Migraitan prescribing information:

Product Name: Migraitan 50mg Film-coated tablets. **Composition:** Sumatriptan succinate 50mg. See SPC for full list of excipients. **Indication:** Acute relief of migraine attacks, with or without aura. Only to be used where there is a clear diagnosis of migraine. **Posology and method administration**: Must not be used prophylactically. Not to be taken concomitantly with other migraine therapies containing any triptan, ergotamine or derivative of ergotamine. Adults (18 to 65 years): Single 50mg tablet swallowed whole with water. It is advisable that Migraitan be taken as soon as possible after the onset of a migraine headache although it is effective at whatever stage of headache it is taken. If there is a response to the first tablet but the symptoms recur, a second tablet may be taken. However, this must be at least 2 hours after the first tablet. No more than two 50mg tablets (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. Elderly (over 65 years): Not to be used in those aged over 65 years. Children (less than 10 years): No clinical data, (10-17 years): Not recommended. **Contraindications:** Hypersensitivity to the active substance / any excipients. Those with: previous myocardial infarction, ischaemic heart disease, coronary vasospasm, cardiac arrhythmias, peripheral vascular disease, signs consistent with ischaemic heart disease, known hypertension, history of stroke, transient ischaemic attack, hepatic or renal impairment, seizures. Not to be used with: - ergotamine, ergotamine derivatives, monoamine oxidase inhibitors (MAOIs) or 2 weeks after stopping use of MAOIs. 5HT-1 receptor agonists. Not for use with rare migraine variants; hemiplegic, basilar or ophthalmoplegic migraines. **Special warnings and precautions for use:** For migraineurs whose headaches continue for more than 24 hours, the pattern of symptoms change, or who do not recover completely between attacks, they should seek advice from their doctor. Patients in whom symptoms occur for the first time after age 50 should seek advice from their doctor. If migraineurs experience 4 or more attacks per month, they should be medically referred. Sumatriptan can be associated with transient symptoms of chest pain and tightness involving the throat. Not to be used in patients in whom unrecognized cardiac disease is likely without prior medical assessment. Special consideration should be given to post-menopausal women and males aged over 40 years. Rare reports of serotonin syndrome, following concomitant use of both SSRIs and serotonin noradrenaline reuptake inhibitors (SNRIs) with sumatriptan. Patients with hypersensitivity to sulphonamides may exhibit an allergic reaction. Women on the oral contraceptive pill have an increased risk of stroke and should seek advice from their doctor if migraine attacks started in last 3 months or have worsened. Patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption, should not take this medicine. **Interactions with other** medicinal **products:** Contraindicated for concomitant use with MAOls, ergotamine or ergotamine derivatives, other triptan/5-HT-l receptor agonists. Advised to wait for at least 24 hours following use of ergotamine containing preparations or other triptan / 5-HT1 receptor agonists before sumatriptan use. Advised to wait 6 hours post sumatriptan use before use of ergotamine containing products and 24 hours before triptan *I* 5-HT1 receptor agonists. Serotonin syndrome reported in patients following co-administration with SSRls, SNRls and triptans. **Pregnancy and lactation:** Only to be used in pregnancy or when breast feeding on the advice of a doctor. Sumatriptan is excreted in breast milk. Minimise infant exposure by avoiding breast feeding for 12 hours after treatment. Expressed milk during these 12 hours should be discarded. **Driving ability/use of machines:** Drowsiness may occur as a result of migraine or its treatment with sumatriptan. **Undesirable effects:** Common effects; Dizziness, drowsiness, sensory disturbance, transient increases in blood pressure, flushing, dyspnea, nausea, vomiting, sensation of heaviness, myalgia, pain, sensations of heat. cold, pressure, tightness, weakness or fatigue; see SmPC for full list of side- effects. **Overdose:**

Seek medical advice. For further information please see the SmPC (Summary of Product Characteristics) for Migraitan. **Product Licence Holder:** Bristol Laboratories Limited, Unit 3, Canalside Northbridge Road, Berkhamsted, Hertfordshire, HP4 1EG **(**PL 17907/0240), **Date of Authorisation:** 08/05/09, **Recommended** Retail **Price: -** £ 8.00, 2 Tablet Pack, **Date of Prescribing Information:**03.08.2018 **Legal Classification**: P

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows monitoring of the benefit/risk balance of the medicinal product.
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 Bristol Laboratories Medical Information Department on Telephone: +44 (0) 1442 200 922

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