NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Mirtazapine (Noumed), film-coated tablets 30 mg & 45 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:
Mirtazapine (Noumed) 30 mg - Each tablet contains 30 mg Mirtazapine
Mirtazapine (Noumed) 45 mg - Each tablet contains 45 mg Mirtazapine

Excipients:
For full list of excipients, see section 6.1.

Tablets contain lactose.

3 PHARMACEUTICAL FORM

Tablet, film-coated.

Presentation

30 mg
Reddish brown, biconvex capsule shaped film-coated tablets with score line on one side and 30 debossed on the other side.
This tablet can be halved to give a 15 mg dose.

45 mg
White, biconvex, capsule shaped film-coated tablets. Plain on one side and 45 debossed on other side.
This tablet cannot be halved.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Episodes of major depression.

4.2 Dose and method of administration

Administration
The tablets should be taken orally, if necessary, with fluid, and swallowed without chewing.
The clearance of mirtazapine may be decreased in patients with renal or hepatic insufficiency. This should be taken into account when prescribing mirtazapine to this category of patients.

Mirtazapine has a half-life of 20-40 hours and, therefore, Mirtazapine (Noumed) is suitable for once-a-day administration. It should be taken preferably as a single night-time dose before going to bed. Mirtazapine (Noumed) may also be given in sub-doses equally divided over the day (once in the morning and once at night-time).
Treatment should preferably be continued until the patient has been completely symptom-free for 4-6 months. After this, treatment can be gradually discontinued. Mirtazapine begins to

exert its effect in general after 1-2 weeks of treatment. Treatment with an adequate dose should result in a positive response within 2-4 weeks. With an insufficient response, the dose can be increased up to the maximum dose. If there is no response within a further 2-4 weeks, then treatment should be stopped.

Dosage in Adults

Treatment should begin with 15 mg daily. The dosage generally needs to be increased to obtain an optimal clinical response. The effective daily dose is usually between 15 and 45 mg.
Do not halve the 45 mg tablets.

Dosage in children and adolescents under the age of 18 years

Mirtazapine should not be used in patients under 18 years of age as efficacy was not demonstrated in two short-term clinical trials and because of safety concerns (see 5.3 Preclinical safety data, 4.4 Special warnings and precautions for use, 4.8 Undesirable effects).

Dosage in the elderly

The recommended dose is the same as that for adults. In elderly patients an increase in dosing should be done under close supervision to elicit a satisfactory and safe response.

4.3 Contraindications

Hypersensitivity to mirtazapine, or to any of the excipients in the tablet. Concomitant use of mirtazapine with monoamine oxidase (MAO) inhibitors (see Interactions).

4.4 Special warnings and precautions for use

Bone marrow depression

Bone marrow depression, usually presenting as granulocytopenia or agranulocytosis, has been reported during treatment with mirtazapine. This mostly appears after 4-6 weeks of treatment and is in general reversible after termination of treatment. However, in very rare cases agranulocytosis can be fatal. Reversible agranulocytosis has also been reported as a rare occurrence in clinical studies with mirtazapine. In the post marketing period with mirtazapine very rare cases of agranulocytosis have been reported, mostly reversible, but in some cases fatal. Fatal cases mostly concerned patients with an age above 65. The physician should be alert for symptoms like fever, sore throat, stomatitis or other signs of infection; when such symptoms occur, treatment should be stopped and blood counts taken.

Clinical worsening and Suicide Risk:

Patients of any age with Major Depressive Disorder may experience worsening of their depression and/or the emergence of suicidal ideation and behaviour (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Patients should be closely monitored, especially at the beginning of therapy or when the dose is changed, until such improvement occurs.

There has been a long-standing concern that some antidepressants may have a role in the emergence of suicidality in some patients. The possible risk of increased suicidality in patients applies to all classes of antidepressant medicines, as available data are not adequate to exclude this risk for any antidepressant. Therefore, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or whose emergent suicidality is severe, abrupt in onset, or was not part of the patient's presenting symptoms. Generally, when stopping an antidepressant, doses should be tapered rather than stopped abruptly.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness), impulsivity, akathisia (psychomotor restlessness), hypomania and mania, have been reported in adult and paediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric.

Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric and non-psychiatric disorders.

Mania and Bipolar Disorder:

A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with any antidepressant alone may increase the likelihood of a mixed-manic episode in patients at risk for bipolar disorder. Prior to initiating treatment with an antidepressant, patients should be adequately screened to determine if they are at risk for bipolar disorder. It should be noted that mirtazapine is not approved for use in treating bipolar depression.

Cardiac disorders

The effect of mirtazapine on QTc interval was assessed in a randomized, placebo and moxifloxacin controlled clinical trial involving 54 healthy volunteers using exposure response analysis. This trial revealed that both 45 mg (therapeutic) and 75 mg (supratherapeutic) doses of mirtazapine did not affect the QTc interval to a clinically meaningful extent. During the post marketing use of mirtazapine, cases of QTc prolongation, Torsades de Pointes (TdP), ventricular tachycardia, and sudden death, have been reported during the post-marketing use of mirtazapine. The majority of reports occurred in association with overdose or in patients with other risk factors for QTc prolongation/TdP including use of other QT prolonging medicines (see Interactions).

Therefore mirtazapine should be used with caution in patients with risk factors for QTc prolongation including congenital long QT syndrome, age >65 years, female sex, structural heart disease/LV dysfunction, hypokalaemia or hypomagnesaemia, medical conditions or concomitant use of medicines that inhibit the metabolism of mirtazapine, and the use of other QT prolonging medicines. An ECG should be performed in all patients experiencing symptoms that could be indicative of an arrhythmia (e.g. dizziness, palpitations, syncope or new onset seizures).

Information for Patients and Families:

Patients and their families should be alerted about the need to monitor for the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, mania, worsening of depression, and suicidal ideation, especially early during antidepressant treatment. Such symptoms should be reported to the patient's doctor, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Conditions which need supervision

Careful dosing as well as regular and close monitoring is necessary in patients with:

- Epilepsy and organic brain syndrome: Although clinical experience indicates that epileptic seizures are rare during mirtazapine treatment, as with other antidepressants mirtazapine should be introduced cautiously in patients who have a history of seizures. Treatment should be discontinued in any patient who develops seizures, or where there is an increase in seizure frequency.
- Hepatic impairment: Following a single 15 mg oral dose of mirtazapine, the clearance of mirtazapine was approximately 35% decreased in patients with mild or moderate hepatic impairment compared to subjects with normal hepatic function. The average plasma concentration of mirtazapine was about 55% increased.
- Renal impairment: Following a single 15 mg oral dose of mirtazapine, in patients with moderate (10 mL/min ≤ creatinine clearance < 40 mL/min) and severe (creatinine clearance < 10 mL/min) renal impairment the clearance of mirtazapine was about 30% and 50% decreased, respectively, compared to normal subjects. The average plasma concentration of mirtazapine was about 55% and 115% increased, respectively. No significant differences were found in patients with mild renal impairment (40 mL/min < creatinine clearance < 80 mL/min) as compared to the control group.
- Cardiac diseases like conduction disturbances, angina pectoris and recent myocardial infarction, where normal precautions should be taken and concomitant medicines carefully administered.
- Low blood pressure.
- Diabetes mellitus: In patients with diabetes, antidepressants may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted and close monitoring is recommended.

Like with other antidepressants, the following should be taken into account:

- Worsening of psychotic symptoms can occur when antidepressants are administered to patients with schizophrenia or other psychotic disturbances; paranoid thoughts can be intensified.
- When the depressive phase of bipolar disorder is being treated, it can transform into the manic phase. Patients with a history of mania/hypomania should be closely monitored. Mirtazapine should be discontinued in any patient entering a manic phase.
- Although mirtazapine is not addictive, post-marketing experience shows that abrupt termination of treatment after long-term administration may sometimes result in withdrawal symptoms. The majority of withdrawal reactions are mild and self-limiting. Among the various reported withdrawal symptoms, dizziness, agitation, anxiety, headache and nausea are the most frequently reported. Even though they have been reported as withdrawal symptoms, it should be realized that these symptoms may be related to underlying disease. As advised under Dosage and Administration, it is recommended to discontinue treatment with mirtazapine gradually.
- Care should be taken in patients with micturition disturbances like prostate hypertrophy and in patients with acute narrow-angle glaucoma and increased intraocular pressure (although there is little chance of problems with mirtazapine because of its very weak anticholinergic activity).
- Akathisia/psychomotor restlessness: The use of antidepressants have been associated with the development of akathisia, characterised by a subjectively unpleasant or distressing restlessness and need to move often accompanied by an inability to sit or stand still. This is most likely to occur within the first few weeks of treatment. In patients who develop these symptoms, increasing the dose may be detrimental.
- With regard to the chance of suicide, in particular at the beginning of treatment, only the smallest amount of Mirtazapine tablets should be given to the patient consistent with good patient management, in order to reduce the risk of overdose.

Jaundice
Treatment should be discontinued if jaundice occurs.

Hyponatremia
Hyponatremia has been reported very rarely with the use of mirtazapine. Caution should be exercised in patients at risk, such as elderly patients or patients concomitantly treated with medications known to cause hyponatremia.

Serotonin syndrome
Interaction with serotonergic active substances: serotonin syndrome may occur when selective serotonin reuptake inhibitors (SSRIs) are used concomitantly with other serotonergic active substances (see Interactions). Symptoms of serotonin syndrome may be hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, mental status changes that include confusion, irritability and extreme agitation progressing to delirium and coma. Caution should be advised, and a closer clinical monitoring is required when these active substances are combined with mirtazapine. Treatment with Mirtazapine (Noumed) should be discontinued if such events occur and supportive symptomatic treatment initiated. From post marketing experience it appears that serotonin syndrome occurs very rarely in patients treated with mirtazapine alone.

Elderly patients
Elderly patients are often more sensitive, especially with regard to the undesirable effects of antidepressants. During clinical research with mirtazapine, undesirable effects have not been reported more often in elderly patients than in other age groups.

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

The patient has the right to treatment meeting appropriate ethical and professional standards, and the patient need to be fully informed with frank discussion of risk/benefit issues relating to this medicine's efficacy and safety when used in the treatment regimen proposed.

Use in Children and Adolescents Under 18 Years of Age
Mirtazapine (Noumed) should not be used in the treatment of children and adolescents under the age of 18 years. Suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms. In addition, long-term safety data in children and adolescents concerning growth, maturation and cognitive and behavioural development are lacking.

4.5 Interaction with other medicines and other forms of interaction

Pharmacokinetics Interactions

- Co-administration of the potent CYP3A4 inhibitor ketoconazole increased the peak plasma levels and the AUC of mirtazapine by approximately 40% and 50% respectively. Caution should be exercised and the dose may have to be decreased when co-administering mirtazapine with potent CYP3A4 inhibitors, HIV protease inhibitors, azole

antifungals, erythromycin, cimetidine or nefazodone.

- Carbamazepine and phenytoin, CYP3A4 inducers, increased mirtazapine clearance about two-fold, resulting in a decrease in average plasma mirtazapine concentration of 60% and 45%, respectively. When carbamazepine or any another inducer of hepatic metabolism (such as rifampicin) is added to mirtazapine therapy, the mirtazapine dose may have to be increased. If treatment with such medicinal product is discontinued, it may be necessary to reduce the mirtazapine dose.
- When cimetidine (weak inhibitor of CYP 1A2, CYP 2D6 and CYP 3A4) is coadministered, the bioavailability of mirtazapine may be increased by more than 50%. The mirtazapine dose may have to be decreased when concomitant treatment with cimetidine is started or increased when cimetidine treatment is discontinued.
- Interaction studies did not indicate any relevant pharmacokinetic effects on concurrent treatment of mirtazapine with paroxetine, amitriptyline, risperidone or lithium.

Pharmacodynamic Interactions

- Mirtazapine should not be administered concomitantly with MAO inhibitors or within two weeks after discontinuation of MAO inhibitor therapy. In the opposite way about two weeks should pass before patients treated with mirtazapine should be treated with MAO inhibitors (see Contraindications). In addition, as with SSRIs, co-administration with other serotonergic active substances (L-tryptophan, triptans, tramadol, linezolid, methylene blue, SSRIs, venlafaxine, lithium and St John's wort – Hypericum Perforatum – preparations) may lead to an incidence of serotonin associated effects (serotonin syndrome). Caution should be advised and a closer clinical monitoring is required when these active substances are combined with mirtazapine.
- Mirtazapine may increase the sedating properties of benzodiazepines and other sedatives (notably most antipsychotics, antihistamine H1 antagonists, opiods). Caution should be exercised when these medicinal products are prescribed together with mirtazapine.
- Mirtazapine may increase the CNS depressant effect of alcohol. Patients should therefore be advised to avoid alcoholic beverages while taking mirtazapine.
- Mirtazapine dosed at 30 mg once daily caused a small but statistically significant increase in the international normalized ratio (INR) in subjects treated with warfarin. As at a higher dose of mirtazapine a more pronounced effect cannot be excluded, it is advisable to monitor the INR in case of concomitant treatment of warfarin with mirtazapine.

Medicines that can prolong the QTc interval

The risk of QT prolongation and/or ventricular arrhythmias (e.g. Torsades de Pointes) may be increased with concomitant use of other medicines which prolong the QTc interval (e.g. some antipsychotics and antibiotics). Please check the data sheet of other medicines administered for information on their effects on the QTc interval (see 4.4 Special Warnings and Precautions for use).

4.6 Fertility, pregnancy and lactation

Category B3

Pregnancy

Although studies in animals have not shown any teratogenic effects of toxicological significance, the safety of Mirtazapine (Noumed) in human pregnancy has not been established. Mirtazapine (Noumed) should be used during pregnancy only if it is clearly needed.

Some neonates exposed to antidepressants late in the third trimester have developed symptoms consistent with a drug discontinuation syndrome, which may require supportive care. If Mirtazapine (Noumed) is used until, or shortly before birth, postnatal monitoring of the newborn is recommended to account for possible discontinuation effects.

Use in lactation

Although animal experiments show that mirtazapine is excreted only in very small amounts in the milk, the use of Mirtazapine (Noumed) in nursing mothers is not recommended since no human data in breast milk are available.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Mirtazapine has minor to moderate influence on the ability to drive and use machines. Mirtazapine (Noumed) may impair concentration and alertness (particularly in the initial phase of treatment).
Patients treated with antidepressants should avoid the performance of potentially dangerous tasks, which require alertness and good concentration, such as driving a motor vehicle or operating machinery, at any time when affected.

4.8 Undesirable effects

Depressed patients display a number of symptoms that are associated with the illness itself. It is therefore, sometimes difficult to ascertain which symptoms are a result of the illness itself and which are result of treatment with mirtazapine.

The most commonly reported adverse reactions, occurring in more than 5% of patients treated with mirtazapine in randomized placebo-controlled trials are somnolence, sedation, dry mouth, weight increased, increase in appetite, dizziness and fatigue.

All randomized placebo-controlled trials in patients (including indications other than major depressive disorder) have been evaluated for adverse reactions of mirtazapine. The meta-analysis considered 20 trials, with a planned duration of treatment up to 12 weeks, with 1501 patients (134 person years) receiving doses of mirtazapine up to 60 mg and 850 patients (79 person years) receiving placebo. Extension phases of these trials have been excluded to maintain comparability to placebo treatment.

The table shows the categorized incidence of the adverse reactions, which occurred in the clinical trials statistically significantly more frequently during treatment with mirtazapine than with placebo, added with the adverse reactions from spontaneous reporting. The frequencies of the adverse reactions from spontaneous reporting are based on the reporting rate of these events in the clinical trials. The frequency of adverse reactions from spontaneous reporting for which no cases in the randomized placebo-controlled patient trials were observed with mirtazapine has been classified as “not known”.

System organ class	Very common (≥1/10)	Common (>1/100 to <1/10)	Uncommon (>1/1,000 to ≤1/100)	Rare (>1/10,000 to ≤1/1,000)	Frequency not known
Blood and the lymphatic system disorders					Bone marrow depression (granulocytopenia, agranulocytosis, aplastic anaemia and thrombocytopenia) (see also 4.4 Special Warnings & Precautions for use) Eosinophilia
Metabolism and nutrition disorders	Increase in appetite[1] Weight increased[1]				Hyponatraemia
Psychiatric disorders		Abnormal dreams Anxiety [2,5] Confusion Insomnia [3,5]	Nightmares[2] Mania Agitation[2] Hallucinations Psychomotor restlessness (including akathisia, hyperkinesia)	Aggression	Suicidal ideation[6] Suicidal behaviour[r6]
Nervous system disorders	Somnolence[1,4] Sedation[1,4] Headache[2]	Lethargy1 Dizziness Tremor	Paraesthesia[2] Restless legs Syncope	myoclonus	Convulsions (insults) Serotonin syndrome Oral paraesthesia Dysarthria
Vascular disorders		Orthostatic hypotension	Hypotension		
Gastrointestinal disorders	Dry mouth	Nausea[3] Diarrhoea[2] Vomiting[2] Constipation[1]	Oral hypoaesthesia	Pancreatitis	Mouth oedema, Increased salivation
Hepato-biliary disorders				Elevations in serum transaminase activities	
Skin and subcutaneous tissue disorders		Exanthema[2]			Stevens-Johnson syndrome Dermatitis bullous Erythema multiforme Toxic epidermal necrolysis Drug reaction with eosinophilia and systemic symptoms (DRESS)
Musculoskeletal, connective tissue and bone disorders		Arthralgia myalgia back pain[1]			Rhabdomyolysis[7]
Renal and urinary disorders					Urinary retention
General disorders and administration site conditions		Oedema peripheral[1] Fatigue			Generalised oedema Localised oedema
Investigations					Increased creatine kinase

1 In clinical trials these events occurred statistically significantly more frequently during treatment with mirtazapine than with placebo.

2 In clinical trials these events occurred more frequently during treatment with placebo than with mirtazapine, however not statistically significantly more frequently.

3 In clinical trials these events occurred statistically significantly more frequently during treatment with placebo than with mirtazapine.

4 N.B. dose reduction generally does not lead to less somnolence/sedation but can jeopardize antidepressant efficacy

5 Upon treatment with antidepressants in general, anxiety and insomnia (which may be symptoms of depression) can develop or become aggravated. Under mirtazapine treatment, development or aggravation of anxiety and insomnia has been reported.

6 Cases of suicidal ideation and suicidal behaviours have been reported during mirtazapine therapy or early after treatment discontinuation (see 4.4 Special Warnings and Precautions for Use).
In laboratory evaluations in clinical trials transient increases in transaminases and gamma glutamyl transferase have been observed (however associated adverse events have not been reported statistically significantly more frequently with mirtazapine than with placebo).

7 Cases of rhabdomyolysis have been reported in association with serotonin syndrome and multi-drug overdose. In the latter, a causative association with mirtazapine cannot be ascertained.

Paediatric population

The following adverse events were observed commonly in clinical trials in children: weight gain, urticaria and hypertriglyceridaemia (see also 5.3 Preclinical safety data).

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

Present experience concerning overdose with mirtazapine alone indicates that symptoms are usually mild. Depression of the central nervous system with disorientation and prolonged sedation have been reported, together with tachycardia and mild hyper- or hypotension.

However, there is a possibility of more serious outcomes (including fatalities) at dosages much higher than the therapeutic dose, especially with mixed overdosages. In these cases, QT prolongation and Torsade de Pointes have also been reported. Cases of overdose should receive appropriate symptomatic and supportive therapy for vital functions. ECG monitoring should be undertaken.

Activated charcoal or gastric lavage should also be considered.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: oral anti-depressant agent, N06AX11.

5.1 Pharmacodynamic properties

General

Mirtazapine is a centrally active presynaptic α2-antagonist, which increases central noradrenergic and serotonergic neurotransmission. The enhancement of serotonergic neurotransmission is specifically mediated via 5-HT1 receptors, because 5-HT2 and 5-HT3 receptors are blocked by mirtazapine. Both enantiomers of mirtazapine are presumed to contribute to the antidepressant activity, the S(+) enantiomer by blocking α2 and 5-HT2 receptors and the R(-) enantiomer by blocking 5-HT3 receptors.
The histamine H1-antagonistic activity of mirtazapine is associated with its sedative properties. Mirtazapine is generally well tolerated. It has practically no anticholinergic activity and, at therapeutic doses, has practically no effect on the cardiovascular system.

5.2 Pharmacokinetic properties

After oral administration of mirtazapine tablets, the active constituent mirtazapine is rapidly and well absorbed (bioavailability ≈ 50%), reaching peak plasma levels after about 2 hours.

Binding of mirtazapine to plasma proteins is approx. 85%. The mean half-life of elimination is 20-40 hours; longer half-lives, up to 65 hours, have occasionally been recorded and shorter half-lives have been seen in young men. The half-life of elimination is sufficient to justify

once-a-day dosing. Steady state is reached after 3-4 days, after which there is no further accumulation. Mirtazapine displays linear pharmacokinetics within the recommended dose range. Food intake has no influence on the pharmacokinetics of mirtazapine.

Mirtazapine is extensively metabolized and eliminated via the urine and faeces within a few days. Major pathways of biotransformation are demethylation and oxidation, followed by conjugation. *In vitro* data from human liver microsomes indicate that cytochrome P450 enzymes CYP2D6 and CYP1A2 are involved in the formation of the 8-hydroxy metabolite of mirtazapine, whereas CYP3A4 is considered to be responsible for the formation of the N-demethyl and N-oxide metabolite. The demethyl metabolite is pharmacologically active and appears to have the same pharmacokinetic profile as the parent compound.

The clearance of mirtazapine may be decreased as a result of renal or hepatic insufficiency.

5.3 Preclinical safety data

Animal Toxicology

Mirtazapine induced no effects of clinical relevance in chronic safety studies in rats and dogs or in reproductive toxicity studies in rats and rabbits. Mirtazapine was not genotoxic in a series of tests for gene mutation and chromosomal and DNA damage. Thyroid gland tumours found in a rat carcinogenicity study and hepatocellular neoplasms found in a mouse carcinogenicity study are considered to be species-specific, non-genotoxic responses associated with long-term treatment with high doses of hepatic enzyme inducers.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mirtazapine (Noumed) film-coated tablets contain the following inactive ingredients:

Core tablets
Lactose Monohydrate
Hydroxypropylcellulose
Maize Starch
Silica, Colloidal Anhydrous
Low-Substituted Hydroxypropyl Cellulose
Magnesium Stearate
Coating ingredients
Hypromellose
Hydroxypropyl Cellulose
Titanium dioxide
30 mg tablets
Iron oxide yellow, iron oxide red and iron oxide black

Mirtazapine (Noumed) film-coated tablets contain lactose.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from date of manufacture

6.4 Special precautions for storage

Store at or below 25°C.

Protect from heat, light, and moisture.

6.5 Nature and contents of container

Blister packs containing 28 or 30 tablets.

6.6 Special precautions for disposal

Not applicable.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

Noumed Pharmaceuticals Limited
Auckland, NZ

Freephone 0800 527545

9 DATE OF FIRST APPROVAL

13/08/2021

10 DATE OF REVISION OF THE TEXT

02/08/2021

SUMMARY TABLE OF CHANGES

New.