NEW ZEALAND DATA SHEET

SUMAGRAN®

1. Product Name

SUMAGRAN, 50 mg and 100 mg, film coated tablets.

2. Qualitative and Quantitative Composition

SUMAGRAN 50mg
Each film coated tablet contains 50 mg sumatriptan (as succinate).

SUMAGRAN 100mg
Each film coated tablet contains 100 mg sumatriptan (as succinate).

Excipient with known effect: lactose.

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

50 mg: A pink, round, film-coated tablet debossed ‘SU50’ on one side and a ‘G’ on the other.

100 mg: A white, round, film-coated tablet debossed ‘SU100’ on one side and a ‘G’ on the other.

4. Clinical Particulars

4.1 Therapeutic indications

SUMAGRAN film-coated tablets are indicated for the acute relief of migraine attacks with or without aura.

There is no information available on the use of SUMAGRAN in the treatment of basilar or hemiplegic migraine.

4.2 Dose and method of administration

SUMAGRAN tablets are indicated for the acute intermittent relief of migraine headaches. It should not be used prophylactically.

Ergotamine or ergotamine derivatives and SUMAGRAN should not be administered concurrently.

Dose

It is recommended to start treatment at the first sign of migraine headache or associated symptoms such as nausea, vomiting or photophobia. The efficacy of sumatriptan is independent of the duration of the attach when starting treatment. Administration during a migraine aura prior to other symptoms occurring may not prevent the development if a headache.

If a patient does not respond to the first dose of SUMAGRAN, a second dose should not be taken for the same attack. SUMAGRAN may be taken for subsequent attacks.

The initial recommended adult dose of oral SUMAGRAN is a single 50 mg tablet. Some patients may require 100 mg. The dose should be adjusted according to the individual's response.

If the symptoms recur further doses may be given in the next 24 hours, provided that not more than 300 mg is taken in any 24 hour period.

Special populations

Elderly (Over 65)

Experience of the use of sumatriptan in patients aged over 65 years is limited. The pharmacokinetics do not differ significantly from a younger population, but until further clinical data are available, the use of sumatriptan in patients aged over 65 years is not recommended.

Paediatric

The safety and effectiveness of sumatriptan in children has not yet been established.

Method of administration

The tablets should be swallowed whole with water.

4.3 Contraindications

SUMAGRAN should not be used in patients who have:

- Hypersensitivity to any component of the preparation (See Section 6.1 List of excipients).
- A history of myocardial infarction
- Peripheral vascular disease or symptoms or signs consistent with ischaemic heart disease (IHD),
- Prinzmetal's angina/coronary vasospasm,
- Uncontrolled hypertension
- Cerebrovascular accident (CVA) or transient ischaemic attack (TIA).
- Severe hepatic impairment.

SUMAGRAN should not be used within 24 hours of treatment with an ergotamine-containing or ergot-type medication such as dihydroergotamine or methysergide.

SUMAGRAN should not be given to patients receiving monoamine oxidase inhibitors (MAOIs) or within two weeks of discontinuation of MAOI therapy.

SUMAGRAN should not be administered to patients with hemiplegic, basilar or ophthalmoplegic migraine.

4.4 Special warnings and precautions for use

SUMAGRAN should only be used where there is a clear diagnosis of migraine. However, if a patient does not respond to the first dose, the opportunity should be taken to review the diagnosis before a second dose is given. The recommended doses of SUMAGRAN should not be exceeded.

Drowsiness

Drowsiness may occur as a result of migraine or its treatment with SUMAGRAN. Caution is recommended in patients performing skilled tasks, e.g. driving or operating machinery.

Use in hepatic or renal impairment

Sumatriptan should be administered with caution to patients with diseases which may affect significantly the absorption, metabolism or excretion of the medicine, such as impaired hepatic or renal function. Studies have shown reduced sumatriptan clearance in patients with hepatic

impairment. Lower doses should be considered in these patients. If appropriate, the first dose should be given under supervision to these patients.

Hypersensitivity to sulphonamides

Patients with known hypersensitivity to sulphonamides may exhibit an allergic reaction following administration of sumatriptan. Reactions may range from cutaneous hypersensitivity to anaphylaxis. Evidence of cross sensitivity is limited, however, caution should be exercised before using sumatriptan in these patients.

Overuse

Overuse of acute migraine treatments has been associated with the exacerbation of headache (medication overuse headache, MOH) in susceptible patients. Withdrawal of the treatment may be necessary.

Co-administration with 5-HT1 agonists

Co-administration of sumatriptan within 24 hours of other 5-HT1 agonists is not recommended due to the potential for vasoconstrictive effects.

Cardiovascular precautions

It is strongly recommended that sumatriptan should not be given to patients in whom risk factors indicate a possibility of unrecognised coronary artery disease (CAD) unless a cardiovascular evaluation provides satisfactory clinical evidence that the patient is reasonably free of coronary artery and ischaemic myocardial disease or other significant underlying cardiovascular disease. The risk factors include hypertension, hypercholesterolaemia, smoker, obesity, diabetes, strong family history of CAD, female with surgical or physiological menopause or males over 40 years of age. The sensitivity of cardiac diagnostic procedures to detect cardiovascular disease or predisposition to coronary artery vasospasm is modest at best and in rare cases (less than 1 in 10,000), serious cardiac events have occurred in patients without underlying cardiovascular disease. If during the cardiovascular evaluation, the patient's medical history of electrocardiographic investigations reveal findings indicative of, or consistent with coronary artery vasospasm or myocardial ischaemia, sumatriptan should not be administered (see Section 4.3 Contraindications).

Sumatriptan may cause short lived elevation of blood pressure and peripheral vascular resistance. Sumatriptan should therefore be administered with caution to patients with controlled hypertension. Transient increases in blood pressure and peripheral vascular resistance have been observed in a small proportion of patients.

Serious cardiac events, including some that have been fatal, have occurred within a few hours following the use of sumatriptan Injection or Tablets. These events are extremely rare (less than 1 in 10,000) and the majority of these case reports were confounded by patients having pre-existing heart disease or risk factors for ischaemic heart disease and may reflect underlying disease and spontaneous events. Under these circumstances the specific contribution of sumatriptan cannot be determined. Events reported have included coronary artery vasospasm, transient myocardial ischaemia, myocardial infarction, and cardiac arrhythmias including ventricular tachycardia and ventricular fibrillation. Therefore, sumatriptan should not be given to patients in whom unrecognised cardiac disease is likely without a prior evaluation for underlying cardiovascular disease. Such patients include postmenopausal women, males over 40 and patients with risk factors for coronary artery disease. Significant cardiovascular sequelae have been reported in patients in whom risk factors were not readily identifiable. There is no experience in patients with recent cardiac arrhythmias (especially tachycardias). Until further information is available, the use of sumatriptan is not recommended in these patients.

A myocardial infarct has been reported in a 14 year old male following the use of oral sumatriptan; clinical signs occurred within 1 day of drug administration.

Following administration, sumatriptan can be associated with transient symptoms, including chest pain and tightness, which may be intense and involve the throat. If symptoms consistent with ischaemic heart disease occur, appropriate investigations should be carried out and further doses should not be given until the results of these investigations are known. Patients should be advised to contact their doctor immediately if they experience symptoms consistent with ischaemic heart disease (see Section 4.3 Contraindications).

Cerebrovascular precautions

Cerebral haemorrhage, subarachnoid haemorrhage, stroke, and other cerebrovascular events have been reported in patients treated with oral or subcutaneous sumatriptan, and some have resulted in fatalities. The relationship of sumatriptan to these events is uncertain. In a number of cases, it appears possible that the cerebrovascular events were primary, sumatriptan having been administered in the incorrect belief that the symptoms experienced were a consequence of migraine when they were not. Sumatriptan should not be administered if the headache being experienced is atypical of the patient. It should be noted that patients with migraine may be at increased risk of certain cerebrovascular events (e.g. cerebrovascular accident, transient ischaemia attack).

Before treating headaches in patients not previously diagnosed as migraineurs, and in migraineurs who present with atypical symptoms, care should be taken to exclude other potentially serious neurological conditions.

Sumatriptan should be used with caution in patients with a history of seizures or other risk factors which lower the seizure threshold.

There is no experience in patients with recent cerebrovascular accidents. Until further information is available, the use of sumatriptan is not recommended in these patients (see Section 4.3 Contraindications).

There is no information available on the use of sumatriptan in the treatment of ophthalmoplegic migraine.

Other vasospastic events

Sumatriptan may cause vasospastic reactions other than coronary artery vasospasm. Both peripheral vascular ischaemia and colonic ischaemia with abdominal pain and bloody diarrhoea have been reported.

Use in adolescents (12-17 years)

The efficacy of oral sumatriptan has not been established in placebo-controlled trials carried out in 794 adolescent migraineurs. High placebo responses were found in these studies and there was a lack of statistically significant difference between placebo and oral doses ranging from 25 to 100 mg. The safety profile of oral and intranasal sumatriptan is similar to that of adults.

Paediatric use

The safety and effectiveness of sumatriptan in children under the age of 12 years has not been established.

Use in the elderly

Experience of the use of sumatriptan in patients aged over 65 is limited. However, the pharmacokinetics do not differ significantly from a younger population. Until further clinical data are available, the use of sumatriptan in patients aged over 65 is not recommended.

The recommended dose of SUMAGRAN should not be exceeded.

Effects on laboratory tests

No data available

4.5 Interaction with other medicines and other forms of interaction

Pharmacodynamic

Prolonged vasospastic reactions have been reported with ergotamine. As these effects may be additive, concomitant use of ergotamine or ergotamine derivatives and sumatriptan should be avoided. Twenty-four hours should elapse before sumatriptan can be taken following any ergotamine containing preparation. Conversely, ergotamine containing preparations should not be taken until 6 hours have elapsed following sumatriptan administration (see Section 4.3 Contraindications).

Pharmacokinetic

An interaction may occur between sumatriptan and MAOIs and concomitant administration is contraindicated (see Section 4.3 Contraindications). Rarely an interaction may occur between sumatriptan and selective serotonin reuptake inhibitors (SSRIs).

There have been rare post-marketing reports describing patients with serotonin syndrome (including altered mental status, autonomic instability, neuromuscular abnormalities, weakness, hyper-reflexia and incoordination) following the use of a SSRI. Serotonin syndrome has been reported following concomitant treatment with triptans and serotonin noradrenaline reuptake inhibitors (SNRIs).

If concomitant treatment with sumatriptan and an SSRI/SNRI is clinically warranted, appropriate observation of the patient is advised.

The concomitant administration of any triptan/5-HT1 agonist with sumatriptan is not recommended.

There is no evidence of interactions with propranolol, flunarizine, pizotifen or alcohol.

Although there is no clear evidence, it is possible that an interaction may occur between serotonin 5-HT1 agonists and the herbal remedy St John's Wort (hypericum perforatum), which may result in an increase in side effects.

Ophthalmic

Intermittent transient changes on the surface of the cornea have been observed in toxicology studies in dogs. No causative mechanism has been established for these changes but there is no evidence to suggest that this is relevant to clinical exposure.

In studies carried out to test for local and ocular irritancy, following administration of sumatriptan nasal spray, there was no irritancy seen in laboratory animals and no ocular irritancy observed when the spray was applied directly to the eyes of rabbits.

4.6 Fertility, pregnancy and lactation

Pregnancy

Category B3

No obvious teratogenic effects have been seen in rats given oral doses of 500 mg/kg and intravenous doses up to 12.5 mg/kg or in rabbits given oral doses up to 100 mg/kg and intravenous doses up to 8 mg/kg during organogenesis (although it is noted that the number of pregnant rabbits investigated was limited).

Reproduction studies in rats have not revealed any clear evidence of impaired fertility (oral doses up to 500 mg/kg, subcutaneous doses up to 60 mg/kg, given before and during mating) or of impaired post-natal pup development (oral doses up to 1000 mg/kg, subcutaneous doses up to 81 mg/kg, given during the peri and post-natal period). In the rabbit embryotoxicity cannot be ruled out. After oral administration, at doses of 5, 25 and 100 mg/kg on days 8-20 of gestation (severe maternal toxicity at 100 mg/kg) there was evidence of a small, increasing dose-related trend in post-implantation intrauterine death with a similar, and significant trend being recorded after intravenous treatment (0.5 to 8 mg/kg, days 8-20 of gestation).

Term foetuses from Dutch Stride rabbits treated during the period of organogenesis with oral sumatriptan exhibited an increased incidence of cervicothoracic vascular defects and skeletal abnormalities.

When administered to pregnant rabbits throughout the period of organogenesis sumatriptan has occasionally caused embryolethality at doses which were sufficiently high to produce maternal toxicity.

Administration of this medicine should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Breast-feeding

Sumatriptan is excreted in breast milk in animals. In rats given oral sumatriptan at 1000 mg/kg during the lactation period, 3 dams out of 20 showed total litter loss whilst in another litter, only 9/15 survived to the end of nursing. It has been demonstrated that following subcutaneous administration sumatriptan is excreted into breast milk. Infant exposure can be minimised by avoiding breast feeding for 24 hours after treatment. Caution should be exercised when considering the administration of sumatriptan to a breast-feeding woman.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Drowsiness may occur as a result of migraine or its treatment with sumatriptan. This may influence the ability to drive and to operate machinery.

4.8 Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (>1/10), common (>1/100, <1/10), uncommon (>1/1000, <1/100), rare (>1/10,000, <1/1000) and very rare (<1/10,000) including isolated reports. The data from clinical trials are estimates. It should be noted that the background rate in comparator groups was not taken into account. Post-marketing data refer to reporting rate rather than true frequency.

The most common side effects associated with treatment with sumatriptan are:

- Pain, sensations of tingling, heat or cold, heaviness, pressure or tightness. These are usually transient and may be intense and can affect any part of the body including the chest and throat.
- Flushing, dizziness and feelings of weakness. These are mostly mild to moderate in intensity and transient.
- Fatigue, drowsiness, sensory disturbance including paraesthesia and hypoaesthesia have been reported.
- Nausea and vomiting occurred in some patients but the relationship to sumatriptan is not clear.
- Transient increases in blood pressure arising soon after treatment have been recorded.
- Dyspnoea

Serious coronary events have been reported (see Section 4.4 Special warnings and precautions for use). Other cardiovascular adverse reactions include hypotension, bradycardia, tachycardia and palpitations. Very rarely (less than 1 in 10,000) Raynaud's phenomenon, angina and ischaemic colitis have been reported.

There have been rare (less than 1 in 1,000) reports of seizures following migraine attacks treated with sumatriptan. Although some have occurred in patients with either a history of seizures or concurrent conditions predisposing to seizures, there are also reports in patients where no such predisposing factors are apparent.

Patients treated with sumatriptan very rarely (less than 1 in 10,000) exhibit visual disorders like flickering and diplopia. Additionally, cases of nystagmus, scotoma and reduced vision have been observed. Very rarely loss of vision has occurred, which is usually transient. However, visual disorders may also occur during a migraine attack itself.

Hypersensitivity reactions ranging from cutaneous hypersensitivity (e.g. rash, urticaria, pruritus or erythema) to, in rare (less than 1 in 10,000) cases, anaphylaxis have been recorded (see Section 4.4 Special warnings and precautions for use).

Minor disturbances of liver function tests have occasionally been observed. There is no evidence that clinically significant abnormalities occurred more frequently than with placebo.

In the clinical trial programme, decreased lymphocyte count post treatment was observed in a number of patients receiving either oral or subcutaneous sumatriptan. This effect was not dose related and was also observed in patients receiving placebo. The significance of these findings is uncertain.

In the clinical trial programme, a similar profile of clinical adverse events was reported in the adolescent and adult populations taking sumatriptan tablets or nasal spray.

Post-Marketing Data

In addition to the drug-related adverse reactions reported from clinical trials, the following serious spontaneous events, reported to be possibly, probably or almost certainly caused following use of either subcutaneous, oral or intranasal sumatriptan in patients less than 18 years of age have been identified.

Cardiovascular: myocardial infarction

Cerebrovascular: cerebellar infarction

Neurology: seizures, tremor & dystonia

Non-site specific: anaphylaxis

Skin: urticaria, rash

General disorders: “Pain trauma activated” and “Pain inflammation activated” – frequency unknown

Table 1: Incidence of Treatment-Emergent* Adverse Events (%) Reported by at least 1% of Patients and all Cardiovascular Events Irrespective of Frequency in Controlled Clinical Trials with Sumatriptan Tablets and Injection.

Event	Tablets (n=1456)	Placebo (n=296)	Subcutaneous Injection (n=2665)	Placebo (n=868)
Atypical:				
tingling	1	<1	9	3
warm/hot sensation	1	<1	9	3
burning sensation	<1	0	5	<1

Event	Tablets (n=1456)	Placebo (n=296)	Subcutaneous Injection (n=2665)	Placebo (n=868)
numbness	2	1	3	2
feeling strange	0	0	1	<1
cold sensation	1	<1	1	<1
Gastrointestinal:				
nausea/vomiting	14	7	10	10
gastric symptoms, abdominal discomfort	3	3	1	<1
dysphagia	1	0	<1	<1
Neurological:				
dizziness/vertigo	6	2	8	4
malaise/fatigue	9	3	3	1
drowsiness/sedation	3	1	3	1
paraesthesia	1	0	1	<1
headache	1	1	2	<1
syncope	1	0	<1	<1
Cardiovascular:				
flushing	<1	1	6	2
hypertension, tachycardia	<1	0	2	<1
bradycardia	<1	0	<1	0
palpitations	1	<1	<1	<1
hypotension	<1	0	<1	<1
pallor	<1	0	<1	<1
pulsating sensation	<1	0	<1	<1
changes in ECG	0	0	<1	0
Symptoms Potentially of Cardiac Origin:				
neck pain/stiffness	3	0	3	<1
feeling of heaviness	3	1	8	1
feeling of tightness	1	0	3	<1
tight feeling in head	<1	0	1	<1
pressure sensation	1	<1	6	1
chest symptoms (including chest pain)	3	<1	5	1
throat symptoms (including sore or swollen throat or throat spasms)	3	0	2	<1
Musculoskeletal:				
Weakness	3	<1	3	<1
Myalgia	2	<1	1	<1
Ear, Nose and Throat:				
disturbance of nasal cavity/sinuses	<1	1	1	<1
Miscellaneous:				

Event	Tablets (n=1456)	Placebo (n=296)	Subcutaneous Injection (n=2665)	Placebo (n=868)
injection site reactions	NA	NA	40	17
Sweating	2	<1	2	1
disorder of mouth and tongue	2	<1	4	2
disturbance of taste	11	3	1	2
dyspnoea	1	0	<1	<1

*Includes all events regardless of causality that occurred at a frequency of ≥ 1% in any sumatriptan treatment group and were more frequent in this group than in the placebo group.
NA Not Applicable.

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

There is no experience of doses in excess of 400 mg orally. Oral doses up to 400mg were not associated with side effects other than those mentioned in section 4.8.

If overdosage occurs, the patient should be monitored for at least ten hours and standard supportive treatment applied as required.

It is unknown what effect haemodialysis or peritoneal dialysis has on the plasma concentrations of sumatriptan.

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

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics, selective 5-HT_1 receptor agonists.

ATC code: N02CC01

Mechanism of action

Sumatriptan has been demonstrated to be a selective vascular 5-hydroxytryptamine-1-($5HT_1$) receptor agonist with no effect at other 5HT receptor ($5HT_2$ - $5HT_7$) subtypes. The vascular $5HT_1$ receptor is found predominantly in cranial blood vessels and mediates vasoconstriction.

In animals sumatriptan selectively constricts the carotid arterial circulation but does not alter cerebral blood flow. The carotid arterial circulation supplies blood to the extracranial and intracranial tissues such as the meninges and dilatation and/or oedema formation in these vessels is thought to be the underlying mechanism of migraine in man. In addition, experimental evidence suggests that sumatriptan inhibits trigeminal nerve activity. Both these actions may contribute to the anti-migraine action of sumatriptan in humans.

Clinical trials

The following table demonstrates 2 and 4 hour efficacy results in two placebo-controlled studies of sumatriptan tablets in 332 adult migraineurs experiencing moderate or severe pain.

Table 2: Efficacy Data for Placebo-controlled Studies of Sumatriptan tablets‡

	Study 1			Study 2		
	Placebo (n=65)	Sumatriptan 50 mg (n=62)	Sumatriptan 100 mg (n=68)	Placebo (n=47)	Sumatriptan 50 mg (n=46)	Sumatriptan 100 mg (n=46)
Results at 2 hours						
Patients with pain relief^	26%	50%*	56%*	17%	54%*	57%*
Patients with no pain	8%	16%	23%*	6%	17%	24%*
Patients with meaningful relief#	34%	55%*	56%*	21%	54%*	57%*
Patients without nausea	57%	68%	65%	40%	61%	72%*
Patients without photophobia	22%	37%*	44%*	13%	26%	39%*
Patients with little or no clinical disability##	35%	60%*	59%*	28%	52%*	67%*
Results at 4 hours						
Patients with pain relief^	38%	68%*	71%*	19%	72%*	78%*
Patients with no pain	15%	32%*	52%*	11%	41%*	41%*
Patients with meaningful relief#	45%	71%*	79%*	26%	72%*	83%*
Patients without nausea	60%	79%*	83%*	45%	70%*	91%*
Patients without photophobia	40%	66%*	71%*	28%	65%*	65%*

	Study 1			Study 2		
	Placebo (n=65)	Sumatriptan 50 mg (n=62)	Sumatriptan 100 mg (n=68)	Placebo (n=47)	Sumatriptan 50 mg (n=46)	Sumatriptan 100 mg (n=46)
Patients with little or no clinical disability##	40%	71%*	71%*	23%	70%*	83%*

^ Pain relief defined as a reduction in headache severity from moderate or severe pain to mild or no pain.
# Meaningful relief is a patient assessment of when he/she felt onset of relief of headache pain.
A successful outcome in terms of clinical disability was defined prospectively as ability to work mildly impaired or ability to work and function normally.
* P<0.05 versus placebo.
‡ Patients were administered either the 50 mg or 100 mg tablet according to the recommended dosing regimen (see 4.2 Dose and method of administration). The dose of the tablet was not titrated.

5.2 Pharmacokinetic properties

The pharmacokinetics of oral sumatriptan do not appear to be significantly affected by migraine attacks. In a pilot study no, significant differences were found in the pharmacokinetic parameters between elderly and young healthy volunteers.

Absorption

After oral administration, sumatriptan is rapidly absorbed, 70% of maximum concentration occurring at 45 minutes. After a 100 mg dose the mean maximum plasma concentration is 54 ng/mL.

Mean absolute oral bioavailability is 14% partly due to pre-systemic metabolism and partly due to incomplete absorption.

Oral absorption of sumatriptan is not significantly affected by food.

Distribution

Plasma protein binding is low (14 - 21%); the mean total volume of distribution is 170 litres.

Biotransformation

The major metabolite, the indole acetic acid analogue of sumatriptan is mainly excreted in urine, where it is present as a free acid and the glucuronide conjugate. It has no known $5HT_1$ or $5HT_2$ activity. Minor metabolites have not been identified.

Elimination

The elimination half-life is approximately 2 hours. The mean total plasma clearance is approximately 1160 mL/min and the mean renal plasma clearance is approximately 260 mL/min.

Non-renal clearance accounts for about 80% of the total clearance. Sumatriptan is eliminated primarily by oxidative metabolism mediated by monoamine oxidase A.

Special Patient Populations

Hepatic impairment

Following oral administration, pre-systemic clearance is reduced in patients with hepatic impairment resulting in increased plasma levels of sumatriptan.

5.3 Preclinical safety data

Genotoxicity

No data available

Carcinogenicity

No data available

6. Pharmaceutical Particulars

6.1 List of excipients

SUMAGRAN film coated tablets also contain:

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- titanium dioxide
- polydextrose
- hypromellose
- glycerol triacetate
- polyethylene glycol
- iron oxide red (50 mg only)
- iron oxide yellow (50 mg only)

Contains sugars as lactose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

4 years

6.4 Special precautions for storage

Store at or below 25°C.

6.5 Nature and contents of container

Blister pack, Al/Al. Pack-sizes of 4, 90 or 100 film coated tablets.

Blister pack, Al/Al. Pack-sizes of 2, 90 or 100 film coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable

7. Medicines Schedule

Prescription Medicine

8. Sponsor Details

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

9. Date of First Approval

03 August 2006

10. Date of Revision of the Text

27 March 2023

Summary table of changes

Section	Summary of new information
2	Minor reformatting.
6.1	Added statement: ‘Contains sugars as lactose.’
-	Attribution statement included for trade mark.

Sumagran® is a Viatris company trade mark.