

## **Sumatran Relief 50mg Tablets**

### **Pharmacist General Migraine Information**

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#### **1. Introduction:**

Sumatran Relief 50mg tablets (sumatriptan) are available as [a non-prescription product](#) under the supervision of a pharmacist.

#### **2. Sumatran Relief indication**

- for the acute treatment of migraine with or without aura
- including the acute treatment of menstrual associated migraine
- where the patient has previously been diagnosed with migraine by a doctor.

#### **3. Mechanism of action:**

Sumatriptan belongs to a group of medicines called triptans, which are 5-HT<sub>1</sub> (serotonin) agonists. They appear to work by stimulating 5-HT<sub>1B</sub> and 5-HT<sub>1D</sub> receptors. Cranial vasoconstriction may contribute to their action.

#### **4. Supply criteria**

- Migraine must be previously diagnosed by a doctor
- Simple analgesics tried and ineffective
- Age 18-65 years

- Due to the need to confirm the patient's diagnosis of migraine and the counselling requirements for the appropriate use of this product, Sumatran Relief must only be supplied by the pharmacist
- The maximum recommended OTC supply within a 30 day period is 6 tablets (3 packs), as if a patient experiences 4 or more migraines in one month, they should be referred to their doctor.

#### 5. **Migraine: Description, symptoms, stages**

The most common type of migraine is migraine WITHOUT aura.

The frequency of attacks can vary widely, typically up to four attacks per month, with the average being about one attack per month. Migraines generally follow a fairly consistent pattern in most sufferers. Patients are usually symptom free between attacks.

Migraine should be differentiated from other types of headaches such as

- a) tension-type headaches
- b) medication overuse headache
- c) chronic daily headache.

Migraine may involve up to four symptom stages:

- i. Prodrome Stage
- ii. Aura Stage
- iii. Headache Stage
- iv. Postdrome (Resolution) Stage.

These phases may not occur in every patient or every migraine.

- i. **Prodromal Stage:** Changes in mood, energy levels, behaviour and appetite can occur several hours or days before an attack
- ii. **Aura Stage:** Migraine with aura involves warning signs (auras) in the hour preceding the headache. Auras include visual changes such as flashes of light, sensory symptoms such as numbness or tingling and speech disturbances.
- iii. **Headache Stage:** Migraine headache usually lasts 4 to 72 hours (untreated or unsuccessfully treated) and is associated with at least two of the following
  - unilateral location (typically affects one side of the head)
  - throbbing character (typically described as pulsating)
  - worsening pain with routine activity
  - moderate to severe intensity
    - **and** at least one of the following
  - nausea and/or vomiting
  - photophobia (sensitivity to bright light) and phonophobia (sensitivity to loud sound)
  - (Occasionally also sweating, poor concentration, feeling very hot or cold, abdominal pain and/or diarrhoea).

**iv. Postdrome (Resolution) Stage:**

When headache and other symptoms gradually fade away, **patients** may feel exhausted and mentally foggy. Tiredness may last up to a week afterwards.

**6. Other types of headache**

- a) Medication Overuse Headache (MOH)
- b) Tension headache.

**a) Medication Overuse Headache (MOH)**

**Previously used terms:**

Rebound headache; drug-induced headache; medication-misuse headache.

Medication-overuse headache is an interaction between a therapeutic agent used excessively and a susceptible patient. Among those with a previous primary headache diagnosis, most patients with medication-overuse headache have:

- Migraine and/or
- Tension-type headache.

**Description of Medication Overuse Headache:**

Headache occurring on 15 or more days per month developing as a consequence of regular overuse of acute or symptomatic headache medication for more than three months. In this context, 'Overuse' is defined as intake of **either**

- $\geq 15$  days/month of simple analgesics (such as paracetamol, ibuprofen, aspirin)
- or**
- $\geq 10$  days/month of ergotamine, 5HT<sub>1</sub> agonist ('triptan'), opioids or combination analgesics.

**Comments:**

The diagnosis of MOH is extremely important clinically. Approximately half of people with headache on 15 or more days per month for more than three months have MOH. Evidence shows that most patients with this disorder improve after discontinuation of the overused medication, as does their responsiveness to preventative treatment.

**b) Tension type headaches**

**Previously used terms:**

Tension headache; muscle contraction headache; psychomyogenic headache; stress headache; ordinary headache; essential headache; idiopathic headache; psychogenic headache.

**Introduction**

Tension-type headache is very common and it has a high socio-economic impact.

It is important to help the patient to differentiate between tension type headache and mild migraine without aura. Patients with frequent headaches often suffer from both disorders.

**Tension Type Headache** lasts anything from 30 min to 7 days. It is accompanied by at least two of the following:

- **bilateral** location (typically affects both sides of the head)
- **non**-pulsatile character (often described as a steady ache)
- **no** aggravation with routine activity
- **mild to moderate** intensity

and **neither** of the following:

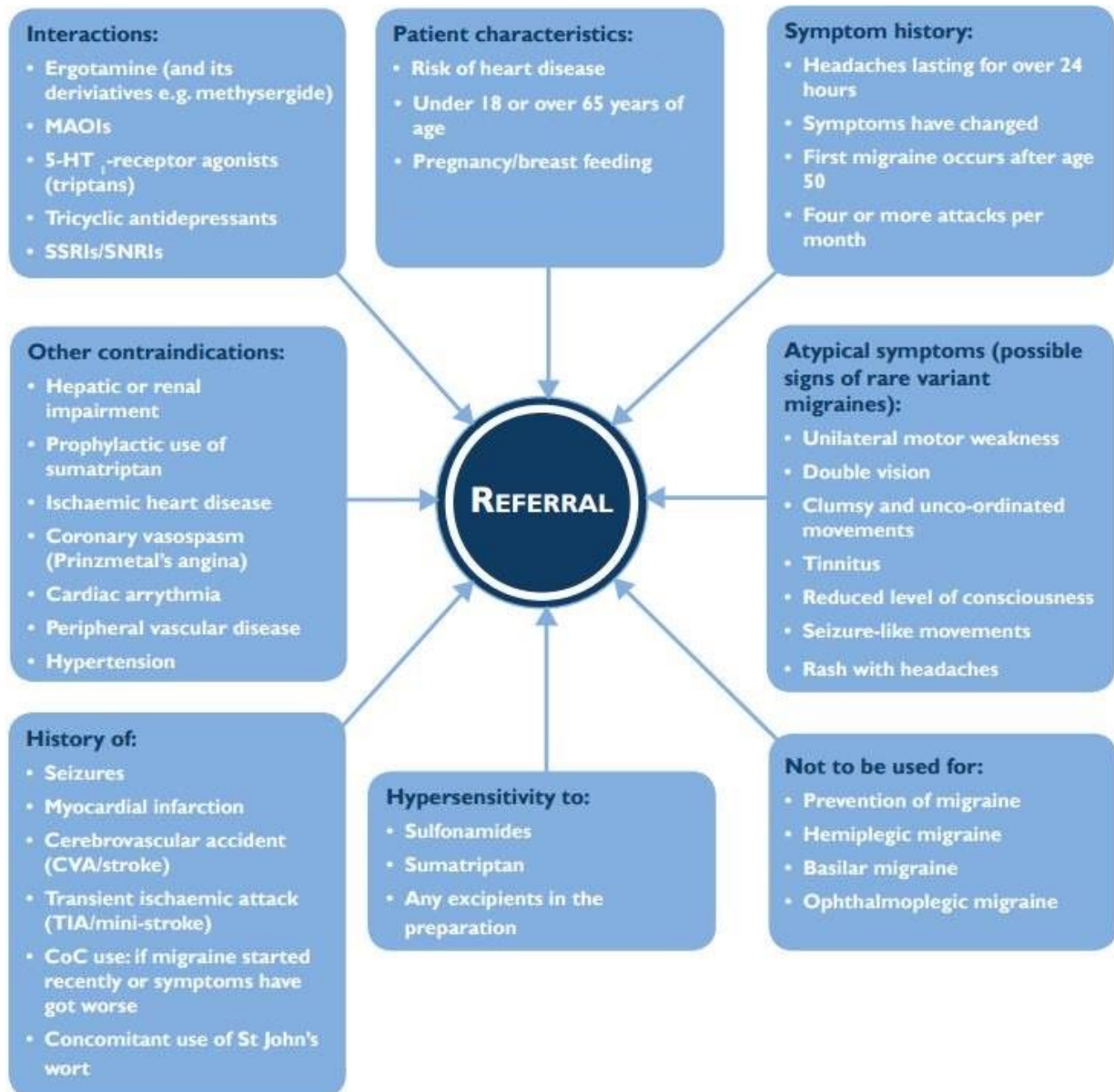
1. nausea and/or vomiting
2. photophobia and phonophobia (but may have one or the other).

**7. Warnings and precautions:**

Refer to a doctor if any of the following symptoms are present:

Who is the patient?	<ul style="list-style-type: none"> <li>• Patients who have not been previously diagnosed with migraine by a doctor.</li> <li>• Those aged under 18 years or over 65 years</li> <li>• Pregnant or breast-feeding migraine sufferers.</li> </ul>
What are the symptoms?	<ul style="list-style-type: none"> <li>• Anyone experiencing migraine-like symptoms for the first time</li> <li>• Where the pattern of symptoms has changed or attacks have become more frequent, more persistent, or more severe</li> <li>• Unilateral motor weakness (muscle weakness on one side of body)</li> <li>• Reduced level of consciousness</li> <li>• A recent rash with a headache, fever or stiff neck</li> <li>• Double vision</li> <li>• Tinnitus</li> <li>• Slurred or garbled speech</li> <li>• Clumsiness or uncoordinated movements</li> <li>• Headache confined to the back of the head</li> <li>• Seizure-like movements.</li> </ul>
<p>How long have the symptoms been present?</p> <p>How frequently recurring are the symptoms?</p> <p>When was the first presentation of the symptoms?</p>	<ul style="list-style-type: none"> <li>• Patients who have a headache (of any type) on 10 or more days per month</li> <li>• If migraine headache lasts for longer than 24 hours.</li> <li>• Patients who had their first ever migraine attack within the previous 12 months.</li> </ul>

	<ul style="list-style-type: none"> <li>• Patients who experience four or more attacks per month</li> <li>• Patients who do not recover fully between attacks.</li> </ul>
What action has already been taken?	<ul style="list-style-type: none"> <li>• Patients who did not respond to previous treatment with a triptan.</li> </ul>
Any other medication?	<ul style="list-style-type: none"> <li>• Patients taking medications such as SSRI/SNRIs, lithium, other triptans, St John’s Wort, ergotamine-based medicines</li> <li>• Pharmacists should exclude potentially serious drug interactions before commencing treatment (See BNF/SmPC for further information)</li> <li>• Women on the combined oral contraceptive pill, if the onset of migraine is within the previous 3 months, if migraine attacks are worsening or if they have a migraine with aura.</li> </ul>
Any other medical conditions / risk factors / family history?	<ul style="list-style-type: none"> <li>• Allergies to active ingredient, sulphonamides or excipients</li> <li>• Patients with cardiovascular risk factors (men aged over 40 years, post-menopausal women, obesity (body mass index &gt;30kg/m<sup>2</sup>), diabetes, hypercholesterolaemia, regular smoker (10 or more a day), family history of early heart disease –either father or brother had a heart attack or angina before age of 55 or mother or sister had a heart attack before the age of 65)</li> <li>• Known hypertension</li> <li>• History of cardiovascular disease e.g. angina, previous stroke, transient ischaemic attack (TIA), myocardial infarction (Heart attack)</li> <li>• Peripheral vascular disease</li> <li>• Liver or kidney impairment</li> <li>• Epilepsy or history of seizures</li> <li>• Migraineurs without a prior cardiac risk assessment. As migraine is a chronic condition, cardiovascular risk should be evaluated regularly in patients who use sumatriptan intermittently, over the longer term, to manage their migraine</li> <li>• Those with medication overuse headache (MOH)</li> <li>• Atypical Migraine, including hemiplegic, basilar or ophthalmoplegic migraine (see below).</li> </ul>



Reference: RPS Sumatriptan Quick Reference Guide

## 8. Contraindications

Sumatriptan administration is contraindicated in the following situations:

- Prophylactic use
- Concomitant administration with ergotamine, ergotamine derivatives, other triptans, MAOI
- Known hypersensitivity to any component of the product
- Known hypersensitivity to sulphonamides
- Known hypertension
- Previous myocardial infarction
- Peripheral vascular disease
- Ischaemic heart disease, e.g., angina
- Cardiac arrhythmias (including Wolff-Parkinson- White syndrome)
- Coronary vasospasm/Prinzmetal's angina

- Epilepsy or history of seizures
- Hepatic or renal impairment
- A history of cerebrovascular accident or transient ischaemic attack
- Atypical migraine (including hemiplegic, basilar or ophthalmoplegic migraine) \*.

\* **Hemiplegic migraine** – migraine with aura including unilateral motor weakness. These symptoms occur about 10 – 90 minutes before the headache.

**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. It occurs mainly in young people.

**Ophthalmoplegic migraine** – migraine headache with involvement of one or more ocular cranial nerves resulting in weakness of the muscles controlling eye movement. This very rare headache tends to occur in younger adults. Attacks can last from hours to months.

### 9. Dose and Patient Advice

The supply of non-prescription Sumatran Relief must only be conducted by the pharmacist, who must confirm that the patient has migraine (as distinct from any other types of headache), previously diagnosed by a doctor. If a supply is deemed appropriate, patient counselling should include information and advice on the following:

- Sumatriptan may be recommended for migraine sufferers who have been unsuccessful with simple analgesics (or analgesics combined with anti-emetics) either because the treatment was ineffective or because it was poorly tolerated
- A single 50mg tablet should be swallowed whole with water. Sumatriptan has a bitter taste, which is masked with a grapefruit flavour.
- It is advisable that sumatriptan be given as early as possible after the onset of migraine symptoms although, it is equally effective at whatever stage of the attack it is administered
- A single dose typically relieves symptoms within 30 minutes. If there is NO response to the first dose of sumatriptan, a second dose should NOT be taken for the same attack. In these cases migraine may be treated with paracetamol, aspirin 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 100 mg should be taken in any 24-hour period, unless prescribed by a doctor, where the maximum dose is 300mg in 24 hours.
- No other triptan (including sumatriptan-containing products), ergotamine or ergotamine derivative should be used concomitantly for the same migraine attack. Advise patients to wait at least 24 hours following the use of ergotamine containing preparations or another triptan/5-HT<sub>1</sub> receptor agonist before administering sumatriptan. Conversely advise patients 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-HT<sub>1</sub> receptor agonist.
- Sumatriptan may cause drowsiness, dizziness and weakness which may influence the ability to drive or operate machinery. If this occurs, skilled tasks should be avoided.
- Patients should be encouraged to read the Patient Information Leaflet. For more information, they can visit [www.migraine.ie](http://www.migraine.ie)

- If migraine headache lasts for longer than 24 hours, the patient should be referred to a doctor for further evaluation and management prior to OTC supply.

### 10. Side Effects and Adverse Events

The reclassification of sumatriptan from POM to P should pose no additional safety concerns additional to those listed in the SmPC, provided the appropriate guidance is followed.

Adverse effects are typically mild, of short duration and resolve without additional treatment.

- The most common side effects include dizziness, drowsiness, sensory disturbances, flushing, nausea, vomiting and fatigue. Some of these side effects may be related to migraine rather than sumatriptan.
- 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.
- Referral is required if there are intense chest pains or sensations, as it may be due to coronary vasoconstriction or anaphylaxis
- There have been very rare reports of seizures and of cardiovascular events such as cardiac arrhythmias, angina and myocardial infarction.

Consult the SmPC for a detailed list of adverse effects.

### Reporting of suspected side effects

Report any suspected serious adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

**OR** to Rowex Ltd., Bantry, Co Cork; tel: 02750077; fax: 02750417; email: [pv@rowa-pharma.ie](mailto:pv@rowa-pharma.ie)

### 11. Pharmacy Storage

Sumatran Relief must be stored behind the counter, out of reach of self-selection.

### 12. Migraine Triggers

Migraine may be precipitated by migraine triggers such as:

- Lack of Sleep / Irregular sleep pattern?
- Changes in routine e.g. travel, shift work, skipped meals?
- Dietary triggers e.g. cheese, chocolate, citrus fruit, artificial sweeteners?
- Increased Stress? Pressure? Conflict? Anxiety?
- Hormonal changes e.g. associated with menstrual cycle?
- Smoking? Alcohol? Caffeine? Dehydration?
- Environmental triggers e.g. weather extremes, strong smells, bright lights, noise?
- Eye strain

A migraine diary may be recommended to help a patient to identify personal trigger factors.



### 13. References and Further Information

- Medication-overuse headache: risk factors, pathophysiology and management  
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- Migraine headaches | University of Maryland Medical Center  
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- National Clinical Programme for Neurology – Headache Pathway  
<http://www.hse.ie/eng/services/publications/Clinical-Strategy-and-Programmes/Neurology-Model-of-Care.pdf> (last accessed 3 Dec 2017)
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- Scottish Intercollegiate Guidelines Network Diagnosis and Management of Headache in Adults Quick Reference Guide 2008 <http://www.sign.ac.uk/assets/qrg107.pdf>

Produced in Consultation with

- Migraine Association of Ireland <http://www.migraine.ie>
- Irish Pharmacy Union <https://ipu.ie/home/>
- Community Pharmacist Focus Group held on 29 Nov 2017 in Cork, Ireland