

# PRACTICE GUIDANCE: OTC SUMATRIPTAN

Following reclassification from prescription-only to pharmacy medicine status sumatriptan 50mg tablets are now available for sale over-the-counter (OTC). This guidance outlines important points to consider when counter prescribing



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## WHO TO REFER TO GP

- Those aged under 18 years or over 65 years
- Those aged 50 years or over and experiencing migraine attacks for the first time. If a doctor confirms a diagnosis of migraine they can be considered for OTC sumatriptan
- Patients who had their first ever migraine attack within the previous 12 months
- Patients who have had fewer than five migraine attacks in the past
- Patients who experience four or more attacks per month. The patient is potentially suitable for OTC sumatriptan but should be referred to a doctor for further evaluation and management
- If migraine headache lasts for longer than 24 hours. The patient is potentially suitable for OTC sumatriptan but should be referred to a doctor for further evaluation and management
- Patients who do not respond to treatment
- Patients who have a headache (of any type) on 10 or more days per month
- Women with migraine who take the combined oral contraceptive pill have an increased risk of stroke so should be referred if the onset of migraine is within the previous three months, if migraine attacks are worsening or if they have a migraine with aura
- Patients who do not recover fully between attacks
- Pregnant or breast-feeding migraine sufferers
- Patients with three or more cardiovascular risk factors (see “Cautions”)

### Urgent referral may be required for patients with:

- Unilateral motor weakness (muscle weakness on one side of body)
- Double vision
- Clumsiness or uncoordinated movements
- Tinnitus
- Reduced level of consciousness
- Seizure-like movements
- A recent rash with a headache
- Headache confined to the back of the head
- A recent marked deterioration in migraine (eg, an increase in duration, severity or frequency of attacks)

## WHAT ARE THE OTC INDICATIONS?

OTC sumatriptan is indicated for the acute treatment of migraine attacks with or without aura in adults aged 18 to 65 years. It should only be used where there is a clear diagnosis of migraine (see flowchart overleaf). It should not be used prophylactically.

## HOW DOES SUMATRIPTAN WORK?

The triptans are 5-HT<sub>1</sub> (serotonin) agonists. They appear to work by stimulation of 5-HT<sub>1B</sub> and 5-HT<sub>1D</sub> receptors. Cranial vasoconstriction and inhibition of trigeminal nerve activity may contribute to their action.

## IS IT MIGRAINE?

Migraine is characterised by recurrent, throbbing, often unilateral headaches. It may be accompanied by nausea, vomiting, and sensitivity to light, sound or movement and is often aggravated by routine activities. A migraine attack may be precipitated by migraine triggers. The most common type of migraine is migraine without aura. Migraine with aura involves warning signs (auras) in the hour preceding the headache. Auras include visual changes (eg, flashes of light); sensory symptoms (eg, numbness) and speech disturbances.

A migraine headache usually lasts four to 72 hours (untreated or unsuccessfully treated). 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 triggers

Bright lights, noise, strong smells	Missing meals
Diet, eg, alcohol, cheese, chocolate, artificial sweeteners	Stress
Eye strain	Too much or too little sleep
Hormonal changes, eg, menstruation	Travel
	Unaccustomed strenuous exercise
	Weather extremes

## PRACTICE POINTS

- OTC sumatriptan is indicated for the acute treatment of migraine attacks with or without aura in adults aged 18–65 years.
- For pharmacy supply patients should have an established pattern of migraine (a history of five or more migraine attacks. Their first ever migraine attack should have occurred more than 12 months ago).
- Patients aged 50 years or over experiencing migraine attacks for the first time need to seek medical advice since there may be a more serious underlying cause.
- OTC sumatriptan is useful as second line therapy for migraine sufferers who have been unsuccessful with analgesics (or analgesics combined with anti-emetics).
- Advise patients to take a single tablet as soon as possible after the onset of a migraine headache although it is effective if taken at any stage of the headache.
- If the first dose of sumatriptan is ineffective, a further dose is unlikely to be effective and should not be taken. However, if symptoms return after initial relief, a second dose can be taken after two hours.
- Patients experiencing four or more attacks per month or requesting four or more packs per month should be referred. The patient is potentially suitable for OTC sumatriptan but should be referred to a doctor for further evaluation and management.
- Excessive use of triptans may lead to chronic daily headache or exacerbation of headache.
- OTC sumatriptan is contraindicated in patients with a history of cardiovascular disease. In addition an individual with high cardiovascular risk should not receive OTC sumatriptan (see “Cautions”).
- Sumatriptan can cause drowsiness. If this occurs, skilled tasks such as driving should be avoided.
- Women with migraine who are taking the combined oral contraceptive pill have an increased risk of stroke so should be referred if the onset of migraine is recent (within the previous three months), if there is a worsening of migraine attacks, or if they have a migraine with aura.
- No other triptan (including sumatriptan-containing products), ergotamine or ergotamine derivative should be used with OTC sumatriptan for the same migraine attack. Patients on sumatriptan should not take St John’s wort preparations. Pharmacists should exclude potentially serious drug interactions before commencing treatment (see British National Formulary/Summary of Product Characteristics (SPC) for complete list).

## WHEN SHOULD SUMATRIPTAN BE COUNTERPRESCRIBED?

Over-the-counter analgesics, either on their own or combined with anti-emetics, can be effective in treating migraine attacks.

OTC sumatriptan is useful for sufferers who have been unsuccessful with analgesics (or analgesics combined with anti-emetics) — either because the treatment was ineffective or because it was poorly tolerated.

OTC sumatriptan is indicated for patients with an established pattern of migraine.

## HOW TO TAKE OTC SUMATRIPTAN

It is advisable that sumatriptan is taken as soon as possible after the onset of a migraine headache, although it is effective if taken at any stage of the headache.

A single 50mg tablet should be swallowed whole with water. If there is a response to the first tablet but the symptoms recur, a second tablet may be taken at least two hours after the first tablet. No more than two 50mg tablets (total dose 100mg) 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.

## CAUTIONS

Anyone who has three or more of these cardiovascular risk factors is not suitable for OTC sumatriptan:

- Men aged over 40 years
- Post-menopausal women
- Hypercholesterolaemia
- Regular smoker (10 or more daily)
- Obesity – body mass index more than 30 kg/m<sup>2</sup>
- Diabetes
- Family history of early heart disease – either father or brother had a heart attack or angina before the age of 55 or mother or sister had a heart attack or angina before the age of 65

## CONTRA-INDICATIONS

- Sumatriptan must not be used prophylactically
- Known hypersensitivity to any component of the product. OTC sumatriptan is also contra-indicated in patients with known hypersensitivity to sulphonamides
- Known hypertension
- Previous myocardial infarction
- Ischaemic heart disease, eg, angina
- Peripheral vascular disease
- Coronary vasospasm/Prinzmetal's angina.
- Cardiac arrhythmias (including Wolff-Parkinson-White syndrome)
- Hepatic or renal impairment
- Epilepsy or history of seizures
- Atypical migraine (including hemiplegic, basilar or ophthalmoplegic migraine)
- A history of cerebrovascular accident or transient ischaemic attack
- Concomitant administration with ergotamine, ergotamine derivatives, other triptans, monoamine oxidase inhibitors (see also "Drug Interactions")

## ADVERSE EFFECTS

The reclassification of sumatriptan to pharmacy status should pose no safety concerns additional to those in the SPC provided the appropriate guidance is followed. Adverse effects are typically mild to moderate, of short duration, and will resolve without additional treatment. Consult SPC for a detailed list of adverse effects.

Common adverse effects include nausea and vomiting; disturbances of sensation (including tingling); dizziness; drowsiness; flushing; warm sensation; feeling of weakness and fatigue; feelings of heaviness, pain or

pressure in any part of the body (including the chest and throat). Referral is required if there are intense chest pains or sensations, as it may be due to coronary vasoconstriction or anaphylaxis.

Transient increases in blood pressure may occur soon after treatment.

There have been very rare reports of hypersensitivity reactions, including anaphylaxis.

Very rare cases of serious cardiovascular events include cardiac arrhythmias, angina and myocardial infarction.

There have also been very rare reports of seizures.

**Pharmacists are reminded to send a yellow card report to the Medicines and Healthcare products Regulatory Agency if a serious adverse drug reaction is suspected.**

## DRUG INTERACTIONS

No other triptan (including sumatriptan-containing products), ergotamine or ergotamine derivative should be used with OTC sumatriptan for the same migraine attack. Twenty-four hours should elapse before sumatriptan can be taken following any ergotamine-containing preparation. Conversely, ergotamine-containing preparations should not be taken until six hours have elapsed following sumatriptan administration.

Triptans should not be taken with monoamine oxidase inhibitors (MAOIs). Sumatriptan must not be used if MAOIs have been taken in the previous two weeks.

Patients on sumatriptan should not take St John's wort preparations.

There is a risk of a pharmacodynamic interaction between sumatriptan and selective serotonin reuptake inhibitors (SSRIs). If concomitant use is considered to be appropriate, the patient should be warned to see their doctor if they develop weakness and/or lack of co-ordination following treatment. (The manufacturer of sertraline advises to avoid concomitant use).

There is a theoretical risk of a similar pharmacodynamic interaction between sumatriptan and tricyclic antidepressants.

## OVERALL ASSESSMENT

Triptans are the first class of OTC drugs to target migraine pathology. Early treatment of a migraine attack is desirable, and availability of OTC sumatriptan through a pharmacy permits a more rapid access to treatment. Community pharmacists are ideally placed to assess if an individual is suitable for OTC sumatriptan therapy.

## MIGRAINE MANAGEMENT

