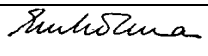
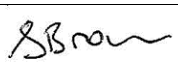
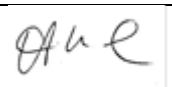
NHS AYRSHIRE & ARRAN

PATIENT GROUP DIRECTION

Name of Medicine :	Azithromycin 250mg tablets/capsules
Legal Classification :	Prescription Only Medicine
PGD Ref No :	CP 23 011
Replacing PGD Ref No :	CP 21 011

Effective Date :	22nd June 2023
Review Date :	21st June 2025

Professional Group authorised to use PGD on completion and submission of an Approved Practitioner Form:	Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC). Pharmacists currently registered with the General Pharmaceutical Council (GPhC).

PGD prepared/reviewed* by : (*delete as appropriate)			
	Doctor	**Pharmacist**	**Other**
Name	**Ruth Holman**	**Scott Brown**	**Attica Wheeler**
Signature			
Date	**25/05/2023**	**23/05/2023**	**01.06.2023**

Approved on behalf of NHS Ayrshire & Arran
Chair or vice chair PGD group:
Name: Jen Pennycook
Signature: 
Date: 22/06/2023

Description of Treatment	
Name of medicine : Azithromycin 250mg tablets/capsules	
POM/P/GSL :	Prescription Only Medicine
Pharmaceutical Form :	Tablets/Capsules
Strength :	250mg
Clinical situation for use of this PGD	This PGD covers the supply of azithromycin for use in the treatment of uncomplicated Chlamydia Trachomatis when first line treatment with doxycycline is contraindicated.
Inclusion criteria	Individuals for whom doxycycline is contraindicated (known allergy, previous adverse effects, pre-existing medical conditions, pregnancy) or inappropriate (photosensitivity, likely poor adherence): and are: • **Individuals with a positive test for *Chlamydia trachomatis* infection in the genitals, rectum or pharynx.** • Individuals with a microscopic diagnosis of non-gonococcal (NGU) or non-specific urethritis (NSU). • Asymptomatic individuals presenting within 2 weeks of sexual contact with an individual with a confirmed diagnosis of chlamydia, NSU/NGU, PID or epididymo-orchitis who are unwilling/unable to defer testing after the 2-week window period. • A single repeat treatment course for individuals who have had sexual intercourse within 7 days of receiving treatment or who have had sex with partner untreated for the above conditions. • Individuals with a definite diagnosis of uncomplicated *Mycoplasma genitalium* where a course of doxycycline has been completed within the previous two weeks (where resistance testing is available, confirmed macrolide sensitivity). • Consent given. • Aged 13 years and over who are assessed as Fraser competent.
Exclusion criteria	• Individuals aged 12 years or under. The Child Protection Team must be contacted for children of 12 years and under who present having had sexual intercourse. **Ensure treatment of the infection is provided by a prescriber.** • Where there is no valid consent. • When consent to provide relevant clinical information is refused.

	Medical history • Individuals with suspected and/or confirmed symptomatic rectal *Chlamydia trachomatis*. • Individual with complicated *Chlamydia trachomatis* infection such as (epididymitis and/or testicular pain or a clinical diagnosis of Pelvic Inflammatory Disease (PID) • Individuals with suspected or confirmed Lymphogranuloma venereum (LGV) • Known severe hepatic impairment • Known severe renal impairment (eGFR <10ml/min/1.73m^2/ CKD stage 5) • Current/past history of cardiac rhythm or conduction disturbance • Presence of concomitant conjunctivitis and/or joint pain/swelling • Acute porphyria • Myasthenia gravis **Medication history** • Any concurrent interacting medicine(s) • Known hypersensitivity or allergy to the azithromycin or other macrolide antibiotics or to any component of the product - see Summary of Product Characteristics • Individuals with known azithromycin resistance. Individuals currently taking ergot derivatives such as ergotamine (Migril®)
Cautions including any relevant action to be taken:	• Some brands of azithromycin contain soya or soya lecithin and are therefore contraindicated in individuals with an allergy to soya or peanuts. If individual is allergic, check manufacturer's information for brand being used and if necessary, exclude from PGD or select an alternative suitable brand if available. • Pregnant individuals/individuals known to be at risk of pregnancy – the SPC states that there is limited data on use in pregnancy however BASHH guidelines state: "While adverse pregnancy outcomes are unlikely with the 2g total azithromycin dose, individuals should be advised of the lack of data." The individual must be informed that although the use of azithromycin in pregnancy is thought to be safe, there is limited research available and be fully informed of the risks and benefits of this treatment. • Breastfeeding individuals – BASHH states that 'Very low levels of azithromycin are detected in breast milk, and systemic exposure in infants does not exceed that observed when azithromycin is administered for treatment, therefore risk is considered to be low'. • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be

	made and documented. • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
Dosage :	Day One: 1g taken as a single dose Day Two: 500mg once daily Day Three: 500mg once daily For uncomplicated Mycoplasma genitalium azithromycin course to be started immediately after the doxycycline course completed – where this is not achieved it must be started within 2 weeks of the doxycycline course being completed. If the azithromycin course is not started within this timeframe the individual should be referred to a specialist practitioner.
Total Dosage:	2g
Route of Administration :	Oral
Frequency of Administration :	One single dose of 1g followed by 500mg for 2 days.
Duration of Treatment :	Three days treatment
Total Treatment Quantity :	Appropriately labelled pack of 4x500mg capsules/tablets or 8x250mg capsules/tablets or appropriate quantity of reconstituted oral suspension (amend locally to reflect pack size to be supplied). A single repeat course can be supplied under the PGD if vomiting occurs within 3 hours of a dose being taken.
Action if patient is excluded from treatment under this PGD	•If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving treatment. •Pregnant individuals/individuals known to be at risk of pregnancy who decline azithromycin treatment should be referred to a prescriber for further consultation. •Explain the reasons for exclusion to the individual and document in the consultation record. •Record reason for decline in the consultation record. •Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

Interactions	All concurrent medications should be reviewed for interactions. The interactions listed as severe in the BNF are: • Berotralstat • Chloroquine • Colchicine • Dabigatran • Digoxin • Edoxaban • Hydroxychloroquine • Rifabutin • Talazoparib • Ticagrelor • Topotecan • Vinblastine • Vincristine • Vindesine • Vinflunine • Vinorelbine A detailed list of all drug interactions is available in the BNF or the product SPC Antacids : in individuals receiving Azithromycin and antacids, Azithromycin should be taken at least 1 hour before or 2 hours after the antacid
Adverse Effects	A detailed list of adverse reactions is available in the SPC and BNF The following side effects are very common/common with azithromycin: • Nausea • Anorexia • Vomiting • Dyspepsia • Dizziness • Headache • Diarrhoea • Abdominal pain/discomfort • Flatulence • Rash • Pruritus • Arthralgia • Fatigue • Visual impairment • Deafness • Paraesthesia • Dysgeusia

	Management and reporting procedure for adverse reactions •Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme •Record all adverse drug reactions (ADRs) in the patient's medical record.
Follow-up treatment	• Every individual should be advised to have a repeat test after 6-12 months because people with previous Chlamydia have high rates of re-infection. • Pregnant individuals should have a repeat test 4 weeks after treatment and again at 36 weeks gestation to ensure the infection is no longer present • If symptoms do not improve after treatment advise to seek medical help
Written/Verbal Advice to be given to patient	Azithromycin capsules should be taken at least 1 hour before or 2 hours after food • Indigestion remedies must not be taken within 1 hour before or 2 hours after Azithromycin • If vomiting occurs within 2 hours of taking tablets individuals who re-present should be referred to Medical Practitioner or sexual health clinic for further treatment • Advise individual regarding common side effects such as gastrointestinal upset, skin rash, antibiotic associated colitis, and candidiasis. For frequent side effects, refer to individual leaflet however it should be noted that Azithromycin is well tolerated by most people. For infrequent side effects refer to current BNF • Advise individual to abstain from all sexual contact (including unprotected sex and oral sex) whilst taking treatment and until 7 days after they and their partner(s) have been treated • Explain that if sexual contact takes place after treatment with untreated partner there is a significant risk of re-infection and further treatment will be required • Chlamydia is a bacteria that can be passed on by having sex. It can be carried with no symptoms. It is cured with these antibiotics. To make sure these work don't have sex for 7 days after you and any partner(s) have been treated or you may get re-infected. If you have had Chlamydia once you can still get it again in the future. The best way to stay safe from it is to use condoms, and get a checkup if you have a new partner.

	• Further info on www.shayr.com • Individual must be advised to notify any partners and • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services. • Where treatment has been supplied for confirmed Mycoplasma Genitalium infection, follow up testing should be arranged with sexual health services by emailing aa.sexual_health_ACH@aapct.scot.nhs.uk Written information : Individual information leaflet provide with medication. This should be available in a form that can be easily understood by the person. Where English is not easily understood, translations and properly recognized interpreters should be used. Information about sexual health services within Ayrshire & Arran www.shayr.com
Record required of Supply/Administration	**Sexual Health Department** Log in to NaSH and record in the 'prescribing detail' page: • Name of preparation administered • Quantity administered • Name of the member of staff administering the medicine • The date of the administration (time will then be recorded automatically) • That the drug has been supplied under a PGD Record any adverse reaction in clinical notes. Complete the allergies section if appropriate. **Administration - Electronic Prescribing (in-patients only)** On completion of the PGD LearnPro module, nurses are granted access rights to add PGD orders on the electronic prescribing system (HEPMA). As per the process explained in the LearnPro module, PGDs are found searching for medicines starting with NURSE and the following information is recorded: • Name of medicine, form and strength administered • Dose administered • Route of administration

	• Electronic signature of staff member who administered the medicine • Date and time of administration • Frequency is recorded as a STAT dose which automatically moves to the "Discontinued Medicines" section of the prescribing record once administered • Adverse reactions are recorded using the Allergies and Notes functions on the system **<u>Administration - Medicine prescription sheet (paper)</u>** • Name of medicine, form and strength administered • Add PGD and the reference number in brackets (PGD ref..) in the other instructions/Doctor's signature section. • Dose administered • Route of administration • Signature of staff member who administered the medicine • Date and time of administration • If a 'one off' dose only to be administered, record the above information on the 'medicines to given once' section on the reverse of the medicine prescription sheet. • Adverse reactions are recorded on the front adverse reaction box on the prescription sheet. **<u>Supply - for out-patients/clinics/emergency departments (record in case notes)</u>** • Name of medicine, form and strength supplied • After the name of the preparation put PGD and reference number in brackets (PGD ref ...) • Quantity/dose supplied • Signature of staff member who supplied the medicine • Date and time of supply • Adverse reaction **<u>Community PGD's</u>** A Patient Medication Record (PMR) should be created for the patient, if it does not already exist, and the following information should be recorded in the PMR • Name of preparation • Quantity • Any directions for use • Date of supply