SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sumatriptan Apofri 50 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains sumatriptan succinate equivalent to 50 mg sumatriptan

Excipient with known effect: lactose monohydrate: 22.5 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablet.

Peach coloured, capsule shaped, biconvex film-coated tablets, 10,6 x 4.4 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sumatriptan Apofri tablet is indicated for the acute treatment of migraine attacks with or without aura.

4.2 Posology and method of administration

Posology

General recommendations with regard to use and administration:

Sumatriptan Apofri tablet should not be used prophylactically.

The recommended doses of Sumatriptan Apofri 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 Apofri tablet be given as early as possible after the onset of migraine attack. However, it is equally effective at whatever stage of the attack it is administered.

Adults (over 18 years)
The recommended dose of Sumatriptan Apofri tablet is a single 50 mg tablet. Some patients may require 100 mg. Higher dose than 100 mg does not improve the effect.

If the patient does not respond to the first dose of Sumatriptan Apofri tablets, a second dose should not be taken for the same attack. Sumatriptan Apofri tablets may be taken for subsequent attacks. However, the migraine attack can be treated with paracetamol, acetylsalicylic acid or NSAIDs. Sumatriptan Apofri can be taken for subsequent attack.

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 300 mg is taken in any 24 hour period.
Experience of higher doses than 300 mg is not documented.

Paediatric Population

The efficacy and safety of sumatriptan in children aged less than 10 years have not been established. No clinical data is available in this age group.
The efficacy and safety of sumatriptan in children and adolescents 10 to 17 years of age have not been demonstrated in the clinical studies performed in this age group. Therefore, the use of Sumatriptan Apofri tablets in children and adolescents 10 to 17 years of age is not recommended.

Elderly (over 65 years of age)
Experience of the use of Sumatriptan Apofri tablets in patients aged over 65 years is limited. The pharmacokinetics in elderly patients is insufficiently studied. Until further clinical data are available, the use of Sumatriptan Apofri tablets in patients aged over 65 years is not recommended.

Method of administration
Oral use.

The tablets should be swallowed whole with a glass of water.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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

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

- The use of sumatriptan tablets 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 reversible (e.g. moclobemide) or irreversible (e.g. selegiline) monoamine oxidase inhibitors (MAOIs) and sumatriptan is contraindicated.

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

4.4 Special warnings and precautions for use

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

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

Before treatment with sumatriptan, care should be taken to exclude other potentially serious neurological conditions (e.g. certain cerebrovascular lesions, transient ischaemic attack (TIA)) should be excluded before treatment of headache in patients not previously diagnosed as migraineurs, and in migraineurs who present with atypical symptoms.

Following administration, sumatriptan can be associated with transient symptoms including chest pain and tightness, which may be intense and involve the throat (see section 4.8). 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, including patients who are heavy smokers or users of nicotine substitution therapies, 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. Even in patients without underlying cardiac disease, serious cardiovascular disease has occurred in very rare cases.

Sumatriptan should be administered with caution to patients with mild controlled hypertension as 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 symptoms) 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 which may affect significantly the absorption, metabolism or excretion of the drug, e.g. impaired hepatic function (mild to moderate impairment (Child Pugh grade A or B); see section 5.2 special patient populations) or impaired renal function.

Sumatriptan tablets 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 tablet. Reactions may range from cutaneous hypersensitivity to anaphylaxis. Evidence of cross-sensitivity is limited, however, caution should be exercised before using sumatriptan tablet in these patients.

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 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 frequently or daily headaches despite (or because of) the regular use of headache medications.

This medicine contains lactose monohydrate and sodium
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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

4.5 Interaction with other medicinal products and other forms of interaction

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 the use of sumatriptan before administering an ergotamine-containing product and at least 24 hours before administering another triptan/5-HT1 receptor agonist (see section 4.3).

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

There are rare 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

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, it does not indicate an increased risk of malformations or any specific pattern of malformations in women treated with sumatriptan during pregnancy compared with the general population. Experience with the use of sumatriptan tablet 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 tablet should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Breastfeeding

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 intake 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 tablets. This may influence the ability to drive and operate machinery.

4.8 Undesirable effects

Undesirable effects are listed below according to system organ class and frequency. The frequencies are defined as: Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000), Very rare (<1/10,000) and not known (cannot be estimated from the available data).
Some of the symptoms reported as undesirable effects may be associated symptoms of migraine.

System Organ Class	**Frequency**	**Adverse reaction**
Immune system disorders	Not known	Hypersensitivity reactions ranging from cutaneous hypersensitivity (such as

System Organ Class	Frequency	Adverse reaction
		urticaria) to rare cases of anaphylaxis.
Psychiatric disorders	Not known	Anxiety
Nervous system disorders	Common	Dizziness, drowsiness, sensory disturbance including paraesthesia and hypoesthesia.
	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 4.3 and 4.4).
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.

System Organ Class	Frequency	Adverse reaction
	Not known	Ischaemic colitis, diarrhoea, dysphagia.
Skin and subcutaneous tissue disorders	Not known	Hyperhidrosis
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
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).
	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 national reporting system listed in Appendix V.

4.9 Overdose

Symptoms and signs

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

Treatment

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 Apofri tablet.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics, antimigraine preparations: selective serotonin (5-HT1) receptor agonists.
ATC code: N02CC01

Sumatriptan is a selective 5-hydroxytryptamine$_1$ (5HT $_{IB/1D}$) receptor agonist with no effect on other 5HT receptor subtypes (5-HT$_2$-5-HT$_7$).

The vascular 5-HT $_{IB/1D}$ receptor is found predominantly in cranial blood vessels and mediates vasoconstriction. In animals, sumatriptan selectively constricts the carotid arterial circulation without changing the cerebral 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 human.
In addition, indicates animal experimental findings that sumatriptan inhibits trigeminal nerve activity. Both these mechanisms of actions (cranial vasoconstriction and inhibition of trigeminal nerve activity) may contribute to the anti-migraine action of sumatriptan in humans.

A clinical response begins around 30 minutes following intake.

Sumatriptan is also effective for the acute treatment of migraine attacks that occur during menstruation, e,g, migraine occurring in close connection with the menstrual period.

A number of placebo-controlled clinical studies assessed the safety and efficacy of oral sumatriptan in 800 adolescent migraineurs aged 10-17 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

The pharmacokinetics of sumatriptan do not appear to change during an ongoing migraine attack.

Absorption

After a dose of 100 mg, the mean maximum plasma concentration is 54 nanograms/ml. The mean value for the bioavailability is 14% partly due to presystematic metabolism and partly due to incomplete absorption.C_{max} for sumatriptan increases with 15% when sumatriptan is taken after a high-fat meal.

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

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. The metabolite has no known $5HT_1$- or $5HT_2$-activity. Other metabolites have not been identified.

Elimination
The elimination half-life is approximately 2 hours. Total plasma clearance is approximately 1160 ml/min and renal plasma clearance is approximately 260 ml/min. Approximately 80% of total clearance is non-renal clearance.

Special patient populations

Hepatic impairment
The pharmacokinetics of sumatriptan following 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, plasma exposure (AUC and C_{max}) to sumatriptan was almost doubled (increased by approximately 80%) in patients with mild to moderate hepatic impairment compared with control subjects with normal hepatic function. There was no difference between patients with hepatic impairment and control subjects following the subcutaneous dose. This indicates that mild to moderate hepatic impairment reduces presystemic clearance and increases the bioavailability and exposure of sumatriptan compared with healthy subject.

The pharmacokinetics of sumatriptan in patients with severe hepatic impairment have not been studied (see section 4.3 Contraindications and section 4.4 Special warnings and precautions for use).

5.3 Preclinical Safety data

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

In a fertility study in rat, a reduction in the number of successful inseminations was seen on exposure to concentrations higher than the maximum exposure in humans. In rabbits embryolethality was observed, without marked teratogenic effects. The significance of these findings in humans is unclear.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose Monohydrate
Cellulose Microcrystalline (E460)
Pregelatinized Maize Starch

Croscarmellose Sodium
Magnesium Stearate (E470b)

Filmcoating:
Hypromellose (E464)
Titanium Dioxide (E171)
Talc (E553b)
Ferric Oxide Red (E172)
Ferric Oxide Yellow (E172)
Macrogol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in the original packaging in order to protect from light.

6.5 Nature and contents of container

50 mg tablets: OPA/Al/PVC/Al blister pack of 2, 3, 4, 6 and 12 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2026-07-09