NEW ZEALAND DATA SHEET

1 NAME OF THE MEDICINE

Terazosin, 1 mg, tablets

Terazosin, 2 mg tablets

Terazosin, 5mg, tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1 mg, 2 mg or 5 mg terazosin as terazosin hydrochloride dihydrate.

Excipient with known effect: Lactose

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Tablets 1 mg: White coloured, round, flat uncoated tablets with bevelled edges, approximately 7.1mm in diameter and a bisecting line on one side of the tablet.

Tablets 2mg: Yellow coloured, round, flat uncoated tablets with bevelled edges, approximately 7.1mm in diameter and a bisecting line on one side of the tablet.

Tablets 5mg: Light pink coloured, round, flat uncoated tablets with bevelled edges, approximately 7.1mm in diameter and a bisecting line on one side of the tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Terazosin Tablets are 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.

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

4.2 Dose and method of administration

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

Initial dose

1 mg at bedtime is the recommended 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

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 reinstituted 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 reinstituted using the initial dosing regimen. In clinical trials, except for the initial dose, the dose was given in the morning.

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 Section 4.5 Interaction with other medicines and other forms of interaction).

Special populations
Use in renal insufficiency

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

Use in the Elderly

No special 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.

Postural hypotension has been reported to occur in patients receiving terazosin for the symptomatic treatment of urinary obstruction caused by BPH. In these cases, the incidence of postural hypotensive events was greater in patients aged 65 years and over (5.6%) than those aged less than 65 years (2.6%).

Paediatric population
Terazosin is not recommended for use in children.

4.3 Contraindications
Terazosin Tablets are contraindicated in patients who are hypersensitive to any component of this product and patients known to be sensitive to terazosin hydrochloride or its analogues.

4.4 Special warnings and precautions for use
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, the patient should be placed in a recumbent position and treated supportively 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 an alpha-blocker.

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 1 kg (1.7 and 2.2 pounds) respectively, compared to losses of 0.1 and 0.5 kg (0.2 and 1.1 pounds) respectively, in the placebo group. Both differences were significant.

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, and to be careful when rising from a sitting or lying position as dizziness, light-headedness, palpitations or fainting may occur. Patients should be advised of this possibility and instructed to lie down if these symptoms occur and then sit for a few minutes before standing to prevent re-occurrence. These adverse effects are self-limiting and in most cases do not recur after the initial period of therapy or during subsequent titration. However, if these symptoms are bothersome, then they should be reported to the physician, so that dosage adjustment can be considered.

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

PDE-5 Inhibitors

Hypotension has been reported when terazosin has been used with phosphodiesterase5 (PDE-5) inhibitors. (see Section 4.5 Interaction with other medicines and other forms of interaction**)**

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.

Carcinogenicity, Mutagenicity and Reproduction Toxicity Studies

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 dosage of 8, 40, and 250 mg/kg/day for two years, was associated with a statistically significant increase in benign adrenal medullary tumours 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 was not oncogenic in mice when administered in feed for 2 years at a maximum tolerated dose of 32 mg/kg/day.

Paediatric Use

Safety and effectiveness in children has not been determined.

4.5 Interaction with other medicines and other forms of interaction

In clinical trials in BPH patients, the proportion reporting dizziness or related side effects was greater in those patients receiving terazosin and ACE inhibitors or diuretics, than in the total population of terazosin treated patients from clinical 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:

- analgesic/anti-inflammatory (e.g. paracetamol, aspirin, codeine, ibuprofen, indomethacin)
- antibiotics (e.g. erythromycin, trimethoprim, sulphamethoxazole)
- anticholinergic/sympathomimetics (e.g. phenylephrine hydrochloride, phenylpropanolamine hydrochloride, pseudoephedrine hydrochloride)
- antigout (e.g. allopurinol)
- antihistamines (e.g. chlorpheniramine)
- cardiovascular agents (e.g. atenolol, hydrochlorothiazide, methyclothiazide, propranolol)
- corticosteroids
- gastrointestinal agents (e.g. antacids)
- hypoglycaemics
- 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 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.

4.6 Fertility, 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 480mg/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. 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

Breast-feeding

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.

Fertility

The absence of mutagenicity in a battery of tests, of tumourigenicity of any cell type in the mouse carcinogenicity assay, of increased total tumour 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 tumours 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 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 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 other selective-alpha-1 blocking agent.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable 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 ≥5% or clinical relevance in previous terazosin hypertension clinical studies;

2) prevalence ≥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 Six double-Blind, Placebo-Controlled Studies In Benign Prostatic Hyperplasia (BPH)

	TERAZOSIN (N=636)	**PLACEBO (N=360)**
BODY AS WHOLE		
Asthenia	7.4%*	3.3%
Headache	3.3%	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		
Blurred Vision/Amblyopia	1.3%	0.6%
UROGENITAL SYSTEM		
Impotence	1.6%*	0.6%
*P ≤0.05 compared to placebo group		

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

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 as monotherapy or in combination with other antihypertensive agents, at doses ranging from 1 to 40mg.

Table 2 summarises those adverse experiences reported for hypertensive patients in these studies where the prevalence rate for 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 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 (See Table 2).

Table 2 Adverse Reactions 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%
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%
+ Includes weakness, tiredness, lassitude and fatigue		
* 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 bother some, 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 3. Overall, 9.9% of 859 patients taking terazosin discontinued therapy because of adverse effects, as compared with 4.2% of 506 patients taking placebo.

Table 3 Discontinuations During Placebo Controlled Studies In Hypertension

	TERAZOSIN (N=859)	**PLACEBO (N=506)**
BODY AS 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 Oedema	0.6%	0.0%
NERVOUS SYSTEM		
Dizziness	3.1%	0.4%
Paraesthesia	0.8%	0.2%
Somnolence	0.6%	0.2%
RESPIRATORY SYSTEM		
Dyspnoea	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.

The following additional adverse reactions 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, diarrhoea, 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.

Post-Marketing Experience

Thrombocytopenia and priapism have been reported. Atrial fibrillation has been reported; however, a cause and effect relationship has not been established. Anaphylaxis has rarely 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 Section 4.4 Special warnings and precautions for use).

Laboratory Tests

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

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.

For advice on the management of overdose please contact the Poisons Information Centre on 0800 764 766.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Urologicals, drugs used in benign prostatic hypertrophy, Alpha-adrenoreceptor antagonists, ATC code: G04CA03 (5 mg)

ATC code: 1 mg and 2 mg (not yet assigned)

Mechanism of action

Terazosin Tablets (terazosin hydrochloride) 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 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.

5.2 Pharmacokinetic properties

After oral administration, the parent drug is completely absorbed with peak plasma concentration about one hour after dosing, and then declines with a half-life of approximately 12 hours. Food has little or no effect on bioavailability. 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. 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 appear to be independent of renal function. This would obviate the need to adjust dosing regimens for patients with impaired renal function.

No special 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate, magnesium stearate, purified –talc, maize starch, quinolone yellow (2 mg only) and ferric oxide (5 mg only).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months (blister packs)

30 months (HDPE bottles)

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

PVC/PVDC/Aluminium foil blister packs. Pack sizes of 7 tablets or 28 tablets.

HDPE bottle packs. Pack sizes of 100 tablets or 500 tablets.

Not all pack sizes or pack types may be marketed.

6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

Prescription Only Medicine

8 SPONSOR

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

9 DATE OF FIRST APPROVAL

31 May 2007

10 DATE OF REVISION OF THE TEXT

1 November 2018

Summary table of changes

Section Changed	Summary of new information
All	Update to new format
5.1	Pharmacotherapeutic group and ATC code added
6.3	Shelf life added
9	Date of first approval added