SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sirah 50mg Film-coated Tablets

Sumatriptan 50mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50mg sumatriptan (as sumatriptan succinate).

Excipient with known effect: lactose.

Each tablet contains 46.50 mg lactose monohydrate.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

White, triangular shaped, biconvex, film-coated tablet, debossed with “SUM” on one side and “50” on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sumatriptan are indicated for the acute relief of migraine attacks, with or without aura**.** Sumatriptan should only be used where there is a clear diagnosis of migraine.

4.2 Posology and method of administration

Adults (18-65 years of age)

The recommended dose is a single 50mg tablet that should be swallowed whole with water. It is advisable that this medicine be taken as soon as possible after the onset of a migraine headache although it is effective at whatever stage of the headache it is taken. If there is a response to the first tablet but the symptoms recur, a second tablet may be taken.
However, this must be at least 2 hours after the first tablet. No more than two 50 mg tablets (total dose 100 mg) may be taken in any 24 hour period or to treat the same attack. If there is no response to the first tablet, a second tablet should not be taken for the same attack.

The tablets should be swallowed whole with water.

Paediatric population
The efficacy and safety of Sumatriptan in children aged less than 10 years have not been established. No clinical data are available in this age group.

The efficacy and safety of Sumatriptan in children 10 to 17 years of age have not been demonstrated in the clinical trials performed in this age group. Therefore the use of Sumatriptan in children 10 to 17 years of age is not recommended (see section 5.1).

Elderly (Over 65 years of age)
Not to be used in those over 65 years of age.
Experience of the use of Sumatriptan in patients over 65 years is limited.

4.3 Contraindications

Hypersensitivity to sumatriptan or to any of the excipients listed in section 6.1.

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) or any triptan/5-hydroxytryptamine1 (5-HT1) receptor agonist with sumatriptan is contraindicated. (see section 4.5)

Concurrent administration of monoamine oxidase inhibitors and sumatriptan is

contraindicated.

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

4.4 Special warnings and precautions for use

Sumatriptan should only be used where there is a clear diagnosis of migraine. For pharmacy supply, patients should have an established pattern of migraine (a history of five or more migraine attacks occurring over a period of at least 1 year).
Sumatriptan should not be taken concomitantly with other migraine therapies containing any triptan, ergotamine or derivative of ergotamine.

If a migraineur fails to respond to the first tablet of sumatriptan, the attack may be treated with simple analgesics. Further, the diagnosis of migraine should be reconsidered with a doctor.

The recommended dose of sumatriptan should not be exceeded.

Migraineurs whose typical headaches persist for longer than 24 hours should seek advice from their doctor.

Migraineurs in whom the pattern of symptoms has changed, or whose attacks have become more frequent, more persistent, or more severe, or who do not recover completely between attacks, should seek advice from their doctor.

Anyone with atypical symptoms which include, but are not limited to, unilateral motor weakness, double vision, clumsy and unco-ordinated movements, tinnitus, reduced level of consciousness, seizure-like movements, or recent onset of rash with headache should seek advice from their doctor.

Patients whose migraine symptoms appear for the first time after age 50 should seek advice from their doctor as there may be a more serious underlying cause.

Migraineurs who experience four or more migraine attacks per month should be referred to a doctor for ongoing management.

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 that may be intense and involve the throat (see Section 4.8, Undesirable effects). Typically, such symptoms develop within 30 minutes of treatment and last for less than 2 hours. Where such symptoms are thought to indicate ischaemic heart disease, medical

evaluation should be obtained immediately and no further doses of Sumatriptan should be taken until considered appropriate by a doctor.

Sumatriptan should not be used by migraineurs in whom unrecognised cardiac disease is likely without a prior risk assessment by a doctor or pharmacist (see Section 4.3, Contra-indications). Special consideration should be given to post-menopausal women and men over 40. Risk factors for heart disease include hypercholesterolaemia, regular smoking, marked obesity, diabetes or a family history of early heart disease (father/brother developed heart disease before the age of 55, mother/sister developed heart disease before the age of 65). Anyone who has three or more of these risk factors is not suitable for pharmacy supply of sumatriptan. These evaluations may not identify everyone who has cardiac disease and, in very rare cases, serious cardiac events have occurred without underlying cardiovascular disease.

There have been rare post-marketing reports describing patients with serotonin syndrome (including altered mental status, autonomic instability and neuromuscular
abnormalities following the use of a selective serotonin reuptake inhibitor (SSRI) and sumatriptan. Serotonin syndrome has been reported following concomitant treatment with triptans and serotonin noradrenaline reuptake inhibitors (SNRIs). If concomitant use of sumatriptan and an SSRI/SNRI is considered to be appropriate, migraineurs should be warned to see their doctor if they develop symptoms of serotonin syndrome.

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

Patients with known hypersensitivity to sulfonamides may exhibit an allergic reaction following administration of sumatriptan. Reactions may range from cutaneous hypersensitivity to anaphylaxis. Although evidence of cross-sensitivity is limited, treatment with Sumatriptan is contraindicated in these patients (see Section 4.3, Contra-indications).

Women with migraine who are taking the combined oral contraceptive have an increased risk of stroke and should seek advice from their doctor if migraine attacks started recently (within the last 3 months), migraine symptoms have worsened or they have migraine with aura.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of Medication Overuse Headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Studies in healthy subjects show that sumatriptan does not interact with propranolol, flunarizine, pizotifen or alcohol.
There are limited data on an interaction with preparations containing ergotamine or another triptan/5-HT1 receptor agonist. The increased risk of coronary vasospasm is a theoretical possibility and concomitant administration is contraindicated (see section 4.3).

The period of time that should elapse between the use of sumatriptan and ergotamine-containing preparations or another triptan/5-HT1 receptor agonist is not known. This will also depend on the doses and types of products used. The effects may be additive. It is advised to wait at least 24 hours following the use of ergotamine-containing preparations or another triptan/5-HT1 receptor agonist before administering sumatriptan. Conversely, it is advised to wait at least 6 hours following use of sumatriptan before administering an ergotamine-containing product and at least 24 hours before administering another triptan/5-HT1 receptor agonist.

An interaction may occur between sumatriptan and monoamine oxidase inhibitors (MAOIs) and concomitant administration is contraindicated (see section 4.3).

There have been rare post-marketing reports describing patients with serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) following the use of SSRIs and sumatriptan. Serotonin syndrome has also been reported following concomitant treatment with triptans and SNRIs (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

Sumatriptan is not to be used in pregnancy or when breastfeeding unless on the advice of a doctor.

Post-marketing data from the use of sumatriptan during the first trimester in over1,000 women are available. Although these data contain insufficient information to draw definitive conclusions, they do not point to an increased risk of congenital defects. Experience with the use of sumatriptan in the second and third trimester is limited.

Evaluation of experimental animal studies does not indicate direct teratogenic effects or harmful effects on peri- and postnatal development. However, embryofoetal viability might be affected in the rabbit (see section 5.3).

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

Lactation

Sumatriptan is secreted into breast milk, with average relative infant doses of <4% following administration of a single dose of sumatriptan. Infant exposure can be minimised by avoiding breast feeding for 12 hours after treatment, during which time any breast milk expressed should be discarded. There have been reports of breast pain and/or nipple pain following sumatriptan use in breastfeeding women (see section 4.8). The pain was usually transient and disappeared in 3 to 12 hours.

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 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 [4]. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10000), not known (cannot be estimated from the available data). Some of the symptoms reported as undesirable effects may be associated symptoms of migraine.

Clinical Trial Data

Nervous System Disorders
Common: Dizziness, drowsiness, sensory disturbance including paraesthesia and hypoaesthesia.

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

Respiratory, Thoracic and Mediastinal Disorders
Common Dyspnoea.

Gastrointestinal Disorders
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).
Myalgia.

General Disorders and Administration Site Conditions
Common: Pain, sensations of heat or cold, 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.

Post-Marketing Data

Immune System Disorders
Not known: Hypersensitivity reactions ranging from cutaneous hypersensitivity to anaphylaxis.

Nervous System Disorders
Not known: Seizures, 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.
Tremor, dystonia, nystagmus, scotoma.

Eye Disorders
Not known: Flickering, diplopia, reduced vision. Loss of vision including reports of permanent defects. However, visual disorders may also occur during a migraine attack itself.

Cardiac Disorders
Not known: Bradycardia, tachycardia, palpitations, cardiac arrhythmias, transient ischaemic ECG changes, coronary artery vasospasm, angina, myocardial infarction (see sections 4.3 and 4.4).

Vascular Disorders
Not known: Hypotension, Raynaud's phenomenon.

Gastrointestinal Disorders
Not known: Ischaemic colitis, diarrhoea, dysphagia.

Musculoskeletal, Connective Tissue and Bone Disorders
Not known: Neck stiffness.
Arthralgia.

General Disorders and Administration Site Conditions
Not known: Pain trauma activated, pain inflammation activated.

Psychiatric disorders
Not known: Anxiety.

Skin and subcutaneous tissue disorders
Not known: Hyperhidrosis.

Reproductive system and breast disorders
Rare: Breast pain

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

In the event of an overdose, medical advice should be sought immediately.

Doses in excess of 400 mg orally were not associated with side effects other than those mentioned.

If overdose 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

5 PHARMACOLOGICAL PROPERTIES

5.1 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 relieves headache and other symptoms of migraine including nausea, and sensitivity to light and sound. Clinical response for relief of migraine headache begins around 30 minutes following a 50 mg oral dose.

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 after the onset of a migraine headache.

A number of placebo-controlled clinical studies assessed the safety and efficacy of oral sumatriptan in approximately 800 children and adolescent migraineurs aged 10 to 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 10-17 years was similar to that reported from studies in the adult population.

5.2 Pharmacokinetic properties

Following oral administration, sumatriptan is rapidly absorbed, 70% of maximum concentration occurring at 45 minutes. After a 50 mg dose, the mean maximum plasma concentration is 32 ng/ml. Mean absolute oral bioavailability is 14% partly due to presystemic metabolism and partly due to incomplete absorption.

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

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 5-HT_1 or 5-HT_2 activity. Minor metabolites have not been identified.

The elimination phase half-life is approximately 2 hours, although there is an indication of a longer terminal phase. 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.

The pharmacokinetics of oral sumatriptan do not appear to be significantly affected by migraine attacks.

5.3 Preclinical safety data

Sumatriptan was devoid of genotoxic and carcinogenic activity in in-vitro systems and animal studies.

In a rat fertility study oral doses of sumatriptan resulting in plasma levels approximately 200 times those seen in man after a 100 mg oral dose were associated with a reduction in the success of insemination.

This effect did not occur during a subcutaneous study where maximum plasma levels achieved approximately 150 times those in man by the oral route.

In rabbits embryolethality, without marked teratogenic defects, was seen. The relevance for humans of these findings is unknown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core tablet:

Microcrystalline cellulose

Lactose monohydrate

Croscarmellose sodium

Magnesium stearate

Film-Coating:

Titanium dioxide

Polydextrose

Hypromellose

Triacetin

Macrogol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

48 months

6.4 Special precautions for storage

This medicinal product does not require any special storage condition

6.5 Nature and contents of container

The tablets are available in ALU-PVC/PVDC blister packs of 2 tablets.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Rudipharm Limited
Unit 6, Salbrook Road Industrial Estate
Salbrook Road, Redhill, Surrey
RH1 5GJ, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 49565/0117

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/03/2024

10 DATE OF REVISION OF THE TEXT

29/09/2025