Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Sumatriptan Film-Coated Tablets Abbreviated Prescribing Information. **Presentation:** Each film-coated tablet contains 50mg or 100mg of sumatriptan (as sumatriptan succinate). **Indications:** Acute treatment of migraine attacks with or without aura. **Dosage and administration:** Oral use. Should not be used prophylactically. *Adults*: The recommended dose for adults is a single dose of 50 mg. Some patients may require 100 mg. No more than 300 mg should be taken in any 24-hour period. *Children (<18 years of age)*: Not recommended for use. *Elderly (over 65 years of age)*: Not recommended for use. *Hepatic impairment*: Doses of 25-50mg should be considered for patients with mild to moderate liver impairment. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Sumatriptan should not be given to patients who have had myocardial infarction or who have ischaemic heart disease, Prinzmetal's variant angina/spasms of the coronary artery or peripheral vascular disease or patients who have symptoms or signs consistent with ischaemic heart disease. Sumatriptan should not be administered to patients with a history of cerebovascular accident (CVA) or transient ischaemic attack (TIA). The use of sumatriptan in patients with moderate or severe hypertension or mild uncontrolled hypertension is contraindicated. Sumatriptan should not be administered to patients with severe hepatic impairment. Concurrent administration of ergotamine or derivatives of ergotamine (including methysergide) or any triptan/5-hydroxytryptamine1 (5-HT1) receptor agonist with sumatriptan is contraindicated. Concurrent administration of monoamine oxidase inhibitors (MAOIs) and sumatriptan is contraindicated. Sumatriptan must not be used within two weeks of discontinuation of therapy with MAOIs. **Precautions and warnings:** Sumatriptan should only be used when there is a clear diagnosis of migraine. In case of doubt, patients should be referred to a neurologist. Before treatment with sumatriptan, it is important to rule out that the patient has a severe neurological condition (eg CVA, TIA) in case of atypical symptoms or that the patient has a diagnosis where the use of sumatriptan is not indicated. It should be noted that migraineurs may be at increased risk of certain cerebrovascular events (e.g. CVA, TIA). Sumatriptan is not indicated for use in the management of hemiplegic, basilar or ophthalmoplegic migraine. Following administration, sumatriptan can be associated with transient symptoms such as chest pain and tightness which may be intense and involve the throat. Where such symptoms are thought to indicate ischaemic heart disease, no further doses of sumatriptan should be given and an appropriate evaluation should be carried out. 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. 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 selective serotonin re-uptake inhibitors (SSRIs) and sumatriptan. Serotonin syndrome has been reported following concomitant treatment with triptans and serotonin noradrenaline reuptake inhibitors (SNRIs). Sumatriptan should be administered with caution to patients with conditions which may affect significantly the absorption, metabolism or excretion of the medicine, such as impaired hepatic or renal function. Lower doses should be considered in patients with hepatic impairment (Child Pugh grade A or B). 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. Patients with known hypersensitivity to sulphonamides may exhibit an allergic reaction following administration of sumatriptan. If ergotamine is used, Sumatriptan should not be taken earlier than 24 hours after taking ergotamine. Similarly, ergotamine should not be taken earlier than 6 hours after taking Sumatriptan and at least 24 hours should elapse before administering another triptan/5-HT1 receptor agonist. 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. Sumatriptan should be administered with caution to patients with mild controlled hypertension, since transient increases in blood pressure and peripheral vascular resistance have been observed in a small amount of patients. **Interactions:** There is no evidence of interactions with propranolol, flunarizine, pizotifen or alcohol. There are limited data on an interaction with ergotamine-containing preparations or another triptan/5-HT1 receptor agonist. The increased risk of coronary vasospasm is a theoretical possibility and concomitant administration is contraindicated. The exact 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 type of ergotamine-containing products used. An interaction may occur between sumatriptan and MAOIs and concomitant administration is contraindicated. There is a theoretical possibility of interactions with lithium. **Pregnancy and lactation:** Administration of sumatriptan should only be considered if the expected benefit to the patients is greater than any possible risk to the foetus. 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. The pain was usually transient and disappeared in 3 to 12 hours. **Effects on ability to drive and use machines:** Drowsiness may occur as a result of migraine or its treatment with sumatriptan. This may influence the ability to drive and to operate machinery. **Adverse reactions:** Hypersensitivity reactions ranging from cutaneous hypersensitivity (such as

urticaria) to anaphylaxis, seizures, serotonin syndrome, bradycardia, tachycardia, cardiac arrhythmia, coronary artery vasospasm, angina, myocardial infarction and ischaemic colitis. *Common*: Dizziness, drowsiness, sensory disturbance including paraesthesia, hypoaesthesia, transient increases in blood pressure arising soon after treatment, flushing, dyspnoea, nausea, vomiting, sensations of heaviness, myalgia, pain, sensations of heat or cold, pressure or tightness, feelings of weakness and fatigue. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** If overdosage occurs, the patient should be monitored for at least 10 hours and standard supportive treatment applied as required. **List Price:** 50mg Tablets, Pack of 6: £0.91; 100mg Tablets, Pack of 6: £1.50. **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/0588-0589. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00462. **Date of Preparation:** November 2025.