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.

Frovatriptan Film-Coated Tablets Abbreviated Prescribing Information. **Presentation:** Each film-coated tablet contains 2.5 mg of frovatriptan (as frovatriptan succinate monohydrate). **Indications:** Acute treatment of the headache phase of migraine attacks with or without aura. **Dosage and administration:** Oral use and should not be used prophylactically. *Adults (18 to 65 years of age)*: The recommended dose of frovatriptan is 2.5mg, and the total daily dose should not exceed 5mg per day. *Children*: Not recommended for use in patients under 18 years of age. *Elderly (over 65 years of age)*: Not recommended for use. *Renal impairment:* No dosage adjustment is required. *Hepatic impairment:* No dosage adjustment is required in patients with mild to moderate hepatic impairment. Contraindicated in patients with severe hepatic impairment. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Patients with a history of myocardial infarction, ischaemic heart disease, coronary vasospasm (e.g. Prinzmetal's angina), peripheral vascular disease, patients presenting with symptoms or signs compatible with ischaemic heart disease. Moderately severe or severe hypertension, uncontrolled mild hypertension. Previous cerebrovascular accident (CVA) or transient ischaemic attack (TIA). Severe hepatic impairment (Child-Pugh C). Concomitant administration of frovatriptan with ergotamine or ergotamine derivatives (including methysergide) or other 5-hydroxytryptamine (5-HT1) receptor agonists. **Precautions and warnings:** Frovatriptan should only be used where a clear diagnosis of migraine has been established. Frovatriptan is not indicated for the management of hemiplegic, basilar or ophthalmoplegic migraine. As with other treatments of migraine attack, it is necessary to exclude other, potentially serious, neurological conditions before treating the headache of patients without a previous diagnosis of migraine, or migraine patients presenting with atypical symptoms. The safety and efficacy of frovatriptan administered during the aura phase, before the headache phase of migraine, has not been established. Frovatriptan must not be administered to patients at risk of coronary artery disease (CAD), including heavy smokers or users of nicotine substitution therapy without a prior cardiovascular evaluation. Frovatriptan administration can be associated with transient symptoms including chest pain or tightness which may be intense and involve the throat. Where such symptoms are thought to indicate ischaemic heart disease no further doses of frovatriptan should be taken and additional investigations should be carried out. Patients should be informed of the early signs and symptoms of hypersensitivity reactions including cutaneous disorders, angioedema and anaphylaxis. In case of serious allergic/hypersensitivity reactions, frovatriptan treatment should be discontinued immediately and it should not be administered again. In case of too frequent use (repeated administration several days in a row corresponding to a misuse of the product), the active substance can accumulate leading to an increase of the side-effects. 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:** It is recommended to wait at least 24 hours after administration of ergotamine-type medication before administering frovatriptan, due to risks of hypertension and coronary artery constriction due to additive vasospastic effects when used concomitantly for the same migraine attack. Conversely it is recommended to wait 24 hours after frovatriptan administration before administering an ergotamine-type medication. Frovatriptan is not a substrate for monoamine oxidase A enzyme, however, concomitant use with monoamine oxidase inhibitors is not recommended as a potential risk of serotonin syndrome or hypertension cannot be excluded. Concomitant use with selective serotonin reuptake inhibitors (e.g. citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) poses a potential risk of hypertension, coronary vasoconstriction or serotonin syndrome. Concomitant use with methylergometrine may cause hypertension and coronary artery constriction. Fluvoxamine is a potent inhibitor of cytochrome CYP1A2 and has been shown to increase the blood levels of frovatriptan. In female subjects taking oral contraceptives, concentrations of frovatriptan were higher than in females not taking oral contraceptives, but no increased incidence of adverse events was reported. As with other triptans the risk of the occurrence of serotonin syndrome may be increased when taken alongside oral St. John's Wort. **Pregnancy and lactation:** Not recommended during pregnancy and in women of childbearing potential not using contraception, unless clearly necessary. Not recommended during breast-feeding unless it is clearly needed. In this case, a 24 hours interval must be observed. **Effects on ability to drive and use machines:** Migraine or treatment with frovatriptan may cause somnolence. Patients should be advised to evaluate their ability to perform complex tasks such as driving during migraine attacks and following administration of frovatriptan. **Adverse reactions:** Hypersensitivity reactions, tachycardia, hypertension, bradycardia, myocardial infarction, coronary arteriospasm, peptic ulcer. *Common:* Dizziness, paraesthesia, headache, somnolence, dysaesthesia, hypoaesthesia, visual disturbance, flushing, throat tightness, nausea, dry mouth, dyspepsia, abdominal pain, hyperhidrosis, fatigue, chest discomfort. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** There is no specific antidote for frovatriptan. The elimination half-life of frovatriptan is approximately 26 hours. The effects of haemodialysis or peritoneal dialysis on serum concentrations of frovatriptan are unknown. In case of overdose with frovatriptan, the patient should be monitored closely for at least 48 hours and be given any necessary supportive therapy. **List Price:** 2.5mg Film-Coated Tablets, pack of 6: £18.13. **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/1817. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00357. **Date of Preparation:** August 2024