SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots Migraine Relief 50 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

50 mg sumatriptan base (as sumatriptan succinate).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.
Peach, oblong shaped cores debossed “5” and “0” on one side and scoreline on each side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sumatriptan Tablets are indicated for the acute relief of migraine attacks, with or without aura.

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

4.2 Posology and method of administration

Sumatriptan is indicated for the acute intermittent treatment of migraine. It should not be used prophylactically. The recommended dose of Sumatriptan should not be exceeded.

Sumatriptan is recommended as monotherapy for the acute treatment of a migraine attack and should not be given concomitantly with ergotamine or derivatives of ergotamine (including methysergide) (see section 4.3).

It is advisable that sumatriptan be given as early as possible after the onset of a migraine headache. It is equally effective at whatever stage of the attack it is administered.

Populations

Adults (18-65 years of age)
The recommended dose is a single 50 mg tablet that should be swallowed whole with water. Some patients may require 100 mg.

If there is no response to the first tablet, a second tablet should not be taken for the same attack. In these cases the attack can be treated with paracetamol, acetylsalicylic acid, or non-steroidal anti-inflammatory drugs. Sumatriptan tablets may be taken for subsequent attacks.

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 2 hours between the two doses. No more than 300 mg should be taken in any 24 hour period.

Paediatric population (under 18 years of age)

The efficacy and safety of sumatriptan tablets 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 tablets 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 tablets in children 10 to 17 years of age is not recommended (see section 5.1).

Elderly (over 65 years of age)

Experience of the use of Sumatriptan Tablets in patients 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.

4.3 Contraindications

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

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

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

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

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

History of seizures or other risk factors which lower the seizure threshold.

Concurrent treatment with the following medications is contra-indicated:
Ergotamine or derivatives of ergotamine (including methysergide) (see Section 4.5, Interactions).

Monoamine oxidase inhibitors (MAOIs). Sumatriptan Tablets must not be used within 2 weeks of discontinuation of therapy with MAOIs.

Any 5- hydroxytryptamine1 (5-HT1) receptor agonist (triptan).
Sumatriptan Tablets is not to be used to treat the following rare variants of migraine:

Hemiplegic migraine - migraine with aura including unilateral motor weakness.

Basilar migraine - migraine with aura symptoms originating from the brain stem and/or both hemispheres such as double vision, difficulty in articulating words, clumsy and uncoordinated movements, tinnitus, reduced level of consciousness.

Ophthalmoplegic migraine – migraine headache with involvement of one or more ocular cranial nerves resulting in weakness of the muscles controlling eye movement.

4.4 Special warnings and precautions for use

Sumatriptan Tablets should only be used where a clear diagnosis of migraine has been made by a doctor or a pharmacist. 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 is not indicated for use in the management of hemiplegic, basilar or ophthalmoplegic migraine.

As with other acute migraine therapies, 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 CVA, TIA) if the patient presents with atypical symptoms or if they have not received an appropriate diagnosis for sumatriptan use..

It should be noted that migraineurs may be at increased 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 Tablets should be taken until considered appropriate by a doctor and an appropriate evaluation should be carried out.

Sumatriptan should be given with caution in patients with mild controlled hypertension, since transient increases in blood pressure and peripheral vascular resistance have been observed in a small proportion of patients (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 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 treatment with Sumatriptan and an SSRI/SNRI is clinically warranted, appropriate observation of the patient is advised (see section 4.5).

Sumatriptan should be administered with caution to patients with conditions that may affect significantly the absorption, metabolism, or excretion of the drug, e.g. impaired hepatic (Child Pugh grade A or B; see section 5.2) or renal function (see section 5.2). 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. Although evidence of cross-sensitivity is limited, treatment with Sumatriptan Tablets is contraindicated in these patients (see Section 4.3, Contra-indications).

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

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.

The recommended dose of Sumatriptan Tablets should not be exceeded.

Sumatriptan should not be given to patients with risk factors for ischaemic heart disease, including those patients who are heavy smokers or users of nicotine substitution therapies, without prior cardiovascular evaluation (see section 4.3). Special consideration should be give 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 Tablets 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 Tablets, the attack may be treated with simple analgesics. Further, the diagnosis of migraine should be reconsidered with a doctor.

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.

Sumatriptan Tablets 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.

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.
Excipient(s)

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

There is no evidence that sumatriptan interacts with propranolol, flunarizine, pizotifen or alcohol.

Sumatriptan has the potential to interact with MAOIs, ergotamine and derivatives of ergotamine, or another triptan/5-HT_1 receptor agonist. The increased risk of coronary vasospasm is a theoretical possibility and therefore concomitant administration with MAOIs, ergotamines or another triptan/5-HT_1 receptor agonist is contra-indicated. (see Section 4.3, Contraindications).

Prolonged vasospastic reactions have been reported with ergotamine. The period of time that should elapse between the use of sumatriptan and ergotamine-containing preparations or another triptan/5-HT_1 receptor agonist is not known. This will also depend on the doses and types of products used. As these effects may be additive, it is advised that 24 hours should elapse before sumatriptan can be taken following any ergotamine-containing preparation or another triptan/5-HT_1 receptor agonist. Conversely, it is advised that ergotamine-containing preparations should not be taken until 6 hours have elapsed following sumatriptan administration and at least 24 hours before administering another triptan/5-HT_1 receptor agonist.

Rarely, an interaction may occur between sumatriptan and SSRIs (see Section 4.4, Special Warnings and special precautions for use). There is a risk of pharmacodynamic interaction between sumatriptan and tricyclic antidepressants.

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).

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

4.6 Fertility, pregnancy and lactation

Pregnancy
Post-marketing data from the use of sumatriptan during the first trimester of pregnancy in over 1,000 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, embryo-foetal 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 its treatment with sumatriptan. This may influence the ability to drive and to operate machinery.

4.8 Undesirable effects

Summary of the safety profile

Adverse events are listed below by system organ class and frequency. 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) and very rare (<1/10,000), not known (cannot be estimated from the available data). Some of the symptoms reported as undesirable effects may be associated symptoms of migraine.

Immune System Disorders
Not known: Hypersensitivity reactions ranging from cutaneous hypersensitivity (such as urticaria) to anaphylaxis.

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

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 (usually transient but includes 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 Contra-indications, Special Warnings and special precautions for use).

Vascular Disorders

Common: Transient increases in blood pressure arising soon after treatment. Flushing.
Not known: Hypotension, Raynaud's phenomenon.

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.
Not known: Ischaemic colitis, diarrhoea , dysphagia.

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.
Not known: Neck stiffness, arthralgia.

Reproductive system and breast disorders

Rare: Breast pain

Psychiatric disorders

Not known: Anxiety.

Skin and subcutaneous tissue disorders

Not known: Hyperhidrosis.

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).
Not known: Pain trauma activated, pain inflammation activated

Investigations

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

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: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms and signs
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 in Section 4.8, Undesirable effects.

Treatment
If overdosage occurs, the patient should be monitored for at least 10 hours and standard supportive treatment applied as required.
It is unknown what effect haemodialysis or peritoneal dialysis has on the plasma concentrations of Sumatriptan Tablets.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics: 0 Selective 5-HT_1 receptor agonists.
ATC code: N02CX04

Sumatriptan has been demonstrated to be a specific and selective 5-hydroxytryptamine-1 (5-$HT_{1B/D}$) receptor agonist with no effect on other 5-HT receptor (5-HT_2-5-HT_7) subtypes. The vascular 5-HT_{1B} 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.

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 standard tablets in over 650 child and adolescent migraineurs aged 10 to 17 years.

These studies failed to demonstrate a statistically significant difference in headache relief at 2 hours between placebo and any sumatriptan dose. The undesirable effects profile of oral sumatriptan in children and 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 100 mg dose, the maximum plasma concentration is 54 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.
Special patient populations
Hepatic Impairment
Sumatriptan pharmacokinetics after an oral dose (50 mg) and a subcutaneous dose (6 mg) were studied in 8 patients with mild to moderate hepatic impairment matched for sex, age, and weight with 8 healthy subjects. Following an oral dose, sumatriptan plasma exposure (AUC and Cmax) almost doubled (increased approximately 80%) in patients with mild to moderate hepatic impairment compared to the control subjects with normal hepatic function. There was no difference between the patients with hepatic impairment and control subjects after the s.c. dose. This indicates that mild to
moderate hepatic impairment reduces presystemic clearance and increases the bioavailability and exposure to sumatriptan compared to healthy subjects.

Following oral administration, pre-systemic clearance is reduced in patients with mild to moderate hepatic impairment and systemic exposure is almost doubled.

The pharmacokinetics in patients with severe hepatic impairment have not been studied (see Section 4.3 Contraindications and Section 4.4 Warnings and Precautions).

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

In a pilot study, no significant differences were found in the pharmacokinetic parameters between the elderly and young healthy volunteers.

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
Lactose monohydrate
Croscarmellose sodium
Cellulose, microcrystalline
Silica colloidal anhydrous
Magnesium stearate
Coating – Opadry peach
Hypromellose E464
Titanium dioxide E171
Lactose monohydrate
Macrogol
Glycerol triacetate
Iron oxide red E172
Iron oxide yellow E172
Iron oxide black E172

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Transparent or white opaque PVC/PVdC aluminium blisters.
Blister packs of 2 film-coated tablets.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/0586

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12/09/2025