



**National Patient Group Direction for the
Supply of Azithromycin, by Pharmacists, for the
Treatment of Uncomplicated Chlamydia Infection**

UNCONTROLLED WHEN PRINTED

**EFFECTIVE FROM OCTOBER 2008
REVIEW DATE - OCTOBER 2010**

1. Authorisation

Developed by Scottish Primary Care Pharmacy Group

Chairman Professor George Downie

Signature



Approved by Scottish Directors of Pharmacy Group

Chairman Professor John Cromarty

Signature

Approved by physician

Name Dr J Paterson

Signature

Authorised for use by NHS Tayside Health Board:

Medical Director Bill Mutch

Signature

Senior Pharmacist Angela Timoney

Signature

Clinical Governance Lead Arlene Napier

Signature

Date Approved 6 November 2008

Effective from October 2008

Review date October 2010

This policy will be reviewed at least every two years or sooner if current treatment recommendations change.

Management of the Patient Group Direction (PGD)

The original signed copy should be held by the NHS Board.

This PGD must be read, agreed to, signed and a copy retained by all pharmacists involved in its use. A copy of the signature sheet should be sent to the NHS Board.

2. Application

This PGD covers the supply of azithromycin for use in the treatment of uncomplicated chlamydia infection by patients (including partners) who are aged 13 years or over, provided none of the exclusion criteria listed below apply.

3. Clinical Situation

Situation	Patient aged 13 years or over either known or suspected to have uncomplicated <i>Chlamydia trachomatis</i> presenting to community pharmacy.
Inclusion Criteria	Male or female patient aged 13 years or over with a laboratory-confirmed positive genital Chlamydia diagnosis. Male or female patient aged 13 or over who is a sexual contact of any patient in the above group. Patients who have previously received treatment for chlamydia who report having unprotected sexual intercourse with an untreated partner. Patient gives their consent to providing the relevant clinical information to the pharmacist after pharmacist has assessed their capacity to consent (see under Staff).
Exclusion Criteria	Patient is 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. Patient who the pharmacist has assessed as not being competent to consent. Where there is no valid consent. Patients who are/or may be pregnant. Consent to provide relevant clinical information is refused. Patients who are breastfeeding. Patients weighing less than 45 Kg. Patients with hepatic impairment. Patients with renal impairment. Female patients with lower abdominal/pelvic pain, intermenstrual or post coital bleeding.

<p>Exclusion Criteria (continued)</p>	<p>Male patients with testicular pain.</p> <p>Patients with known heart arrhythmia.</p> <p>Complicated chlamydial infection:</p> <ul style="list-style-type: none"> ◦ Presence of urinary symptoms ◦ Presence of penile discharge in men ◦ Presence of unusual vaginal discharge in women ◦ Presence of concomitant conjunctivitis <p>Patients allergic to macrolide antibiotics such as azithromycin, erythromycin and clarithromycin.</p> <p>Patients with known hypersensitivity to any of the excipients of azithromycin.</p> <p>Patients with known myasthenia gravis or systemic lupus erythematosus.</p> <p>Patients who have known human immunodeficiency virus (HIV) infection.</p> <p>Patients on medicines which interact with azithromycin (see current British National Formulary or Summary of Product Characteristics (SPC) for full list) such as:</p> <ul style="list-style-type: none"> • ciclosporin • digoxin • ergot derivatives • theophylline • reboxetine
<p>Consent</p>	<p>Prior to the supply of azithromycin, consent must be obtained, preferably written, either from the patient, parent, guardian or person with parental responsibility.</p> <p>Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. Where English is not easily understood, translations and properly recognised interpreters should be used.</p> <p>Individuals (patient, parent, guardian or person with parental responsibility) should also be informed about how data on the supply will be stored, who will be able to access that information and how that data may be used.</p>
<p>Consent for under 16s</p>	<p>A patient under 16 years of age may give consent for the supply of azithromycin, provided he/she understands fully the benefits and risks involved. The patient should be encouraged to involve a parent/guardian, if possible, in the decision.</p> <p>Where there is no parental involvement and the patient indicates that he/she wishes to accept the supply, supply should proceed, if the pharmacist deems the patient to have the legal capacity to consent.</p> <p>The Age of Legal Capacity (S) Act 1991, s2(4) states that <i>‘a person under the age of 16 years shall have legal capacity to consent on his/her own behalf to</i></p>

	<p><i>any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending him/her, he/she is capable of understanding the nature and possible consequences of the procedure or treatment.'</i></p> <p>Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical procedure which is normally that of a medical practitioner, then that health care professional can be considered to have the necessary power to assess the capacity of a child under the 1991 Act, for that procedure.</p>
Referral criteria	<p>Patient presents seeking re-treatment having vomited previous dose of azithromycin.</p> <p>Patient presenting within 3 months of previous treatment, except treatment in circumstances where, in the pharmacist's opinion, it is appropriate.</p> <p>Patient's symptoms indicate another sexual infection</p>
Action if Excluded	All excluded patients should be referred to their GP or Genitourinary medicine (GUM) clinic.
Action if Patient Declines	<p>Patient should be advised of the risks of not receiving the treatment.</p> <p>Record outcome in Patient Medication Record and, if appropriate, patient should be advised to contact their GP practice or GUM clinic.</p>

5. Characteristic of Staff and Premises authorised under the PGD

Staff	<p>Pharmacist whose name is currently on the practicing section of the pharmaceutical register held by The Royal Pharmaceutical Society of Great Britain</p> <p>Pharmacists must be competent to assess a patient's capacity to understand the nature and purpose of the treatment in order to give or refuse consent (Age of Legal Capacity (Scotland) Act 1991). A short guide is included with the implementation pack.</p> <p>Pharmacists must maintain their own level of competence and knowledge in this area to provide the service.</p>
Premises	Premises should provide an acceptable level of privacy to respect patient's right to confidentiality and safety.

6. Description of Treatment

Name of Medicine	Azithromycin
Legal Status	Prescription only medicine (PoM)
Dosage Form/Strength	Capsule/tablet 250mg
Storage	Store in original container below 25°C
Dose	<p>Patients aged 13 years and over: Take 1000mg (4x250mg) as a single oral dose.</p> <p>Ideally the dose should be supervised, but the patient can be supplied with the azithromycin to take at a later time.</p> <p>Azithromycin 250mg must be taken on an empty stomach i.e. one hour before food or two hours after food.</p>
Total Dose	1000mg as a single dose (4x250mg capsule/tablet).
Duration of Treatment	Single oral dose.
Advice to Patient (verbal)	<p>Azithromycin should be taken at least 1 hour before or 2 hours after after food</p> <p>If vomiting occurs within 3 hours of taking azithromycin patients who re-present should be referred to their GP practice or GUM clinic for further treatment.</p> <p>Patients should be advised to use a condom and preferably avoid all sexual contact until 7 days after they and their partner/s have been treated.</p> <p>If patient taking the combined oral contraceptive pill or using contraceptive patches they should be advised to use barrier methods for 8 days following antibiotics. If the antibiotics are taken in the last 7 days of the cycle of taking COC or using the combined patch in that cycle then they should be advised to omit the pill-free or patch-free period and start the next pack without a break.</p> <p>Avoid direct exposure to sunlight, ultraviolet light and sun beds.</p> <p>Advice about risk of candidiasis (thrush) in patient taking antibiotics.</p> <p>Advice about common side effects of azithromycin- these include gastrointestinal upset; skin rash; antibiotic-associated colitis; candidiasis. For infrequent side effects see current BNF.</p> <p>Patients should receive advice regarding chlamydia infection at the time of antibiotic treatment.</p> <p>Patient must be advised to notify any sexual partners.</p>

	<p>Patient must be advised to follow local protocols around contact tracing.</p> <p>Patient must be advised to be re-tested in 6 months or as per local protocol.</p>
Patient Information (written)	<p>Patient Information Leaflet provided with medication.</p> <p>A leaflet on sexual health.</p> <p>Information about GUM services within Board area.</p>
Documentation	<p>The pharmacist must ensure maintenance of records (see Appendix 1 for example proforma) for each supply and may be required to share information with appropriate parties in line with confidentiality protocols.</p>
Follow-up	<p>Patient should be offered a test for re-infection 6 months after treatment or as per local protocol</p>
Side Effects	<p>Common side effects include nausea, vomiting, abdominal discomfort and diarrhoea.</p> <p>Urticaria and other allergic reactions are rare, patients experiencing signs of serious allergic reaction should be advised to contact their GP/NHS 24.</p> <p>For complete list of side effects refer to patient information leaflet.</p>
Drug Interactions	<p>A full list is available in Appendix 1 of the relevant section of the British National Formulary or in the Summary of Product Characteristics (SPC) for the product being used.</p> <p>Antacids: In patients receiving azithromycin and antacids, azithromycin should be taken at least 1 hour before or 2 hours after the antacid.</p> <p>Ciclosporin: In a pharmacokinetic study with healthy volunteers that were administered a 500 mg/day oral dose of azithromycin for 3 days and were then administered a single 10 mg/kg oral dose of ciclosporin, the resulting ciclosporin C_{max} and AUC_{0-5} were found to be significantly elevated (by 24% and 21% respectively), however no significant changes were seen in $AUC_{0-\infty}$. Consequently, caution should be exercised before considering co-administration of these two drugs. If co-administration is necessary, ciclosporin levels should be monitored and the dose adjusted accordingly.</p> <p>Digoxin: Some of the macrolide antibiotics have been reported to impair the metabolism of digoxin (in the gut) in some patients. Therefore, in patients receiving concomitant azithromycin and digoxin the possibility of raised digoxin levels should be borne in mind.</p> <p>Ergot derivatives: Because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be co-administered.</p> <p>Theophylline: Theophylline levels may be increased in patients taking azithromycin.</p>

Patient Charges	Current NHS charging / exemption arrangements apply i.e. patients who normally pay for their prescriptions should be charged the current prescription fee.
Record/Audit Trail	There must be appropriate records (see Appendix 1 for example pro-forma) kept and maintained by the pharmacist to enable verification of service provision and training requirements, and to provide information for internal and external audit and for evaluation purposes.
References	<ol style="list-style-type: none"> 1. British National Formulary 56 September 2008 2. Zithromax[®] SPC – Updated May 2008 3. NES –The Pharmaceutical Care of Sexual Health, 2007

PATIENT GROUP DIRECTION FOR SUPPLY OF AZITHROMYCIN, BY PHARMACISTS, FOR THE TREATMENT OF UNCOMPLICATED CHLAMYDIA INFECTION

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. It is also your responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

Note to Authorising Authority: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

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

Name of Pharmacist _____

RPSGB Registration Number _____

Normal Pharmacy Location
(if pharmacy locum please
provide contact details) _____

Signature _____ Date _____

Signed copy to be returned to _____ NHS Health Board

EXAMPLE AZITHROMYCIN SUPPLY PROFORMA

Appendix 1

Pharmacy stamp

PATIENT NAME _____ **DATE OF SUPPLY** _____

DOB _____

REASON FOR SUPPLY Notification of positive Y / N chlamydia test Notification of partner of positive Y / N chlamydia test patient

AUTHORISATION TO SUPPLY (according to local protocol)
Phone call from sexual health advisor
Patient positive test - written confirmation
Other _____

COMPETENT TO CONSENT Yes
Not competent/ under 13 yrs old/ child protection issues
Refer (according to local protocol)

If 13, 14, 15 YEARS OLD
Explain confidentiality and limits

Who is with him/her? _____ Who knows he/she is here? _____
How old is partner? _____
Attends school? _____ Lives with family / friends / in care / homeless
Concerns re:- assault/abuse? _____ Concerns drugs/alcohol? _____

AZITHROMYCIN SUPPLY

BATCH NUMBER _____
EXPIRY _____

SIGNATURE AND PRINTED NAME OF PHARMACIST

DATE: _____