

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.



## STRIPTAN-50 (Sumatriptan Succinate Tablets 50 mg)

### Name of product

STRIPTAN-50 (Sumatriptan Succinate Tablets 50 mg)

### Name and strength of active ingredient

Sumatriptan Succinate Ph. Eur. eq. to Sumatriptan

50 mg

### Dosage form

Film Coated Tablet

### Product Description

**Sumatriptan Succinate Tablets 50 mg:** Pink colored, capsule shaped biconvex, film coated tablet plain on both sides.

### Pharmacodynamics & Pharmacokinetics

#### Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics: Selective 5-HT1 receptor agonists.

ATC code: N02CC01

Sumatriptan has been demonstrated to be a specific and selective 5-Hydroxytryptamine1 (5HT1D) receptor agonist with no effect on other 5HT receptor (5-HT2-5-HT7) subtypes. The vascular 5-HT1D 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 of and/or oedema formation in these vessels is thought to be the underlying mechanism of migraine in man.

In addition, evidence from animal studies suggests that sumatriptan inhibits trigeminal nerve activity. Both these actions (cranial vasoconstriction and inhibition of trigeminal nerve activity) may contribute to the anti-migraine action of sumatriptan in humans.

Sumatriptan remains effective in treating menstrual migraine i.e. migraine without aura that occurs between 3 days prior and up to 5 days post onset of menstruation. Sumatriptan should be taken as soon as possible in an attack.

Clinical response begins around 30 minutes following a 100mg oral dose.

Although the recommended dose of oral sumatriptan is 50mg, migraine attacks vary in severity both within and between patients. Doses of 25-100mg have shown greater efficacy than placebo in clinical trials, but 25mg is statistically significantly less effective than 50 and 100mg.

A number of placebo-controlled clinical studies assessed the safety and efficacy of oral sumatriptan in approximately 600 adolescent migraineurs aged 12 - 17 years. These studies failed to demonstrate relevant differences in headache relief at 2 hours between placebo and any sumatriptan dose. The undesirable effects profile of oral sumatriptan in adolescents aged 12 - 17 years was similar to that reported from studies in the adult population.

### Pharmacokinetic properties

Following oral administration, sumatriptan is rapidly absorbed, 70% of maximum concentration occurring at 45 minutes. After 100mg dose, the maximum plasma concentration is 54ng/ml. Mean absolute oral bioavailability is 14% partly due to presystemic metabolism and partly due to incomplete absorption. The elimination phase half-life is approximately 2 hours, although there is an indication of a longer terminal phase. Plasma protein binding is low (14-21%), mean volume of distribution is 170 litres. Mean total plasma clearance is approximately 1160ml/min and the mean renal plasma clearance is approximately 260ml/min. Non-renal clearance accounts for about 80% of the total clearance. 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 5HT1 or 5HT2 activity. Minor metabolites have not been identified. The pharmacokinetics of oral Sumatriptan do not appear to be significantly affected by migraine attacks.

### Indication/Usage

Sumatriptan Tablets are indicated for the acute relief of migraine attacks with or without aura. Sumatriptan remains effective in treating menstrual migraine i.e. migraine without aura that occurs between 3 days prior or up to 5 days post onset of menstruation. Sumatriptan should be taken as soon as possible in an attack.

### Recommended Dose

#### Adults

Sumatriptan Succinate Tablets is indicated for the acute intermittent treatment of migraine. It should not be used prophylactically.

It is advisable that Sumatriptan Succinate Tablets be given as early as possible after the onset of migraine attack but it is equally effective at whatever stage of the attack it is administered.

The recommended dose of Sumatriptan Succinate Tablets is a single 50mg tablet. Some patients may require 100mg. If the patient has responded to the first dose but the symptoms recur a second dose may be given in the next 24 hours provided that there is a minimum interval of two hours between the two doses and no more than 300mg is taken in any 24 hour period.

Patients who do not respond to the prescribed dose of Sumatriptan Succinate Tablets should not take a second dose for the same attack. Sumatriptan Succinate Tablets may be taken for subsequent attacks.

The tablets should be swallowed whole with water.

#### Children (under 18 years of age)

Sumatriptan Succinate Tablets have not been studied in children under 12 years of age.

#### Elderly (Over 65)

Experience of the use of Sumatriptan Succinate Tablets 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 Succinate Tablets in patients aged over 65 years is not recommended

#### Route of Administration

Oral

#### Contraindication

Hypersensitivity to any component of the preparation.

Sumatriptan should not be given to patients who have had myocardial infarction or have ischaemic heart disease, coronary vasospasm (Prinzmetal's angina), peripheral vascular disease or patients who have symptoms or sign consistent with ischaemic heart disease.

Sumatriptan should not be administered to patients with a history of cerebrovascular accident (CVA) or transient ischaemic attack (TIA).

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

The use of Sumatriptan in patients with moderate and severe hypertension and mild uncontrolled hypertension is contraindicated.

The concomitant administration of ergotamine or derivatives of ergotamine (including methysergide) is contraindicated. (See interactions)

Concurrent administration of monoamine oxidase inhibitors and Sumatriptan is contraindicated.

Sumatriptan Succinate Tablets must not be used within two weeks of discontinuation of therapy with monoamine oxidase inhibitors.

#### Warnings & Precaution

Sumatriptan Succinate tablets should only be used where there is a clear diagnosis of migraine.

Sumatriptan is not indicated for use in the management of hemiplegic, basilar or ophthalmoplegic migraine.

The recommended doses of Sumatriptan should not be exceeded. As with other migraine therapies, before treating headaches in patients not previously diagnosed as migraineurs, and in migraineurs who present atypical symptoms, care should be taken to exclude other potentially serious neurological conditions. It should be noted that migraineurs may be at risk of certain cerebrovascular events (e.g. cerebrovascular accident, transient ischaemic attack).

Following administration, Sumatriptan can be associated with transient symptoms including chest pain and tightness which may be intense and involve the throat (See Side effects). Where such symptoms are thought to indicate ischaemic heart disease, no further doses of Sumatriptan should be given and appropriate evaluation should be carried out.

Sumatriptan should not be given to patients with risk factors for ischaemic heart disease without prior cardiovascular evaluation (See Section 4.3 Contraindications). Special consideration should be given to postmenopausal women and males over 40 with these risk factors. These evaluations however, may not identify every patient who has cardiac disease and, in very rare cases, serious cardiac events have occurred in patients without underlying cardiovascular disease.

Sumatriptan should be administered with caution to patients with controlled hypertension as transient increases in blood pressure and peripheral vascular resistance have been observed in a small proportion of patients.

There have been rare post-marketing reports describing patients with weakness, hyper-reflexia, and incoordination following the use of a selective serotonin reuptake inhibitor (SSRI) and Sumatriptan. If concomitant treatment with Sumatriptan and an SSRI is clinically warranted, appropriate observation of the patient is advised.

Sumatriptan should be administered with caution to patients with conditions which may affect significantly the absorption, metabolism or excretion of drugs, e.g. impaired hepatic or renal function. A 50mg dose should be considered in patients with hepatic impairment.

Sumatriptan should be used with caution in patients with a history of seizures or other risk factors which lower the seizure threshold, as seizures have been reported in association with Sumatriptan (see section 4.8).

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.

Undesirable effects may be more common during concomitant use of triptans and herbal preparations containing St John's Wort (*Hypericum perforatum*).

As with other acute migraine treatments, chronic daily headache/exacerbation of headache have been reported with overuse of Sumatriptan, which may necessitate a drug withdrawal.

#### Interaction with other medicaments

There is no evidence of interactions with propranolol, flunarizine, pizotifen or alcohol. Sumatriptan has the potential to interact with MAOIs, ergotamine and derivatives of ergotamine. The increased risk of coronary vasospasm is a theoretical possibility and concomitant administration is contra-indicated. (see also contraindications).

Prolonged vasospastic reactions have been reported with ergotamine. As these effects may be additive, 24 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. Rarely, an interaction may occur between Sumatriptan and SSRI's (see Special Warnings and special Precautions for Use).

#### Pregnancy and Lactation

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

It has been demonstrated that following subcutaneous administration, Sumatriptan is excreted into breast milk. Infant exposure can be minimised by avoiding breast feeding for 12 hours after treatment, during which time any breast milk expressed should be discarded.

#### Side effects/Adverse Reactions

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.

#### Nervous System Disorders

Common: Tingling, dizziness, drowsiness.

#### Vascular disorders

Common: Transient increases in blood pressure arising soon after treatment. Flushing.

#### Gastrointestinal

Common: Nausea and vomiting occurred in some patients but it is unclear if this is related to Sumatriptan or the underlying condition.

#### Musculoskeletal and Connective Tissue Disorders

Common: Sensations of heaviness (usually transient and may be intense and can affect any part of the body including the chest and throat).

#### General Disorders and Administration Site Conditions

Common: Pain, sensations of heat, pressure or tightness (these events are usually transient and may be intense and can affect any part of the body including the chest and throat).

Feelings of weakness fatigue (both events are mostly mild to moderate in intensity and transient).

#### Investigations

Very rare : Minor disturbances in liver function tests have occasionally been observed.

#### Signs & Symptoms of overdose and Treatment

There have been some reports of overdosage with Sumatriptan Succinate Tablets. Doses in excess of 400mg orally were not associated with side effects other than those mentioned.

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 Succinate Tablets.

#### Storage Conditions

Sumatriptan Succinate Tablets should be kept in a safe place where children cannot reach them.

Do not store above 30°C.

Keep out of reach of children.

Do not use the tablets after the expiry date printed on the packaging.

#### Shelf life

36 months from date of manufacturing.

#### Pack Size

Sriptan 50 mg Tablets is available in Alu-Alu blister of 6 tablets (1x6 tablets)

Manufactured by:



#### INTAS PHARMACEUTICALS LTD.

Camp road, Selaqui-248011,

Dehradun, Uttarakhand (India).

Product Registration Holder

Jetpharma Sdn Bhd,

No.13, Jalan Rajawali 2,

Bandar Puchong Jaya, 47100 Puchong,

Selangor, Malaysia

Date of Revision: Dec, 2023

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## Front Side

8620537 - Sumatriptan 50 mg(-Malaysia)Multiple Pack Style PIL

Size : 160 x 270 mm (Front/Back side) Final fold size: 160x35(mm)

Colour: Pantone Black

Date : 04\*10\*25, 20\*10\*25

## Back Side