperature 15°-30°C (59°-86°F).
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Manufactured by: ZENITH GOLDLINE PHARMACEUTICALS, INC. MIAMI, FL 33137
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LOT:
EXP: