

This Patient Group Direction (PGD) must only be used by registered pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the supply of

Sumatriptan 50mg tablets

by registered pharmacists for the

Acute relief of migraine attacks with or without aura

under the Wirral Clinical Commissioning Group Minor Ailments Service

Version number: 4

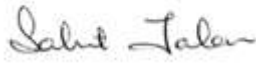

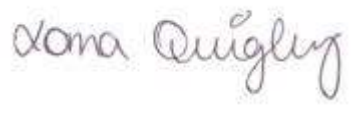
Change history

Version number	Change details	Date
1.0	Original Document developed with the PGD Development and review group	May 2015
2.0	Review and Amendments by the PGD Development and review group	March 2016
2.1	Update in line with Wirral CCG self-care policy	February 2017
3.0	Review and Amendment by PGD Development and Review Group	March 2019
3.1	<p>Inclusion and Exclusion criteria updated and reviewed</p> <p>Under cautions – SPC link updated</p> <p>Actions to be taken if patient excluded – refer to GP</p> <p>Dose & frequency reviewed and updated</p> <p>Adverse effects reviewed and updated</p> <p>Records to be kept reviewed and updated – removed the need for pharmacist signature – pharmacist name is sufficient due to electronic records</p> <p>Key references updated:</p> <ul style="list-style-type: none"> • https://cks.nice.org.uk/topics/migraine/ • https://www.medicines.org.uk/emc/product/945/smpc 	January 2021
4.0	Review and Amendments by the PGD Development and review group	March 2021

PGD development

Name	Job title and organisation
Lead author Nicola Bradley Updated by Mariah Zavery (March 2019) and Abigail Cowan (January 2021)	Medicines Optimisation Pharmacists Midlands & Lancashire Commissioning Support Unit (MLCSU)
Lead doctor Dr Saket Jalan	GP, Clinical Lead for Urgent Care & Medicines Management NHS Wirral CCG
Lead pharmacist Rob Hebdon	Senior Prescribing Advisor, MLCSU
Representative of other professional group using PGD Adam Irvine	Community Pharmacy Cheshire and Wirral (CPCW)
Other members of the PGD working group: Richard Crockford, Deputy Director of Quality & Safety NHS Wirral CCG	

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Saket Jalan	Clinical Lead for Urgent Care & Medicines Management (NHS Wirral CCG)		08/03/21
Senior pharmacist Robert Hebdon	Senior Medicines Optimisation Lead, MLCSU		08/03/21
Person signing on behalf of Wirral CCG Lorna Quigley	Director of Quality and Safety NHS Wirral CCG		05/03/21

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Training and competency of registered pharmacist

	Requirements of registered pharmacists working under the PGD
Qualifications and professional registration	Qualified pharmacist registered with the General Pharmaceutical Council (GPhC)
Initial training	Competent to work under Patient Group Directions, including satisfactory completion of training to administer/supply in accordance with this Patient Group Direction. Working as a community pharmacist and accredited to provide the Minor Ailments Service
Competency assessment	CPPE Declaration of Competence Documents (DoCs)
Ongoing training and competency	Commitment to continuing updating and re-validation according to the accreditation requirements of the commissioning organization. Commitment to keep up to date with clinical developments in this area or changes to the recommendations for the medicine listed, as part of their Continual Professional Development.

Clinical conditions

Clinical condition or situation to which this PGD applies	Treatment of an acute attack of migraine with or without aura.
Inclusion criteria	<p><i>Adults who have received a clear previous diagnosis of migraine from their GP and who have:</i></p> <ul style="list-style-type: none"> • Attacks that have not previously responded to OTC analgesia • Previous prescription history with the presenting pharmacy for the dispensing of at least one prescription for sumatriptan 50mg tablets for the treatment of migraine or able to provide evidence of previous diagnosis and prescription • Given valid consent • Patient has no more than two of the following 3 or more cardiovascular risk factors: <ul style="list-style-type: none"> ○ Women who have reached the menopause ○ Men aged over 40 years ○ Family history of early heart disease – either a father or brother had a heart attack or angina before the age of 55 years, or mother or sister had a heart attack or angina before the age of 65 years. ○ Diabetes ○ Known high cholesterol ○ Regularly smoke more than 10 cigarettes a day ○ Obese (BMI>30kg/m²)
Exclusion criteria	<ul style="list-style-type: none"> • No valid consent • Patients under 18 years of age • Patients over 65 years of age • Pregnancy or breastfeeding • Patients with three or more of the above cardiovascular risk factors • Current prophylactic treatment • Attacks that last less than 4 hours without treatment • Attacks occurring on 4 or more days a month • Patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as it contains lactose. • Patients whose pattern of symptoms has changed, whose recovery between attacks is incomplete or whose attacks have become: <ul style="list-style-type: none"> ○ more frequent ○ more persistent ○ more severe • Women taking a combined oral contraceptive pill experiencing worsening of migraine attacks or migraine with aura.

	<ul style="list-style-type: none"> Patients experiencing atypical symptoms which include, but are not limited to: <ul style="list-style-type: none"> Unilateral motor weakness Double vision Clumsy and uncoordinated movements Tinnitus Reduced level of consciousness Seizure-like movements Recent onset of rash with headache <p><i>Urgent referral to a doctor may be required if any of these are reported:</i></p> <ul style="list-style-type: none"> Known hypersensitivity to sumatriptan or any other excipient in the product Known hypersensitivity to sulphonamides Taking or planning to take any medicines or other treatments for migraine. E.g. other triptan, ergotamine or ergotamine derivative Previous myocardial infarction Ischaemic heart disease, angina, cardiac arrhythmias, peripheral vascular disease Previous stroke or transient ischaemic attack (TIA) Known or uncontrolled hypertension Known hepatic or renal impairment History of seizures Patients taking any of the following medication: <ul style="list-style-type: none"> Ergotamine or derivatives of ergotamine (including methysergide) Monoamine Oxidase Inhibitors (MAOIs) Any other 5HT₁ agonists Selective serotonin receptor inhibitors (SSRIs) Patients who have discontinued MAOIs in the past 2 weeks Rare variants of migraine: hemiplegic migraine, basilar migraine, ophthalmoplegic migraine Previous ineffective treatment with sumatriptan
Cautions (including any relevant action to be taken)	<ul style="list-style-type: none"> Refer to Summary of Product Characteristics http://www.medicines.org.uk/emc/
Arrangements for referral for medical advice	<ul style="list-style-type: none"> Supply the patient with a referral note to hand to the GP indicating the reasons for the referral
Action to be taken if patient excluded	<ul style="list-style-type: none"> Refer to GP Clearly record the decision on the patient's consultation proforma including any advice given and action taken.
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> Record the decision on the patient's consultation proforma including any advice given and action taken. Refer to GP as appropriate

Details of the medicine

Name, form and strength of medicine <i>Include ▼ for black triangle medicines</i>	Sumatriptan 50mg tablets
Legal category	POM
Indicate any off-label use (if relevant)	N/A
Route/method of administration	Oral
Dose and frequency	<p>One 50mg tablet taken as soon as possible after the onset of a migraine headache although it is effective at whatever stage of the headache it is taken</p> <p>If there is a response to the first dose, but symptoms recur, a second 50mg tablet may be taken. This must be at least 2 hours after the first tablet.</p> <p>No more than 300mg should be taken in any 24 hour period or to treat the same attack (as per current SPC & BNF)</p> <p>If there is no response to the first tablet, a second tablet should not be taken for the same attack.</p>
Quantity to be administered and/or supplied	<p>Supply 6 tablets per treatment episode</p> <p>Two treatment courses in any 12 month period under this PGD</p>
Maximum or minimum treatment period	As detailed in 'Dose and frequency'

Adverse effects	<p>Common</p> <ul style="list-style-type: none"> • Pain, sensations of heat or cold, tightness or pressure (usually transient, may be intense and can affect any part of the body including the chest and throat), feelings of weakness, fatigue (both events are mostly mild to moderate in intensity and transient). • Dizziness, drowsiness, sensory disturbance including paraesthesia and hypoaesthesia. • Transient increases in blood pressure arising soon after treatment. Flushing • Nausea and vomiting. (May also be due to the migraine) • Dyspnoea • Dysphagia • Sensations of heaviness (usually transient and may be intense and can affect any part of the body including the chest and throat). Myalgia. <p>Rare</p> <ul style="list-style-type: none"> • Visual disturbances, flickering, reduced vision, double vision or loss of vision (may also be due to the migraine) • Tremor, seizures, stiff neck, tachycardia or bradycardia, palpitations, irregular heartbeat <p>Refer to SPC or current BNF for full details</p>
Records to be kept	<p>The following will be recorded in the patient's consultation proforma:</p> <ul style="list-style-type: none"> • Advice given to patient • Patients name, address, date of birth and GP • Date and time of supply • The batch number and expiry date • The signature of the person supplying the medicine

Patient information

<p>Verbal/written advice to be given to patient</p>	<ul style="list-style-type: none"> • Advise the patient how to take the product and discuss side effects • Provide a manufacturers patient information leaflet • Can cause drowsiness – if affected do not drive or operate machinery. • If there is no response to the first dose a second dose should not be taken; the attack may be treated with simple analgesics. See GP for reconsideration of migraine diagnosis. • If the attack persists longer than 24 hours contact the GP • Four or more attacks in any one-month MUST be reported to the GP • Discuss the possibility of medication overuse headache • Consider using a headache diary. • Give practical advice on avoidance of triggers where possible e.g., stress, cheese, caffeine, chocolate, alcohol, strong smells, bright lights, dehydration, missed meals etc.
<p>Follow-up advice to be given to patient or carer</p>	<p>Contact GP if no improvement after 24 hours or sooner if symptoms worsen</p>

Appendices

Appendix A Key references

1. Clinical Knowledge Summaries Guideline. [Migraine](#). (Last Accessed January 2021)
2. [Summary of Product Characteristics](#) (Last Accessed January 2021)
3. NICE Patient Group Direction, Medicines Practice Guideline (MPG2). Updated March 2017.
<https://www.nice.org.uk/guidance/mpg2>

Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD.

Name of pharmacist	Signature	Senior representative authorising pharmacist	Date