NEW ZEALAND DATA SHEET

1. PRODUCT NAME
Clustran, Solution for injection, 6 mg/0.5 mL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each mL contains sumatriptan (as succinate) 6 mg in 0.5 mL.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for injection.

A clear colourless to pale yellow solution filled in a prefilled syringe, in an autoinjector drug delivery device.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Clustran is indicated for the acute relief of migraine attacks with or without aura.

Clustran is also indicated for the acute treatment of cluster headaches.

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

4.2 Dose and method of administration
Dose

Product is for single use in one patient only. Discard any residue.

Clustran is indicated for the acute intermittent relief of both migraine and cluster headache. It should not be used prophylactically.

Migraine

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

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

The recommended adult dose of Clustran is a single 6 mg, subcutaneous injection. If symptoms recur a further subcutaneous dose of 6 mg may be given at any time in the next 24 hours provided that one hour has elapsed since the first dose. The maximum dose in 24 hours is 2 x 6 mg injections (12 mg).

Cluster Headache

The recommended adult dose is a single 6 mg subcutaneous injection for each cluster attack. The maximum dose in 24 hours is two 6 mg injections (12 mg) providing at least one hour has elapsed between injections.

For information on use in children, adolescents and elderly, see Section 4.4 Special warnings and precautions for use.

Method of administration

Clustran should be injected subcutaneously. Patients should be advised to observe strictly the instruction leaflet for the Clustran, especially regarding the safe disposal of the pen device (autoinjector).

The first dose of Clustran should be given by, or under the direct supervision of, a physician. As with the administration of the first dose of any injectable therapeutic product, appropriate resuscitative equipment should be available. Appropriate advice on the future use of Clustran by the patient should also be given at this time. The physician should ensure that the patient is familiar with and understands the Consumer Medicine Information.

Ergotamine or ergotamine derivatives and Clustran should not be administered concurrently (see Section 4.3 Contraindications).

4.3 Contraindications

Sumatriptan 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
- Prinzmetal's angina/coronary vasospasm
- Uncontrolled hypertension
- Cerebrovascular accident (CVA) or transient ischaemic attack (TIA)
- Severe hepatic impairment

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

Sumatriptan should not be administered to patients with severe hepatic impairment.

Sumatriptan should not be given to patients receiving monoamine oxidase inhibitors (MAOIs) or within two weeks of discontinuation of MAOI therapy. (see Section 4.5 Interactions with other medicines and other forms of interactions)

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

4.4 Special warnings and precautions for use

General

Sumatriptan 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 sumatriptan should not be exceeded.

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

Sumatriptan should also be administered with caution to patients with diseases which may affect significantly the metabolism, absorption and excretion of the drug, 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.

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 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.

Reversible cerebral vasoconstriction syndrome (thunderclap headache) has been reported with use of serotonergic agents such as SSRIs or triptans (see Section 4.5 Interaction with other medicines and other forms of interactions).

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

Cardiovascular

It is strongly recommended that sumatriptan 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 male 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 extremely 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. 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.

When given intravenously sumatriptan can cause angina in susceptible patients. Sumatriptan injection should therefore not be given intravenously.

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
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 (eg. 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.

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.

Use in the Elderly
Patients Over 65 Years

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.

Paediatric Use
Adolescents (12-17 years) and Children (under 12 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. The safety and effectiveness of sumatriptan in children under the age of 12 years has not been established.

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 is 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. 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. Seretonin syndrome has been reported following concomitant treatment with triptans and serotonin noradrenaline reuptake inhibitors (SNRIs).

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

The concomitant administration of any triptan/5-HT_1 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-HT_1 agonists and the herbal remedy St John's Wort (hypericum perforatum), which may result in an increase in side effects.

Effects on laboratory

No data available.

4.6 Fertility, pregnancy and lactation

Use in 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).

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.

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.

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

Use in Lactation
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 breastfeeding 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
Drowsiness may occur as a result of migraine or treatment with sumatriptan.

Caution is recommended in patients performing skilled tasks, eg. driving or operating machinery.

4.8 Undesirable effects
The most common side effect associated with treatment with sumatriptan administered subcutaneously is:

- transient pain at the site of injection.
- stinging/burning, swelling, erythema, bruising and bleeding at the injection site have also been reported.

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.

Although direct comparisons are not available, nausea, vomiting and fatigue appear to be less frequent with subcutaneous administration of sumatriptan, than with tablets. Conversely, flushing, parasthesia and sensations of tingling, heat or cold, pressure and heaviness may be more common after the injection.

Serious coronary events have been reported. (see Section 4.4 Special warnings and precautions for use).

Serious cardiac events, including some that have been fatal, have occurred within a few hours following the use of sumatriptan Injection. 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.

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 (eg. 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 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

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 Injection.

Event	Subcutaneous Injection (n = 2665)	Placebo (n = 868)
Atypical		
tingling	9	3
warm/hot sensation	9	3
burning sensation	5	<1
numbness	3	2
feeling strange	1	<1
cold sensation	1	<1
Gastrointestinal		
nausea/vomiting	10	10
gastric symptoms, abdominal discomfort	1	<1
dysphagia	<1	<1
Neurological		
dizziness/vertigo	8	4
malaise/fatigue	3	1
drowsiness/sedation	3	1
paraesthesia	1	<1
headache	2	<1
syncope	<1	<1
Cardiovascular		
flushing	6	2
hypertension/tachycardia	2	<1
bradycardia	<1	0
palpitations	<1	<1
hypotension	<1	<1
pallor	<1	<1
pulsating sensation	<1	<1
changes in ECG	<1	0
Symptoms Potentially of Cardiac Origin		
neck pain/stiffness	3	<1
feeling of heaviness	8	1
feeling of tightness	3	<1
tight feeling in head	1	<1
pressure sensation	6	1
chest symptoms (including chest pain)	5	1
throat symptoms (including sore or swollen throat or throat spasms)	2	<1
Musculoskeletal		
weakness	3	<1
myalgia	1	<1
Ear, Nose and Throat		
disturbance of nasal cavity/sinuses	1	<1
Miscellaneous		
injection site reactions	40	17
sweating	2	1
disorder of mouth and tongue	4	2
disturbance of taste	1	2
dyspnoea	<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.

Additional adverse effects not observed in the subcutaneous injection dosage form, which were observed in other dosage forms at an incidence above that of placebo are listed below:

Tablets and nasal spray: palpitations, disturbance of taste, nausea/vomiting;

Nasal spray: throat and tonsil signs and symptoms, burning/stinging sensation;

Tablets: dysphagia, syncope, hypotension, pallor, pulsating sensation, dyspnoea.

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 have been some reports of overdosage with sumatriptan injection. Patients have received single injections of up to 12 mg subcutaneously without significant adverse effects. Single doses of up to 40 mg intranasally, up to 16 mg subcutaneously, and up to 400mg with sumatriptan tablets orally, were not associated with side effects other than those mentioned. There is no experience of doses greater than these.

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

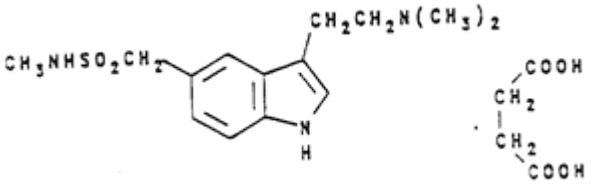
It is unknown what effect haemodialysis or peritoneal dialysis has on the plasma concentrations of sumatriptan.

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

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Analgesics, selective 5-HT_1 receptor agonists; ATC code: N02CC01.

Chemical Name: 3-[2-(dimethylamino)ethyl]-N-methyl-1H-indole-5-methane sulphonamide, butane-1,4-dioate (1:1)

Chemical Structure:



Sumatriptan succinate

Molecular Formula: $C_{14}H_{21}N_3O_2SC_4H_6O_4$
Relative molecular mass: 413.5
CAS Registry number: 103628-48-4

Mechanism of action

Sumatriptan has been demonstrated to be a specific 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 Efficacy and Safety

Clinical Studies Conducted In The Adult Population

Table 2 shows 1 and 2 hour efficacy results for two placebo-controlled trials of sumatriptan injection in 1,104 adult migraineurs with moderate or severe migraine pain.

Table 2: Efficacy Data for Phase III Placebo-controlled Trials of Sumatriptan Injection‡

Results at 1 hour	Study 1		Study 2	
	Placebo (n = 190)	Sumatriptan 6 mg (n = 384)	Placebo (n = 180)	Sumatriptan 6 mg (n = 350)
Patients with pain relief^	18%	70%*	26%	70%*
Patients with no pain	5%	48%*	13%	49%*
Patients without nausea	48%	73%*	50%	73%*
Patients without photophobia	23%	56%*	25%	58%*
Patients with little or no clinical disability	34%	76%*	34%	76%*
Results at 2 hours	Study 1		Study 2	
	Placebo+	Sumatriptan 6 mg++	Placebo+	Sumatriptan 6 mg++
Patients with pain relief^	31%	81%*	39%	82%*
Patients with no pain	11%	63%*	19%	65%*
Patients without nausea	56%	82%*	63%	81%*
Patients without photophobia	31%	72%*	35%	71%*
Patients with little or no clinical disability	42%	85%*	49%	84%*

^ Pain relief defined as a reduction in headache severity from moderate or severe pain to mild or no pain.

\+ Includes patients that may have received additional placebo injection 1 hour after the initial injection.

++ Includes patients that may have received an additional 6 mg of sumatriptan injection 1 hour after the initial injection.

* $P<0.05$ versus placebo.

‡ Patients were administered the study drug according to the recommended dosing regimen (see Section 4.2 Dose and method of administration).

5.2 Pharmacokinetic properties

Absorption

Following subcutaneous injection, sumatriptan has a high mean bioavailability (96%) with peak serum concentrations occurring in 25 minutes. Average peak serum concentration after a 6 mg subcutaneous dose is 72 ng/mL.

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.

Metabolism

Sumatriptan is eliminated primarily by oxidative metabolism mediated by monoamine oxidase A. The major metabolite, the indole acetic acid analogue of sumatriptan, is mainly excreted in the 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.

Excretion

The elimination phase half-life is approximately 2 hours. Non-renal clearance accounts for about 80% of the total clearance. The major metabolite, the indole acetic acid analogue of sumatriptan, is mainly excreted in the urine.

The pharmacokinetics of oral or intranasal 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.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Water for injections.

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C. Brief temperature excursions above or below 25°C permitted. Protect from light.

6.5 Nature and contents of container

Pre-filled pen (autoinjector) that contains 0.5 mL solution in a clear Type 1 glass 1 mL syringe.

A box containing either one or two prefilled pens.

Not all strengths or pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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

Patients should be advised to pay strict attention to the instruction leaflet for sumatriptan injection, especially regarding the safe disposal of the pen device (autoinjector).

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

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

9. DATE OF FIRST APPROVAL

20 October 2016

10. DATE OF REVISION OF THE TEXT

18 February 2019

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
	Update to the SPC-style format