

## New Zealand Data Sheet

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### 1 **PARNATE® (10 MG FILM-COATED TABLETS)**

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PARNATE 10 mg film-coated tablets.

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### 2 **QUALITATIVE AND QUANTITATIVE COMPOSITION**

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Parnate 10 mg film-coated tablets: each tablet contains tranylcypromine sulfate equivalent to 10 mg of tranylcypromine.

**Excipients with known effect:** each tablet contains sucrose 6 mg.

For the full list of excipients, see section 6.1.

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### 3 **PHARMACEUTICAL FORM**

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Parnate 10 mg film-coated tablets contain "geranium rose" coloured, biconvex, film-coated tablets.

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### 4 **CLINICAL PARTICULARS**

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#### 4.1 **Therapeutic indications**

Parnate is indicated for the treatment of symptoms of depressive illness especially where treatment with other types of anti-depressants has failed. It is not recommended for use in mild depressive states resulting from temporary situational difficulties.

#### 4.2 **Dose and method of administration**

##### **Adults**

Begin with 20 mg a day given as 10 mg in the morning and 10 mg in the afternoon. If there is no satisfactory response after two weeks, add one more tablet at midday. Continue this dosage for at least a week. A dosage of 3 tablets a day should only be exceeded with caution. When a satisfactory response is established, dosage may be reduced to a maintenance level. Some patients will be maintained on 20 mg per day, some will need only 10 mg daily. If no improvement occurs, continued administration is unlikely to be beneficial.

When given together with a tranquilliser, the dosage of Parnate is not affected. When the medicine is given concurrently with electroconvulsive therapy, the recommended dosage is 10 mg twice a day during the series and 10 mg a day afterwards as maintenance therapy.

Refer to section 4.4 Special warnings and precautions for use - Stopping treatment section.

#### Special populations

##### *Elderly*

Parnate should not be administered to adults older than 60 years of age. Refer to section 4.3.

##### Paediatric population

Parnate is not indicated for children under 18 years of age (see section 4.4).

### **4.3 Contraindications**

Because the effect of many antidepressant medicines may persist for several days, do not commence Parnate therapy within less than the time periods specified below, then use half the normal dosage for the first week. Similarly, allow at least a week (or longer as specified below) to elapse between the discontinuance of Parnate and the administration of any other medicine that is contraindicated with tranylcypromine.

Parnate is contraindicated:

1. **In patients with a known hypersensitivity** to tranylcypromine or to any of the excipients listed in section 6.1.
2. **In patients with cerebrovascular or cardiovascular disease, a history of recurrent or frequent headaches, blood dyscrasias or porphyria.** Parnate should not be administered to any patient with a confirmed or suspected cerebrovascular defect or to any patient with cardiovascular disease or hypertension. Parnate should not be used in patients with known blood dyscrasia or porphyria.
3. **In patients with phaeochromocytoma.** Parnate should not be used in the presence of phaeochromocytoma, or if it is suspected, as such tumours secrete pressor substances.

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**tranylcypromine film-coated tablets 10 mg**

4. **In combination with other monoamine oxidase inhibitors (MAOIs)**, such as phenelzine, moclobemide, furazolidone, iproniazid, isocarboxazid, nialamid, pargyline, and procarbazine hydrochloride. Avoid for at least 2 weeks after stopping previous MAOI and then start at a reduced dose. Similarly, at least a week should elapse between the discontinuance of tranylcypromine and the administration of another MAOI, or the re-administration of tranylcypromine. Hypertensive crises or severe convulsive seizures may occur in patients receiving such combinations.
5. **In combination with, or within 3 weeks of, clomipramine or imipramine.** Clomipramine, in combination with a MAOI, has been reported to result in hyperpyrexia, diffuse intravascular coagulation, and status epilepticus.
6. **In combination with other tricyclic antidepressants and other dibenzazepine derivatives**, such as amitriptyline, desipramine, dosulepin (dothiepin), nortriptyline, protriptyline, trimipramine, doxepin, and carbamazepine, as these combinations may induce hypertensive crises or severe convulsive seizures. Reports of hyperactivity, hypertonicity, hyperpyrexia, coma and death have been associated with the use of tranylcypromine in combination with tricyclic antidepressants. Tetracyclic antidepressants should also be avoided. After stopping Parnate, do not start tricyclic-related antidepressants for 2 weeks, also MAOIs should not be started until at least 1 to 2 weeks (3 weeks in case of clomipramine or imipramine) after stopping tricyclic antidepressants.
7. **In combination with sympathomimetics**, including amfetamines, fenfluramine or similar anti-obesity agents, ephedrine, phenylpropanolamine and over-the-counter medicines such as cold, hay fever and weight-reducing preparations that contain vasoconstrictors, as severe hypertensive reactions may result. Also with methyldopa, dopamine, levodopa and tryptophan, as they may result in potentiation, precipitating hypertension, severe headache, and hyperpyrexia; cerebral haemorrhage may occur. MAOIs in combination with tryptophan have been reported to cause behavioural and neurologic syndromes including disorientation, confusion, amnesia, delirium, agitation, hypomanic signs, ataxia, myoclonus, hyperreflexia, shivering, ocular oscillations and Babinski's signs. Patients must be warned against self-medication with proprietary medicines such as cold, hay fever or weight-reducing medicines that contain pressor agents.
8. **With pethidine, closely related narcotic analgesics and nefopam**, as central nervous system excitation or depression, respiratory depression, hypotension or hypertension, restlessness and coma may ensue. Wait until two weeks after stopping MAOIs before starting treatment with opioid analgesics.

9. **In combination with fluoxetine and other Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin-Noradrenaline Reuptake Inhibitors (SNRIs).** There have been reports of serious and sometimes fatal reactions (including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation leading to delirium and coma) when MAOIs are given before, with, or shortly after discontinuation with some SSRIs. There have also been cases presented with features resembling neuroleptic malignant syndrome. Use of MAOIs with or after fluvoxamine has been reported to produce a serotonin syndrome, sometimes fatal.

Parnate should not be used in combination with SSRIs or SNRIs. If the two therapies are used consecutively, a suitable washout period should be observed as follows:

- Parnate followed by SSRI or SNRI - 2 weeks
- Fluoxetine followed by Parnate - 5 weeks
- Other SSRI (e.g. paroxetine, sertraline) or SNRI (e.g. venlafaxine) followed by Parnate - 2 weeks

10. **In combination with dextromethorphan.** The combination of MAOIs and dextromethorphan has been reported to cause brief episodes of psychosis or bizarre behaviour.
11. **In combination with bupropion.** The concurrent administration of bupropion and a MAOI is contraindicated. At least two weeks should elapse between discontinuation of a MAOI and initiation of treatment with bupropion.
12. **In combination with buspirone hydrochloride.** Parnate should not be used in combination with buspirone hydrochloride since several cases of elevated blood pressure have been reported in patients taking MAOIs who were then given buspirone hydrochloride. At least 10 days should elapse between the discontinuation of Parnate and the institution of buspirone hydrochloride.
13. **In combination with cheese or other foods with high tyramine content.** Hypertensive crises have sometimes occurred during tranylcypromine therapy after ingestion of foods with a high tyramine content. In general, the patient should avoid protein foods in which aging or protein breakdown is used to increase flavour. In particular, patients should be instructed not to consume foods and drinks such as cheese (particularly strong or aged varieties), sour cream, Chianti wine, sherry, beer (including non-alcoholic beer), caviar, sauerkraut, pickled herrings, liver, canned figs, raisins, banana or avocados (particularly if overripe), chocolate, soy beans, soy sauce, the pods of broad beans (contain levodopa), yeast extracts, or meals prepared with tenderisers.

It is important that patients be warned to avoid cheese, protein extracts, such as Marmite, Vegemite, Bonox, Bovril etc, and the other prohibited dietary items while taking Parnate. They should also be advised not to consume excessive amounts of caffeine in any form.

14. **In patients with hyperthyroidism.** These patients have increased sensitivity to pressor amines.
15. **In the elderly.** Parnate should not be administered to any patient beyond 60 years of age because of the possibility of existing cerebral sclerosis with damaged blood vessels.
16. **In patients with impaired hepatic function.** Parnate should not be used in patients with a history of liver disease or in those with abnormal liver function tests.

#### **4.4 Special warnings and precautions for use**

Parnate may occasionally provoke serious adverse effects. If patients are kept under regular and frequent observation, the medicine can be stopped should any adverse effects occur. It is important for the physician to be fully aware of the undesirable effects, contraindications, special warnings and precautions described in the data sheet.

##### **Paediatric population**

The safety and efficacy of Parnate for the treatment of depression or other psychiatric disorders in children and adolescents aged less than 18 years of age has not been satisfactorily established. Parnate should not be used in this age group for the treatment of depression or other psychiatric disorders.

##### **Clinical worsening and suicide risk**

The risk of suicide attempt is inherent in depression and may persist until significant remission occurs.

Patients of any age with depression may experience worsening of their depressive symptoms 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.

The risk is increased in patients less than 25 years old. As improvement may not occur during the initial treatment period (usually one to two months), all patients should be closely monitored for clinical worsening of suicidality, especially at the beginning of therapy or when the dose is changed (dose increase or dose decrease).

Patients (and caregivers of patients) should be alerted about the need to monitor for any worsening of their condition and/or the emergence of suicidal ideation/behaviour or thoughts of harming themselves, and to seek medical advice immediately if these symptoms present. Patients with co-morbid depression associated with other psychiatric disorders being treated with antidepressants should be similarly observed for clinical worsening and suicidality.

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, adolescent and paediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric (see section 4.8). 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, there is concern that such symptoms may be precursors of emerging suicidality. 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.

**Patients and caregivers of patients should be alerted about the need to monitor for the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, mania, unusual changes in behaviour, worsening of depression, and suicidal ideation, especially early during antidepressant treatment or at times of dose increase or decrease. 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.**

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.

Prescriptions for Parnate should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

Note: The Medicines Act 1981 allows a doctor to prescribe a medicine for any indication regardless of whether it is approved or not for that indication. There are limitations to this authority embedded in the Code of Health and Disability Services Consumers' Rights 1996. Unapproved use of medicines must comply with this Code, which states that the patient has the right to treatment of an appropriate ethical and professional standard, and the doctor has the responsibility to ensure that treatment, whether approved or unapproved, meets this standard. The patient also has the right to be fully informed. If the use of a medicine is unapproved, the patient should be so advised and the doctor should be frank about the level of evidence for the medicine's efficacy as well as any safety concerns. The doctor must fully discuss the risk/benefit issues with the patient/parent, and in appropriate circumstances this may lead to the use of an antidepressant with informed consent. (Information on unapproved use of medicines is provided on the Medsafe website: [www.medsafe.govt.nz](http://www.medsafe.govt.nz)).

### **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 Parnate is not approved for use in treating bipolar depression.

Caution is required when giving Parnate in the following conditions:

1. **In patients with diabetes.** Some MAOIs have contributed to hypoglycaemic episodes in diabetic patients receiving insulin or oral hypoglycaemic agents. Therefore, Parnate should be used with caution in diabetics under treatment with these medicines.
2. **In epileptic patients.** Because the influence of tranylcypromine on the convulsive threshold is variable in animal experiments, suitable precautions should be taken if epileptic patients are treated with Parnate.
3. **In surgery.** Although excretion of tranylcypromine is rapid, it is advisable wherever possible to discontinue Parnate therapy at least two weeks before surgery, because of possible interference with the action of certain anaesthetics and analgesics. Patients taking MAOIs should not be given cocaine or local anaesthesia containing vasoconstrictors. The possible combined hypotensive effects of MAOIs and spinal anaesthesia should be kept in mind.
4. **Patients with angina.** MAOIs have the capacity to suppress anginal pain that would otherwise serve as a warning of myocardial ischaemia.
5. **In patients with impaired renal function.** There is a possibility of cumulative effects in patients with impaired renal function.
6. **Patients with a history of drug or alcohol dependence.**
7. **Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.** Parnate contains sucrose. Patients with these conditions should not take this medicine.

### **Stopping treatment**

Parnate therapy should be withdrawn gradually to reduce the risk of withdrawal symptoms (refer to section 4.8).

#### **4.5 Interaction with other medicines and other forms of interaction**

Patients should be specifically asked if they are taking any other medication because of the possibility of drug interactions.

Refer to section 4.3 for medicines that should not be taken with Parnate.

Exercise caution when giving Parnate with the following medicines:

1. **Guanethidine**, as its action may be antagonised.
2. **Reserpine**, as hyperactivity may occur.
3. **Other hypotensive agents**, because of the possibility of additive hypotensive effects.
4. **Barbiturates, and possibly other hypnotics, and antimuscarinic agents**, as their action may be prolonged or potentiated.
5. **Anti-Parkinsonism agents**, as the combination may result in potentiation, with profuse sweating, tremulousness, and rise in body temperature.
6. **Anticoagulants**, as some animal studies have suggested that the effect of anticoagulants may be potentiated if a MAOI is given concurrently. One suspected case of potentiation has been reported in man.
7. **Oral hypoglycaemic agents or insulin**, as their action may be potentiated.
8. **Metrizamide** should be avoided since it may lower the seizure threshold.
9. **Antiepileptics**, since MAOIs possibly antagonise anticonvulsant effects of antiepileptics (convulsive threshold lowered).
10. **Antihistamines**, since antimuscarinic and sedative effects of antihistamines are increased by MAOIs.

Patients should be advised not to consume excessive amounts of caffeine in any form. Refer to section 4.3 for other foods and drinks to avoid while taking Parnate.

Effect on laboratory test  
No information available

#### **Paediatric population**

Interaction studies have only been performed in adults.

#### **4.6 Fertility, pregnancy and lactation**

##### **Pregnancy**

Adequate human data on use during pregnancy and adequate animal reproduction studies are not available. Parnate should not be used in pregnant women unless considered essential by the physician.

Use of any medicine in pregnancy requires that the potential benefits of the medicine be weighed against its possible hazards to mother and child. Animal reproductive studies show that tranylcypromine passes through the placental barrier into the foetus of the rat.



Epidemiological studies have suggested an increased risk of congenital abnormalities associated with use of antidepressants in pregnancy.

Neonates exposed to antidepressants late in the third trimester have shown drug withdrawal symptoms such as dyspnoea, lethargy, colic irritability, hypotension or hypertension and tremor or spasms.

Epidemiological data suggest that the use of antidepressants in pregnancy may be associated with an increase in pre-term delivery.

### **Breastfeeding**

Adequate human data on use during breastfeeding and adequate animal reproduction data are not available. Tranylcypromine is secreted into breast milk of lactating mothers but the clinical significance of this has not been fully evaluated.

Therefore, Parnate should be only be taken by women who are breastfeeding if clearly needed and if the potential benefits justify the potential risk.

### **Fertility**

No information available.

#### **4.7 Effects on ability to drive and use machines**

Parnate may affect ability to drive or operate machinery (see section 4.8).

#### **4.8 Undesirable effects**

***The most important adverse reaction associated with tranylcypromine is the occurrence of hypertensive crises which have sometimes been fatal.***

Cases of sudden paroxysmal rise in blood pressure have occurred, notably in association with foods containing tyramine (see section 4.3). These crises are characterised by some or all of the following symptoms: occipital headache which may radiate frontally, palpitation, neck stiffness or soreness, multiple extrasystoles, often with substernal pain, nausea or vomiting, sweating with early pallor, sometimes followed later by flushing. Either tachycardia or bradycardia may be present and associated mydriasis and photophobia may also occur. Throbbing headache may be an early warning of hypertensive crisis. This headache, together with pain and stiffness in the cervical muscles, may mimic subarachnoid haemorrhage but can equally be associated with actual intracranial bleeding, as in other conditions where a sudden rise in blood pressure occurs. Cases of such bleeding have been reported, some of which have been fatal.

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Therapy should be discontinued immediately upon the occurrence of palpitation or frequent headache during Parnate therapy. These signs may be prodromal of a hypertensive reaction. Patients should be instructed to report promptly the occurrence of headache or other symptoms.

Recommended treatment in hypertensive reactions

If a hypertensive reaction occurs, Parnate should be discontinued and therapy to lower blood pressure should be instituted immediately, if indicated. Headache tends to abate as blood pressure falls. On the basis of present evidence, phentolamine is recommended (the dosage reported for phentolamine is 5 mg I.V.). Reserpine should not be used. Care should be taken to administer phentolamine slowly in order to avoid producing an excessive hypotensive effect. Fever should be managed by means of external cooling. Other symptomatic and supportive measures may be desirable in particular cases. Acute symptoms generally subside within 24 hours.

Other undesirable effects

The most frequently seen side effect is insomnia, which can usually be overcome by giving the last dose of the day not later than 3 pm, by reducing the dose, or by prescribing a mild hypnotic. Occasional cases of dizziness, palpitation, weakness, fatigue, dry mouth and drowsiness have been reported as have nausea, vomiting, diarrhoea, abdominal pain, constipation, sleep disturbances and skin rash. Most of these effects can be relieved by lowering the dosage or by giving suitable concomitant medication.

Palpitations or unusually frequent headaches, unaccompanied by paroxysmal hypertension, may possibly be dose-related in some patients. Such symptoms may respond to reduction of dosage. If improvement is not rapid, the medicine should be discontinued.

Hypotension, which may be postural, has been observed during tranylcypromine therapy. Syncope has been rarely seen. Dosage should not be increased in the presence of hypotension. This adverse effect is usually temporary, but if it persists, the medicine should be discontinued. The blood pressure will then return rapidly to pre-treatment level.

Tachycardia, significant anorexia, oedema, blurred vision, chills and impotence have each been reported.

Impaired water excretion compatible with the syndrome of inappropriate antidiuretic hormone secretion (SIADH) has been reported.

Overstimulation, which may include increased anxiety and agitation, and manic symptoms, may sometimes occur with normal dosage but is more commonly associated with overdosage. Reduction of the dose is indicated. In certain instances it may be helpful to administer a sedative phenothiazine tranquilliser, such as chlorpromazine, concomitantly.

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There is a risk of dependency development, with tolerance to high doses, which can occur in patients without past history of drug dependence. This should be distinguished from the return of features of the original illness on cessation of treatment. Withdrawal symptoms may be anticipated.

Rare instances of hepatitis, hepatocellular damage, jaundice, hallucinations and blood dyscrasias have been reported.

Tinnitus, muscle spasm, tremors, myoclonic jerks, numbness, paraesthesia, urinary retention, micturation difficulty and retarded ejaculation have been reported.

Haematological disorders including anaemia, leukopenia, agranulocytosis, and thrombocytopenia have been reported.

Cases of suicidal ideation and suicidal behaviours have been reported during tranylcypromine therapy or early after treatment discontinuation (see section 4.4).

**Paediatric population**

For information about neonate withdrawal see section 4.6 - Fertility, pregnancy and lactation - Pregnancy section.

The following symptoms: anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness), impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adolescent and paediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric (see section 4.4).

**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://nsphvc.otago.ac.nz/reporting/>.

**4.9 Overdose****Symptoms**

The characteristic symptoms that may be caused by overdosage are usually those described in section 4.4. Tachycardia, sweating and hyperpyrexia with restlessness and excitement are usually produced. Tremor, convulsions, depression, stupor or coma may however be present or develop. Blood pressure may be raised, but hypotension may supervene.

**Treatment**

Gastric lavage is helpful if performed early. Treatment should normally consist of general supportive measures, close observation of vital signs and steps to counteract specific symptoms as they occur since MAO inhibition may persist. The management of hypertensive reactions is described under section 4.8.

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External cooling is recommended if hyperpyrexia occurs. Barbiturates have been reported to help myoclonic reactions, but frequency of administration should be controlled carefully because tranylcypromine may prolong barbiturate activity. When hypotension requires treatment, the standard measures for managing circulatory shock should be initiated. If pressor agents are required, noradrenaline is the most suitable; however, its action may be potentiated, and the rate of infusion should be regulated by careful observation of the patient. Metaraminol may be required if marked refractory hypotension occurs (left ventricular failure should be excluded).

A successful recovery following haemodialysis after a self-administered overdose of 350 mg of tranylcypromine has been reported.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

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## **5 PHARMACOLOGICAL PROPERTIES**

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### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: non-selective monoamine oxidase inhibitors  
ATC code: N06AF04

#### **Pharmacodynamic effects**

Tranylcypromine is a non-hydrazine monoamine oxidase inhibitor with a rapid onset of activity. It increases the concentration of adrenaline (epinephrine), noradrenaline (norepinephrine), and serotonin in storage sites throughout the nervous system and in theory this increased concentration of monoamines in the brainstem is the basis for its antidepressant activity. When tranylcypromine is withdrawn, monoamine oxidase activity is recovered in 3 to 5 days, although the drug is excreted in 24 hours.

### **5.2 Pharmacokinetic properties**

Tranylcypromine is rapidly absorbed from the gastrointestinal tract following oral administration and distributed widely throughout the body. Peak plasma concentrations occur within 1 hour of dosing. The drug is excreted in the urine, mainly in the form of metabolites.

### **5.3 Preclinical safety data**

No further information of clinical relevance.

#### **Carcinogenicity**

No information available.

#### **Genotoxicity**

No information available.

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## **6 PHARMACEUTICAL PARTICULARS**

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### **6.1 List of excipients**

Parnate film-coated tablets contain the following excipients:

Calcium sulfate dihydrate

Maize starch

Sucrose

Erythrocine CI 45430

Magnesium stearate

Gelatin

Opadry Red 06H250000

Carnauba wax

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf-life**

24 months.

### **6.4 Special precautions for storage**

Store below 25°C.

### **6.5 Nature and contents of container**

Parnate is supplied in PVC/PVDC blister packs of 50 tablets.

### **6.6 Special precautions for disposal**

No special requirements for disposal.

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## **7 MEDICINE SCHEDULE**

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Prescription Medicine

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## **8 SPONSOR**

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Boucher & Muir (NZ) Ltd t/a Mercury Pharma (NZ)  
39 Anzac Road  
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Phone 0800 565 633

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## **9 DATE OF FIRST APPROVAL**

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Date of publication in the New Zealand Gazette of consent to distribute the medicine:  
31 December 1969

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## **10 DATE OF REVISION OF THE TEXT**

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24 April 2019

Summary table of changes:

<b>Section changed</b>	<b>Summary of new information</b>
All	Format update only.