Prescribing Information: Migard (frovatriptan) 2.5 mg film-coated tablets.
Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.
Presentation: Film-coated tablets containing 2.5 mg of frovatriptan. Contains lactose.
Use: Acute treatment of the headache phase of migraine attacks with or without aura in adults.
Dosage and administration: Oral administration. Adults: Initial dose is 2.5mg, if the migraine recurs after initial relief, a second dose may be taken providing there is an interval of at least 2 hours between doses. Frovatriptan should be taken as early as possible after the onset of a migraine attack but it is also effective when taken at a later stage. Should not be taken prophylactically. If a patient does not respond to the first dose, a second dose should not be taken for the same attack. May be used for subsequent migraine attacks. Total daily dose should not exceed 5 mg. Paediatric patients: No data are available in children and adolescents below the age of 18 years. Elderly: Data in patients over 65 years remains limited and is therefore not recommended. Renal impairment: No dosage adjustment is required. Hepatic impairment: No dosage adjustment is required with mild to moderate hepatic impairment, contraindicated in severe hepatic impairment. Tablets should be swallowed whole with water.
Contraindications: Hypersensitivity to the active substance or to any of the excipients. Patients with a history of myocardial infarction, ischaemic heart disease, coronary vasospasm, peripheral vascular disease, symptoms or signs of ischaemic heart disease. Moderately severe or severe hypertension. Uncontrolled mild hypertension. Previous cerebrovascular accident or transient ischaemic attack. Severe hepatic impairment (Child-Pugh C). Concomitant administration with ergotamine or ergotamine derivative or other 5-hydroxytryptamine (5-HT_1) receptor agonist.
Warnings and Precautions: Use only when a clear diagnosis of migraine has been established and other potentially serious neurological conditions have been excluded. Must not be administered to patients at risk of coronary artery disease without a prior cardiovascular evaluation. May be associated with transient symptoms including intense chest pain or tightness and involve the throat. Treatment with frovatriptan should be stopped when symptoms are thought to indicate ischaemic heart disease or when allergic/hypersensitivity reactions occur. Advised to leave 24 hours between initiating or cessation of ergotamine type medication and frovatriptan administration. Repeated administration for several days can cause an increase in side effects. Undesirable effects may be more common with the concomitant use of St John's Wort. Avoid in patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.
Interactions: Avoid: ergotamine, ergotamine derivative and other 5-HT_1 agonist. Not recommended: monoamine oxidase inhibitors. Caution: SSRIs, methylergometrine, fluvoxamine, oral contraceptives and St John's Wort.
Pregnancy and lactation: Not recommended during pregnancy and in women of child bearing potential not using contraception. Not recommended in lactation, if breast-feeding is clearly needed a 24 hour interval must be observed.
Side-effects: Common ($\geq$ 1/100 to < 1/10): dizziness, paraesthesia, headache, somnolence, dysaesthesia, hypoaesthesia, visual disturbance, flushing, throat tightness, nausea, dry-mouth, dyspepsia, abdominal pain, hyperhidrosis, fatigue, chest discomfort. Uncommon ($\geq$ 1/1000 to < 1/100): Dehydration, anxiety, insomnia, confusional state, nervousness, agitation, depression, depersonalisation, dysgeusia, tremor, disturbance in attention, lethargy, hyperaesthesia, sedation, vertigo, involuntary muscle contractions, eye pain, eye irritation, photophobia, tinnitus, ear pain, palpitations, tachycardia, peripheral coldness, hypertension, rhinitis, sinusitis, pharingolaringeal pain, diarrhoea, dysphagia, flatulence, stomach discomfort, abdominal distension, pruritus, musculoskeletal stiffness and pain, pain in extremity, back pain arthralgia, pollakiuria, polyuria, chest pain, feeling hot, temperature intolerance, pain, asthaenia, thirst, sluggishness, energy increased, malaise. Not known: Hypersensitivity reactions, myocardial infarction, arteriospasm coronary.
Package quantities and price: 6 tablets. £16.67.
Legal category: POM.
Marketing Authorisation Holder: Menarini International Operations Luxembourg S.A.
Marketing authorisation numbers: PL 16239/0017
Marketed by: A. Menarini Farmaceutica Internazionale SRL.
Further information is available on request to A. Menarini Farmaceutica Internazionale SRL, Menarini House, Mercury Park, Wycombe Lane, Wooburn Green, Buckinghamshire, HP10 0HH, UK or may be found in the SmPC.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to A. Menarini Farmaceutica Internazionale SRL. Phone no. 0800 085 8678 or email: menarini@medinformation.co.uk