



New Zealand Data Sheet

APO-TERAZOSIN

Terazosin hydrochloride dihydrate 1mg, 2mg and 5mg Tablets

Presentation

APO-TERAZOSIN 1mg tablets are a white, round, flat-faced, beveled-edge tablet, engraved "APO" on one side and "T1" on the other side. Each tablet typically weighs approximately 150mg. APO-TERAZOSIN 2mg tablets are a orange, round, flat-faced, beveled edged tablet, engraved "APO" on one and "T2" on the other side. Each tablet weighs approximately 150mg. APO-TERAZOSIN 5mg tablets are a tan, round, flat-faced, beveled edged tablet, engraved "APO" on one and "T5" on the other side. Each tablet weighs approximately 150mg.

Please note: These tablets are not capable of providing a divided dose. Do not halve the tablets.

Uses

Actions

APO-TERAZOSIN for benign prostatic hyperplasia, is an alpha-1-selective adrenoceptor blocking agent.

Studies suggest that alpha-1-adrenoceptor blockade is 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 has been shown to antagonize phenylephrine-induced contractions in human prostatic tissue. In clinical trials terazosin has been shown to improve the urodynamics and symptomatology in patients with BPH.

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

The 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 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.

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.

During controlled clinical studies, patients receiving terazosin had an improved lipid profile. Patients receiving terazosin monotherapy had a small but statistically significant decrease compared to placebo in total cholesterol and the combined low-density and very-low-density



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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 (6 months or longer) administration of terazosin has produced no pattern of clinically significant changes attributable to terazosin 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 suggested the possibility of haemodilution based on decreases in haematocrit, haemoglobin, white blood cells, total protein, and albumin. Decreases in haematocrit and total protein have been observed with alpha-blockade and are attributed to haemodilution.

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

Pharmacokinetics

Relative to solution, terazosin hydrochloride administered as Terazosin tablets is essentially completely absorbed in man. Food has little or no effect on the bioavailability of terazosin administered in a capsule formulation. Terazosin has been shown to undergo minimal hepatic first-pass metabolism and nearly all of the circulating dose is in the form of parent compound. The plasma levels peak about one hour after dosing, and then decline with a half-life of approximately 12 hours. Terazosin 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 medicine in the urine and approximately 20% is excreted in the faeces. The remainder is eliminated as metabolites. Overall, approximately 40% of the administered dose is excreted in the urine and approximately 60% in the faeces. The disposition of the compound in animals is qualitatively similar to that in man.

The pharmacokinetics of Terazosin appears to be independent of renal function. This would prevent the need to adjust dosing regimens for patients with impaired renal function.

No special dosing dosage recommendations are required for elderly patients. Studies have shown that there were no significant correlations between the age of the subjects and Terazosin pharmacokinetics.

Indications

APO-TERAZOSIN is indicated for the symptomatic and pathophysiologic treatment of benign prostatic hyperplasia (BPH) when:
prostatectomy is not indicated
patient is not fit for surgery
elective surgery must be postponed (e.g., waiting list)
patient refuses surgical treatment.
(See also INTERACTIONS Section)



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APO-TERAZOSIN is also indicated for the treatment of hypertension. It can be used alone or in combination with other antihypertensive agents such as diuretics or beta-adrenergic blocking agents.

Dosage and Administration

The dose of APO-TERAZOSIN should be adjusted according to the patients response. The following is a guide to its administration.

Adults

Initial dose

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

Subsequent Doses

Benign Prostatic Hyperplasia: The dose may be slowly increased to achieve the desired clinical response in BPH patients. The usual recommended dose range is 5 to 10 mg administered once a day. Urine flow rate measured approximately 24 hours after the last dose has shown that 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. Improvements in flow rate may be seen somewhat later. If terazosin administration is discontinued for several days or longer, therapy should be reinstated using the initial dosing regimen.

Hypertension: The dose may be slowly increased to achieve the desired blood pressure response. The usual recommended dose range is 1mg to 5mg administered once a day. However, some patients may benefit from doses as high as 20mg per day. Doses over 20mg do not appear to provide further blood pressure effect and doses over 40mg 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 reinstated using the initial dosing regimen. In clinical trials, except for the initial dose, the dose was given in the morning.

These tablets are not capable of providing a divided dose. Do not halve the tablets.

Use with Other Medications

Caution should be observed when Terazosin 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. (see Interactions)



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Children

Not recommended for use in children.

Contraindications

APO-TERAZOSIN is contraindicated in patients known to be sensitive to terazosin hydrochloride or its analogues.

Warnings and Precautions

Syncope and “First-dose” Effect

Terazosin, 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 restarted. Syncope has also been reported with other alpha-adrenergic blocking agents in association with rapid dosage increases or the introduction of another antihypertensive medicine. 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 120-160 beats per minute. To decrease the likelihood of syncope or excessive hypotension, treatment should always be initiated with a 1 mg dose of terazosin, 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 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, place the patient in the recumbent position and institute supportive measures as necessary. There is evidence that the orthostatic effect of Terazosin is greater, even in chronic use, shortly after dosing.

Patients with a history of micturition syncope should not receive Terazosin hydrochloride.

Orthostatic Hypotension

While syncope is the most severe orthostatic effect of terazosin 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.

Weight Gain

There is 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 0.8 and 1kg



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respectively, compared to losses of 0.1 and 0.5kg respectively, in the placebo group. Both differences were significant.

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.

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 dosage increase, and after resumption of therapy when treatment has been interrupted. 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, requiring caution in people who must drive or operate heavy machinery.

Concomitant use of phosphodiesterase-5-inhibitors (e.g. sildenafil, tadalafil, vardenafil) and terazosin may lead to symptomatic hypotension in some patients. In order to minimise the risk of developing postural hypotension the patient should be stable on the alpha-blocker therapy before initiating use of phosphodiesterase-5-inhibitors.

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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Terazosin hydrochloride was devoid of mutagenic potential when evaluated *in vivo* and *in vitro*.

Terazosin hydrochloride, administered in the feed to rats at doses of 8, 40 and 250mg/kg/day for two years, was associated with a statistically significant increase in benign adrenal medullary tumors of male rats exposed to the 250mg/kg dose. Female rates were unaffected. Terazosin hydrochloride was not oncogenic in mice when administered in feed for 2 years at a maximum tolerated dose of 32mg/kg/day.



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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 of carcinogenicity in man.

Effect 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 120mg/kg/day. Four of 20 males rats given 30mg/kg and five of 19 male rats given 120mg/kg failed to sire a litter. Testicular weights and morphology were unaffected by treatment. Vaginal smears at 30 and 120mg/kg/day, however, appeared to contain less sperm than smears from control mating pairs. A 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 250mg/kg/day, but not in rats exposed to 8mg/kg/day. Testicular atrophy was also observed in dogs dosed with 300mg/kg/day for 3 months, but not after one year when dosed with 20mg/kg/day.

Use in Pregnancy and Lactation

Pregnancy Category B2

Teratogenic effects - Terazosin was not teratogenic in either rats or rabbits when administered in oral doses up to 1330 and 165 times, respectively, the maximum recommended human dose. Foetal resorptions occurred in rats dosed with 480 mg/kg/day, approximately 1330 times the maximum recommended human dose. Increased foetal resorptions, decreased foetal 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 in pregnancy has not been established.

APO-TERAZOSIN is not recommended during pregnancy unless the potential benefit justifies the potential risk to the mother and foetus.

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 three-week postpartum period.

Use in nursing mothers

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



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Ability to drive or operate machinery

Patients should be advised of the possibility of syncopal and orthostatic symptoms, and to avoid driving or hazardous tasks for 12 hours after the initial dose of Terazosin, after the dose is increased and after interruption of therapy when treatment is resumed. They should be cautioned to avoid situations where injury could result should syncope occur. Patients should be told that drowsiness or somnolence can occur with Terazosin, requiring caution in people who must drive or operate heavy machinery.

Adverse Effects

Benign Prostatic Hyperplasia (BPH)

Each selected adverse event in Table 1 was chosen on the basis of meeting one or more of the following criteria: 1) prevalence of $\geq 5\%$ or clinical relevance in previous terazosin hypertension clinical studies; 2) prevalence $\geq 5\%$ in terazosin 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 1 Summary Of Selected Adverse Events From Sixdouble-Blind, Placebo-Controlled Studies In Benign Prostatic Hyperplasia (BPH)

	TERAZOSIN (N=636)	PLACEBO (N=360)
*P ≤ 0.05 compared to placebo group		
BODY AS WHOLE		
Asthenia	7.4%*	3.3%
Headache	4.9%	5.8%
CARDIOVASCULAR SYSTEM		
Hypotension	0.6%	0.6%
Palpitation	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 Oedema	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		
Dyspnoea	1.7%	0.8%
Nasal Congestion/Rhinitis	1.9%*	0.0%
SPECIAL SENSES		



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Blurred Vision/Amblyopia	1.3%	0.6%
UROGENITAL SYSTEM		
Impotence	1.6%*	0.6%

The most common adverse events with terazosin 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.

Post-Marketing Experience: Priapism has been reported. Thrombocytopenia has been reported. Atrial fibrillation has been reported; however, a cause and effect relationship has not been established. Anaphylaxis has rarely been reported.

Hypertension

The incidence of adverse reactions presented in the table below are based on the combined information from 14 placebo-controlled studies involving once-a-day administration of Terazosin as monotherapy or in combination with other antihypertensive agents, at doses ranging from 1 to 40mg.

Asthenia, blurred vision, dizziness, nasal congestion, nausea, peripheral oedema, palpitations, and somnolence were the only symptoms that were significantly (p less than or equal to 0.05) more common in patients receiving Terazosin than in patients receiving placebo. Similar adverse reaction rates were observed in placebo-controlled monotherapy trials as in combination therapy trials.

ADVERSE EFFECTS DURING PLACEBO-CONTROLLED STUDIES IN HYPERTENSION

	TERAZOSIN (N=859)	PLACEBO (N=506)
BODY AS A WHOLE		
Asthenia	11.3%*	4.3%
Back pain	2.4%	1.2%
Headache	16.2%	15.8%
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		
Oedema	0.9%	0.6%
Periphera Oedema	5.5%*	2.4%
Weight Gain	0.5%	0.2%
MUSCULOSKELETAL SYSTEM		
Pain Extremities	3.5%	3.0%



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NERVOUS SYSTEM		
Depression	0.3%	0.2%
Dizziness	19.3%*	7.5%
Libido Decreased	0.6%	0.2%
Nervousness	2.3%	1.8%
Paraesthesia	2.9%	1.4%
Somnolence	5.4%	2.6%
RESPIRATORY SYSTEM		
Dyspnoea	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 $p \leq 0.05$ 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 group and being reported more often than in placebo group are shown in the table below. Overall, 9.9% of the 859 patients taking Terazosin discontinued therapy because of adverse effects, as compared with 4.2% of 506 patients taking placebo.

DISCONTINUATIONS DURING PLACEBO-CONTROLLED STUDIES IN HYPERTENSION

	TERAZOSIN (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		
Periphera Oedema	0.6%	0.0%
NERVOUS SYSTEM		
Dizziness	3.1%	0.45
Paraesthesia	0.8%	0.2%
Somnolence	0.6%	0.2%
RESPIRATORY SYSTEM		
Dyspnoea	0.9%	0.6%
Nasal congestion	0.6%	0.0%

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SPECIAL SENSES		
Blurred Vision	0.6%	0.0%

Additional adverse effects 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 effects were reported by at least 1% of 1987 patients who received Terazosin in controlled or open, short- or long-term clinical studies or have been reported during marketing experience.

Body as a whole – chest pain, facial oedema, 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 – 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.

Post-Marketing Experience: Pripism has been reported. Thrombocytopenia has been reported. Atrial fibrillation has been reported; however, a cause and effect relationship has not been established. Anaphylaxis has rarely been reported.

Interactions

In clinical trials in BPH patients the number reporting dizziness or other dizziness-related adverse events appears to be greater in those patients receiving terazosin and ACE inhibitors or diuretics than in the total population of terazosin patients from double-blind, placebo-controlled studies. No interactions were observed in patients treated concurrently with theophylline, anti-anginal agents or oral hypoglycaemic agents. In controlled trials in hypertensive patients, terazosin has been added to diuretics, and several beta-adrenergic blockers; no unexpected interactions were observed. Terazosin has also been used in patients on a variety of concomitant therapies; while these were not formal interaction studies, no interactions were observed. Terazosin has been used concomitantly in at least 50 patients on the following medicines or types of medicine.

1. analgesic/anti-inflammatory (e.g. paracetamol, aspirin, codeine, ibuprofen, indomethacin)
2. antibiotics (e.g. erythromycin, trimethoprim, sulphamethoxazole)
3. anticholinergic/sympathomimetics (e.g. phenylephrine hydrochloride, phenylpropranolamine 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. hypoglycaemics



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10. sedatives and tranquillizers (e.g. diazepam).

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

Caution should be observed when Terazosin is administered concomitantly with other antihypertensive agents to avoid the possibility of significant hypotension. When adding a diuretic or other antihypertensive agent dosage reduction and retitration may be necessary.

Concomitant use of phosphodiesterase-5-inhibitors (e.g. sildenafil, tadalafil, vardenafil) and terazosin may lead to symptomatic hypotension in some patients.

Overdosage

Should overdosage of APO-TERAZOSIN lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalisation 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 and therefore, dialysis may not be of benefit.

Pharmaceutical Precautions

Shelf life for APO-TERAZOSIN 1mg tablets – 24 months from date of manufacture
Shelf life for APO-TERAZOSIN 2mg and 5mg tablets – 36 months from date of manufacture.
Store at or below 25 °C
Protect from heat, light and moisture.

Medicine Classification

Prescription Only Medicine

Package Quantities

1mg Tablets – Bottles of 28 and 100 tablets.
2mg Tablets – Bottles of 100 and 500 tablets.
5mg Tablets – Bottles of 100 and 500 tablets.

Further Information

All tablets contain Lactose and Corn Starch.



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Name and Address

Apotex NZ Ltd
32 Hillside Road
Glenfield
Private Bag 102-995
North Shore Mail Centre
Auckland
Telephone: (09) 444 2073
Fax: (09) 444 2951

Date of Preparation

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