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.

Naratriptan 2.5mg Film-coated Tablets Abbreviated Prescribing Information **Presentation:** Each film-coated tablet contains 2.5mg naratriptan (as naratriptan hydrochloride). **Indications:** Acute treatment of the headache phase of migraine attacks with or without aura. **Dosage and administration:** Oral use. Naratriptan should not be used prophylactically. *Adults (18 to 65 years of age)*: Recommended dose is 2.5mg. The total dose should not exceed 5mg in any 24 hour period. *Children (<18 years of age)*: Not recommended for use. *Elderly (over 65 years of age)*: Not recommended for use. *Renal and Hepatic impairment:* The maximum total daily dose in patients with mild or moderate impairment is a single 2.5mg tablet. The use of naratriptan is contraindicated in patients with severe renal or hepatic impairment. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Previous myocardial infarction, ischaemic heart disease, Prinzmetal's angina/coronary vasospasm, peripheral vascular disease, patients who have symptoms or signs consistent with ischaemic heart disease. History of cerebrovascular accident (CVA) or transient ischaemic attack (TIA). Moderate or severe hypertension, mild uncontrolled hypertension. Severely impaired renal (creatinine clearance < 15 ml/min) or hepatic function (Child-Pugh grade C). Concomitant administration of ergotamine, derivatives of ergotamine (including methysergide) and any triptan/5-hydroxytryptamine1 (5-HT1) receptor agonist with naratriptan. **Precautions and warnings:** Naratriptan should only be used where there is a clear diagnosis of migraine. Naratriptan is not indicated for use in the management of hemiplegic, basilar or ophthalmoplegic migraine. 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. It should be noted that migraineurs may be at risk of certain cerebrovascular events (e.g. CVA or TIA). The safety and efficacy of naratriptan when administered during the aura phase, prior to the onset of migraine headache, has yet to be established. As with other 5-HT1 receptor agonists, naratriptan 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 therapy, without prior cardiovascular evaluation. Following administration, naratriptan can be associated with transient symptoms including 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 naratriptan should be taken and appropriate evaluation should be carried out. The recommended dose of naratriptan should not be exceeded. Serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) has been reported following concomitant treatment with triptans and selective serotonin reuptake inhibitors (SSRIs) or serotonin noradrenaline reuptake inhibitors (SNRIs). If concomitant treatment with naratriptan and an SSRI or SNRI is clinically warranted, appropriate observation of the patient is advised, particularly during treatment initiation, with dose increases, or with addition of another serotonergic medication. 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. **Interactions:** Significant metabolic drug interactions involving specific cytochrome P450 enzymes are unlikely. In clinical studies no evidence of interaction was found with β-blockers, tricyclic antidepressants or selective serotonin reuptake inhibitors. Oral contraceptives decrease the total clearance of naratriptan by 30%, and smoking increases total clearance by 30%, however, no dosing adjustments are required. There are limited data on interactions with ergotamine, ergotamine-containing preparations, dihydroergotamine (DHE) or sumatriptan. The increased risk of coronary vasospasm is a theoretical possibility with co-administration of these and 5-HT1 receptor agonists. At least 24 hours should elapse after the administration of naratriptan before an ergotamine-containing preparation or any triptan/5-HT1 receptor agonist is given. Conversely, at least 24 hours should elapse after the administration of an ergotamine-containing preparation before naratriptan is given. **Pregnancy and lactation:** Administration of naratriptan during pregnancy should only be considered if the expected benefit to the patient is greater than any possible risk to the foetus. No studies have been conducted to determine the level of transference of naratriptan into breast milk of nursing patients. It is recommended that infant exposure be minimised by avoiding breast-feeding for 24 hours after treatment. **Effects on ability to drive and use machines:** Drowsiness may occur as a result of migraine or its treatment with naratriptan. Caution is recommended when skilled tasks are to be performed e.g. driving or operating machinery. **Adverse reactions:** Anaphylaxis, bradycardia, tachycardia, coronary artery vasospasm, angina, myocardial infarction, peripheral vascular ischaemia and ischaemic colitis. *Common:* Sensations of tingling, dizziness, drowsiness, nausea, vomiting, sensations of heat, and malaise/fatigue. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** If overdosage with naratriptan occurs, the patient should be monitored for at least 24 hours and standard supportive treatment applied as required. **List Price:** 2.5mg Tablets, Pack of 6: £2.24; 2.5mg Tablets, Pack of 12: £4.64. **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/1106. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00359. **Date of Preparation:** August 2024.