HYTRIN

1 mg/2 mg/5 mg Terazosin Hydrochloride Tablets

DESCRIPTION

Terazosin hydrochloride, an alpha-1-selective adrenoceptor blocking agent, is a quinazoline derivative represented by the following chemical name:

1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-[(tetrahydro-2-furanyl) carbonyl]-Piperazine, monohydrochloride, dihydrate. The empirical formula is $C_{19}H_{25}N_5O_4.HCl•2H_2O$.

Terazosin hydrochloride is a white, crystalline substance, freely soluble in water and isotonic saline and has a molecular weight of 459.93.

HYTRIN tablets for oral ingestion are supplied in three dosage strengths containing terazosin hydrochloride dihydrate equivalent to 1 mg, 2 mg and 5 mg terazosin.

Hytrin 1mg:	White, round, flat beveled tablets embossed with a logo and triangular facets on one face and plain on the other.
Hytrin 2mg:	Yellow, round, flat beveled tablets embossed with a logo and triangular facets on one face and plain on the other.
Hytrin 5mg:	Tan, round, flat beveled tablets embossed with a logo and triangular facets on one face and plain on the other.

CLINICAL PHARMACOLOGY

Pharmacodynamics

In animals, terazosin hydrochloride causes a decrease in blood pressure by decreasing total peripheral vascular resistance. The vasodilatory hypotensive action of terazosin hydrochloride appears to be produced mainly by blockade of alpha-1-adrenoceptors.

Terazosin hydrochloride decreases blood pressure gradually within 15 minutes following oral administration.

In man, systolic and diastolic blood pressures are lowered in both the supine and standing positions. The effect is most pronounced on the diastolic blood pressure. These changes are usually not accompanied by reflex tachycardia. A greater blood pressure effect associated with peak plasma concentrations (first few hours after dosing) appears somewhat more position-dependent (greater in the erect position) than the effect of terazosin hydrochloride at 24 hours, and in the erect position there is also a six to ten beat per minute increase in heart rate in the first few hours after dosing.

Studies suggest that alpha-1-adrenoceptor blockade is also useful in improving the urodynamics in patients with chronic bladder outlet obstruction, such as in benign prostatic hyperplasia (BPH).

The symptoms of BPH are caused mainly by the presence of an enlarged prostate and by the increased smooth muscle tone of the bladder outlet and the prostate, which is regulated by alpha-1-adrenergic receptors.

In *in vitro* experiments, terazosin hydrochloride has been shown to antagonize phenylephrine-induced contractions in human prostatic tissue. In clinical trials terazosin hydrochloride has been shown to improve the urodynamics and symptomatology in patients with BPH.

There is a tendency for patients to gain weight during terazosin hydrochloride therapy. In placebo-controlled monotherapy trials, male and female patients receiving terazosin hydrochloride 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 significant.

During controlled clinical studies, patients receiving terazosin hydrochloride had an improved lipid profile. Patients receiving terazosin hydrochloride monotherapy had a small but statistically significant decrease compared to placebo in total cholesterol and the combined low-density and very-low-density lipoprotein fractions. These patients had increases from baseline in high-density lipoproteins, the HDL/LDL cholesterol ratio, and decreases from baseline in triglycerides. However, these changes were not significant when compared to placebo.

Long-term (six months or longer) administration of terazosin hydrochloride has produced no pattern of clinically significant changes attributable to the drug in the following clinical laboratory measurements: Glucose, uric acid, creatinine, BUN, liver function tests, and electrolytes. Analysis of clinical laboratory data following administration of terazosin hydrochloride 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 is essentially completely absorbed in man. Food had little or no effect on the bioavailability of terazosin hydrochloride administered in a capsule formulation. Terazosin hydrochloride 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. The drug is highly bound to plasma proteins and binding is constant 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. 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.

The pharmacokinetics of terazosin hydrochloride appear to be independent of renal function. This would obviate the need to adjust dosing regimens for patients with impaired renal function.

PRE-CLINICAL SAFETY DATA

Carcinogenesis, Mutagenesis, Impairment of Fertility

Terazosin hydrochloride 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 hydrochloride, administered in the feed to rats at doses of 8, 40, and 250 mg/kg/day for two years, was associated with a statistically significant increase in benign adrenal medullary tumors in male rats exposed to the 250 mg/kg dose. This dose is 695 times the maximum recommended human dose of 20 mg/55 kg patient. Female rats were unaffected. Terazosin hydrochloride was not oncogenic in mice when administered in feed for two years at a maximum tolerated dose of 32 mg/kg/day.

The absence of mutagenicity in a battery of tests, of tumorigenicity of any cell type in the mouse carcinogenicity assay, of increased total tumor incidence in either species, and of proliferative adrenal lesions in female rats, suggests a male rat species-specific event. Numerous other diverse pharmaceutical 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 hydrochloride 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 and five of 19 male rats given 120 mg/kg 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 hydrochloride 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, but not in rats exposed to 8 mg/kg/day (greater than 20 times the maximum recommended human dose). Testicular atrophy was also observed in dogs dosed with 300 mg/kg/day (greater than 800 times the maximum recommended human dose) for three months but not after one year when dosed with 20 mg/kg/day. This lesion has also been seen with prazosin, another selective-alpha-1 blocking agent.

INDICATIONS

Terazosin hydrochloride used alone or in combination with other antihypertensive agents is indicated for the treatment of hypertension.

Terazosin hydrochloride single therapy is also used to relieve the signs and symptoms of benign prostatic hyperplasia (BPH).

CONTRAINDICATIONS

Terazosin hydrochloride is contraindicated in patients known to be hypersensitive to terazosin hydrochloride or its analogues.

WARNINGS AND PRECAUTIONS

Syncope and "First-dose" Effect

Terazosin hydrochloride, 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 doses of therapy. A similar effect can be anticipated if therapy is interrupted for more than a few doses and then re-started. Syncope has also been reported with other alpha-adrenergic blocking agents in association with rapid dosage increases or the introduction 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 120 to 160 beats per minute.

To decrease the likelihood of syncope or excessive hypotension, treatment should always be initiated with a 1 mg dose of terazosin hydrochloride, given at bedtime. The 2 mg, and 5 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 where injury could result should syncope occur during initiation of therapy.

In multiple dose clinical trials involving nearly 2000 hypertensive patients, syncope was reported in about 1% of patients, in no case severe or prolonged, and was not necessarily associated with early doses. In clinical studies involving treatment of approximately 1200 patients with BPH, the incidence of syncope was 0.7%.

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 hydrochloride is greater, even in chronic use, shortly after dosing.

Patients with a history of micturition syncope should not receive an alpha-blocker.

General

Orthostatic Hypotension

While syncope is the most severe orthostatic effect of terazosin hydrochloride (see **WARNINGS AND PRECAUTIONS**), other symptoms of lowered blood pressure, such as dizziness, lightheadedness, and palpitations, are more common. Patients with occupations in which such events represent potential problems should be treated with particular caution.

Information for Patients

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 hydrochloride 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 drowsiness or somnolence can occur with terazosin hydrochloride, requiring caution in people who must drive or operate heavy machinery.

PDE-5 Inhibitors

Hypotension has been reported when terazosin has been used with phosphodiesterase-5 (PDE-5) inhibitors (see **DRUG INTERACTIONS**).

Cataract Surgery

Intraoperative Floppy Iris Syndrome (IFIS) has been observed during cataract surgery in some patients on/or previously treated with alpha-1 blockers. This variant of small pupil syndrome is characterized by the combination of a flaccid iris that billows in response to intraoperative irrigation currents, progressive intraoperative miosis despite preoperative dilation with standard mydriatic drugs, and potential prolapse of the iris toward the phacoemulsification incisions. The patient's ophthalmologist should be prepared for possible modifications to their surgical technique, such as the utilization of iris hooks, iris dilator rings, or viscoelastic substances. There does not appear to be a benefit of stopping alpha-1 blocker therapy prior to cataract surgery.

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 hydrochloride for up to 24 months had no significant effect on prostate specific antigen (PSA) levels.

Pediatric Use

Safety and effectiveness in children have not been determined.

DRUG INTERACTIONS

Hypertension

In hypertensive patients terazosin hydrochloride has been added to diuretics, and several betaadrenergic blockers; no unexpected interactions were observed. Terazosin hydrochloride has also been used in patients on a variety of concomitant therapies; while these were not formal interaction studies, no interactions were observed.

Terazosin hydrochloride has been used concomitantly in at least 50 patients on the following drugs or drug classes: 1) analgesic/anti-inflammatory (*e.g.*, acetaminophen, aspirin, codeine, ibuprofen, indomethacin); 2) antibiotics (*e.g.*, erythromycin,

trimethoprim, and sulfamethoxazole); 3) anticholinergic/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, methyclothiazide, propranolol); 7) corticosteroids; 8) gastrointestinal agents (*e.g.*, antacids); 9) hypoglycemics; 10) sedatives and tranquilizers (*e.g.*, diazepam).

Caution should be observed when terazosin hydrochloride is administered concomitantly with other antihypertensive agents (*e.g.*, calcium antagonists) to avoid the possibility of significant hypotension. When adding a diuretic or other antihypertensive agent, dosage reduction and retitration may be necessary.

Benign Prostatic Hyperplasia (BPH)

In BPH patients the adverse event profile of patients treated concurrently with non-steroidal anti-inflammatory drugs (NSAID), theophylline, anti-anginal agents, oral hypoglycemic agents, angiotensin converting enzyme (ACE) inhibitors or diuretics was compared against the profile in the general treated population. No clinically significant interactions have been observed except for ACE inhibitors and diuretics. In this small subset of patients, the percent reporting dizziness or other dizziness-related adverse events appears to be greater in those patients than in the total population of terazosin hydrochloride patients from double-blind, placebo-controlled studies.

PDE-5 Inhibitors
Hypotension has been reported when terazosin has been used with phosphodiesterase-5 (PDE- 5) inhibitors (see WARNINGS AND PRECAUTIONS).

PREGNANCY

Teratogenic Effects

Terazosin hydrochloride was not teratogenic in either rats or rabbits when administered at oral doses up to 1330 and 165 times, respectively, the maximum recommended human dose. Fetal resorptions occurred in rats dosed with 480 mg/kg/day, approximately 1330 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 165 times the maximum recommended human dose. These findings (in 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 hydrochloride in pregnancy has not been established. Terazosin hydrochloride 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 (greater than 300 times the maximum recommended human dose) than in the control group during the 3-week postpartum period.

Nursing Mothers

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

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Syncopal and orthostatic symptoms are possible, especially at the initiation of therapy, and driving or hazardous tasks should be avoided for 12 hours after the first dose, after a dosage increase, and after interruption of therapy when treatment is resumed. Drowsiness or somnolence can also occur with terazosin hydrochloride, requiring caution in people who must drive or operate heavy machinery.

ADVERSE REACTIONS

Hypertension

The prevalence rates presented below are based on adverse experiences (events) combined from 14 placebo-controlled studies involving once-a-day administration of terazosin hydrochloride as monotherapy or in combination with other antihypertensive agents, at doses ranging from 1 to 40 mg. Table 1 summarizes those adverse experiences reported for hypertension patients in these studies where the prevalence rate for the terazosin hydrochloride group was at least 5%, where the prevalence rate for the terazosin hydrochloride 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 hydrochloride than in patients receiving placebo. Similar adverse reaction rates were observed in placebo-controlled monotherapy trials as in combination therapy trials (see Table 1).

TABLE 1
ADVERSE REACTIONS DURING
PLACEBO-CONTROLLED STUDIES IN HYPERTENSION

	TERAZOSIN HYDROCHLORIDE N = 859	PLACEBO N = 506
CARDIOVASCULAR SYSTEM		
Palpitations	4.3%*	1.2%
Postural Hypotension	1.3%	0.4%
Syncope	1.0%	0.2%
Tachycardia	1.9%	1.2%
DIGESTIVE SYSTEM		
Nausea	4.4%*	1.4%
METABOLIC/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%
Nervousness	2.3%	1.8%
Paresthesia	2.9%	1.4%
Somnolence	5.4%*	2.6%
RESPIRATORY SYSTEM		
Dyspnea	3.1%	2.4%
Nasal Congestion	5.9%*	3.4%
Sinusitis	2.6%	1.4%
SPECIAL SENSES		
Blurred Vision	1.6%*	0.0%
UROGENITAL SYSTEM		
Impotence	1.2%	1.4%
* Statistically significant at p = 0.05 level		

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 hydrochloride group and being reported more often than in the placebo group, are shown in Table 2. Overall, 9.9% of 859 patients taking terazosin hydrochloride discontinued therapy because of adverse effects, as compared with 4.2% of 506 patients taking placebo.

TABLE 2

DISCONTINUATIONS DURING PLACEBO-CONTROLLED STUDIES IN HYPERTENSION

	TERAZOSIN HYDROCHLORIDE N = 859	PLACEBO N = 506
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/NUTRITIONAL DISORDERS		
Peripheral Edema	0.6%	0.0%
NERVOUS SYSTEM		
Dizziness	3.1%	0.4%
Paresthesia	0.8%	0.2%

TABLE 2

DISCONTINUATIONS DURING PLACEBO-CONTROLLED STUDIES IN HYPERTENSION

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%

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 hydrochloride.

The following additional adverse reactions were reported by at least 1% of 1987 patients who received terazosin hydrochloride in controlled or open, short- or long-term clinical studies 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 tract infection, and urinary incontinence primarily reported in postmenopausal women.

Benign Prostatic Hyperplasia (BPH)

Each selected adverse event in Table 3 was chosen on the basis of meeting one or more of the following criteria: 1) incidence of ≥ 5% or clinical relevance in previous terazosin hydrochloride hypertension clinical studies; 2) incidence ≥ 5% in terazosin hydrochloride BPH clinical studies; 3) it was a component of the dizziness-related adverse event complex, which includes dizziness, hypotension, postural hypotension, syncope and vertigo; or 4) it was related to sexual function.

TABLE 3
SUMMARY OF SELECTED ADVERSE EVENTS FROM 6 DOUBLE-BLIND, PLACEBO-CONTROLLED STUDIES IN BENIGN PROSTATIC HYPERPLASIA (BPH)

	TERAZOSIN HYDROCHLORIDE N = 636	PLACEBO N = 360
BODY AS A WHOLE		
Asthenia	7.4%*	3.3%
Headache	4.9%	5.8%
CARDIOVASCULAR SYSTEM		
Hypotension	0.6%	0.6%
Palpitations	0.9%	1.1%
Postural Hypotension	3.9%*	0.8%
Syncope	0.6%	0.0%
Tachycardia	0.3%	0.0%
DIGESTIVE SYSTEM		
Nausea	1.7%	1.1%
METABOLIC/NUTRITIONAL DISORDERS		
Peripheral Edema	0.9%	0.3%
Weight Gain	0.5%	0.0%
NERVOUS SYSTEM		
Dizziness	9.1%*	4.2%
Libido Decreased	0.9%	0.3%
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	1.6%*	0.6%
* $p \leq 0.05$ compared to placebo group.		

The most common adverse events with terazosin hydrochloride were dizziness, asthenia, headache, postural hypotension, somnolence, nasal congestion and impotence. All but headache were significantly ($p \leq 0.05$) more frequent than with placebo.

ADR -Post-Marketing Experience

Thrombocytopenia has been reported. Atrial fibrillation has been reported. Priapism has also been reported. Anaphylaxis has rarely been reported. Angioedema has been reported. Hypersensitivity has been reported.

During cataract surgery, a variant of small pupil syndrome known as Intraoperative Floppy Iris Syndrome (IFIS) has been reported in association with alpha-1 blocker therapy (see **WARNINGS AND PRECAUTIONS**).

OVERDOSAGE

Should overdosage of terazosin hydrochloride 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, hypotension should 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 terazosin hydrochloride is highly protein bound; therefore, dialysis may not be of benefit.

DOSAGE AND ADMINISTRATION

The dose of terazosin hydrochloride should be adjusted according to the patient's individual response. The following is a guide to its administration:

Initial Dose

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

Subsequent Doses

Hypertension

The dose may be slowly increased to achieve the desired blood pressure response. The usual recommended dose range is 1 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 to 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 hydrochloride administration is discontinued for several days or longer, therapy should be reinstituted using the initial dosing regimen. In clinical trials, except for the initial dose, the dose was given in the morning.

Benign Prostatic Hyperplasia (BPH)

The dose may be slowly increased to achieve the desired clinical response in BPH patients. The usual recommended dose range is 5 to10 mg administered once a day. Urine flow rate measured approximately 24 hours after the last dose has shown the beneficial effect in BPH persists for the recommended dosing interval. Symptom improvements have been detected as early as two weeks after starting treatment with terazosin hydrochloride. Improvements on flow rate may be seen somewhat later. If terazosin hydrochloride administration is discontinued for several days or longer, therapy should be reinstituted using the initial dosing regimen.

STORAGE

Stored at 30˚C

Shelf Life: 60 months

HOW SUPPLIED

28’s X 1mg tablet
28’s X 2mg tablet
28’s X 5mg tablet

MANUFACTURER

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