

Azithromycin for the treatment of genital tract *Chlamydia trachomatis* infection identified during the ClaSS Chlamydia screening study.

1. Medicine

Azithromycin

2. Clinical Condition or Situation

2.1. Definition of clinical condition/situation and eligibility for inclusion

Patients identified as having lower genital tract infection with Chlamydia as part of the ClaSS research project

2.2. Exclusion criteria and circumstances in which further advice should be sought from doctor

- Patient suffers from liver disease
- Previous known allergy to erythromycin, azithromycin or clarithromycin (macrolide antibiotics)
- Patient is taking any of the following:
 - Terfenadine (Triludan)
 - Cyclosporin
 - Warfarin
 - Ergot derivatives (Ergotamine, Cafergot, Lingraine, Migranal, Migril. These are all drugs for migraine that are very rarely used these days)
- Pregnancy or breast feeding[#]
- Female patient at risk of pregnancy^{*}

[#] Azithromycin is not known to be harmful in pregnancy or breast milk but the manufacturer advises using an alternative if possible. Erythromycin is not known to be harmful, and there is more experience with this drug.

^{*} Patient has had sexual intercourse since her last menses and inadequate contraception was used.

2.3. Action following exclusion or refusal

- If patient is pregnant or breast-feeding administer erythromycin – see protocol.
- If the patient is at risk of pregnancy - is the patient suitable for emergency contraception? If the answer is yes proceed according to your practice protocol and administer erythromycin. If PC4 is used erythromycin should be delayed 24hrs after the 2nd dose. This does not apply to Levonelle.
- If the patient is allergic to macrolide antibiotic and not pregnant/at risk of pregnancy nor breast feeding administer doxycycline – see protocol
- For all other exclusions the patient should be discussed with one of your GPs. They can seek advice from your GUM clinic consultant if necessary.

3. Authorised staff**3.1. Class of health professional who are authorised**

Registered nurses employed as practice nurses, nurse practitioners or treatment room nurses in general practice

3.2. Additional required qualifications, training, experience and competences

Nurses have attended the ClaSS Chlamydia Screening Study training course or have had individual training by one of ClaSS study research personnel

3.3. Requirements for on-going training/education

To attend update training courses for ClaSS study when and where applicable

4. Treatment**4.1. Names and legal status of medicines for administration and/or supply**

Azithromycin – prescription only medicine

4.2. Appropriate dosage, frequency of administration and maximum total dosage

One gram is administered as a once only. If the client is on antacids they should be advised to take azithromycin at least 1 hour before they next take antacids or at least 2 hours afterwards.

4.3. Quantity to be supplied

Four capsules of 250mg if not already administered.

4.4. Route of administration

Oral

4.5. Minimum or maximum period over which the medicine should be administered

The tablets must be taken all at once, preferably in the surgery. This should be an hour before food and if taking antacids at least 1 hour before they next take antacids or at least 2 hours afterwards.

4.6. Patient advice and relevant warnings

- Give patient information leaflet
- The nurse should check the following:
 - ◆ That the patient has read the chlamydia fact sheet and understands the following:
 - If asymptomatic it could have been present for months or even years
 - It is often asymptomatic especially in women
 - The main complications of **untreated** chlamydia are pelvic inflammatory disease, ectopic pregnancy and infertility in women. Therefore treatment of women is very important. Treatment of men is equally important to prevent infection of female sexual partners.
 - Importance of complying fully with treatment.
 - Interaction between antibiotics and combined oral contraceptive pill is probably not a problem with azithromycin. No additional contraceptive precautions are needed.
 - The importance of their sex partner(s) being evaluated and treated
 - Advised to abstain from sexual intercourse until they **and** their partner have completed therapy. (For azithromycin this is a week after they have taken it)
 - ◆ That the patient understands the potential side effects associated with azithromycin and its efficacy:
 - Side effects: Azithromycin is well tolerated with a low incidence of side effects. The most common side effect is nausea. Other occasional side effects include loss of appetite, vomiting and diarrhoea.
 - Rarely: Anaphylaxis or other allergic reactions.
 - Effectiveness: It is believed that the medication is over 95% effective in treating chlamydia. This means that less than one person in twenty will need re-treatment. However, this needs to be confirmed in a large study. Treating the partner is also important to prevent re-infection, and to avoid re-treatment.

4.7. Potential adverse reactions and their management

Some patients may complain of gastro-intestinal side effects. These usually settle by themselves and the patient should be reassured. Very occasionally allergic reactions such as a rash may occur. If this happens the patient should be discussed with one of your GPs

4.8. The Case Report File must be completed

Checklist for the administration of Azithromycin

Azithromycin maybe contra-indicated in cases where a patient gives a positive answer to ANY of the following questions. Please ensure that the patient's response is negative to all the following questions before administering the drug. If any answers are in the positive please refer to the practice GP or use a recommended alternative.

		Yes	No
1	Does the patient suffer from liver disease		
2	Is the patient allergic to , erythromycin or clarithromycin (macrolide antibiotics)		
3	Is the patient taking any of the following: (a) Terfenadine (Triludan) (b) Cyclosporin (c) Warfarin (d) Ergot derivatives (Ergotamine, Cafergot, Lingraine, Migranal, Migril. These are all drugs for migraine, which are very rarely used these days)		
4	Is the patient pregnant or breast feeding		
5	If the patient is female, is she at risk of pregnancy		

In addition to the preceding questions, please check the following have been discussed with the patient

		Yes	No
1	Have the side effects of azithromycin been discussed?		
2	Has the patient read the Chlamydia fact sheet and have outstanding questions been discussed?		
3	Has partner notification been discussed and has the importance of abstaining from sexual intercourse until their partner has been treated been understood?		
4	If taking combined oral contraceptives, has patient been advised of reduced efficacy?		
5	It is advised to take medication before food (preferably in clinic) and if taking antacids, 1 hour before, has the patient been informed of this?		
6	Have the patients details been recorded in Case Report File?		

I have read the *Azithromycin drug protocol for the ClaSS Chlamydia screening Study, Version 4 dated 07/03/2001*, and confirm that the details relating to dosage, contraindications, side effects and patient information comply with current statutory regulations.

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Signature:



Date: 07/03/01

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Doxycycline for the treatment of genital tract *Chlamydia trachomatis* infection identified during the ClaSS Chlamydia screening study in patients allergic to macrolide antibiotics.

1. Medicine

Doxycycline

2. Clinical Condition or Situation

2.1. Definition of clinical condition/situation and eligibility for inclusion

Patients identified as having lower genital tract infection with chlamydia as part of the ClaSS project and are allergic to macrolide antibiotics

2.2. Exclusion criteria and circumstances in which further advice should be sought from doctor

- Previous known allergy to the tetracyclines
- Pregnancy or breast feeding
- Female patient at risk of pregnancy. (Patient has had sexual intercourse since her last menses and inadequate contraception was used.)
- Patient with known liver disease
- Patient with myasthenia gravis
- Patient is travelling abroad and plans to sunbath/ uses UV sun-bed (see patient advice)
- Patient is taking any of the following:
 - Combined oral contraceptive (COC) pill (see patients advice section)[#]
 - Anticoagulant such as Warfarin or heparin^{*}
 - Antiepileptics e.g. Carbamazepine[@], Phenytoin[@], Barbiturates[@]
 - Antibiotics - Penicillin/amoxycillin
 - Antacids (see patients advice section)[@]
 - Oral zinc or iron salts (see patients advice section)[@]
 - Bismuth preparations (see patients advice section)[@]

[#] Efficacy of COC pill reduced

^{*} Reduced doses of anticoagulant may be required

[@] Doxycycline levels may be reduced

2.3. Action following exclusion or refusal

- If the patient is at risk of pregnancy - is the patient suitable for emergency contraception? If the answer is yes proceed according to your practice protocol
- The patient should be discussed with one of your GPs. They can seek advice from your GUM clinic consultant if necessary.

3. Authorised staff

3.1. Class of health professional who are authorised

Registered nurses employed as practice nurses, nurse practitioners or treatment room nurses in general practice

3.2. Additional required qualifications, training, experience and competences

Nurses have attended the ClaSS Chlamydia Screening Study training course or have had individual training by one of ClaSS study research personnel

3.3. Requirements for on-going training/education

To attend update training courses for ClaSS study when and where applicable

4. Treatment

4.1. Names and legal status of medicines for administration and/or supply

Doxycycline – prescription only medicine

4.2. Appropriate dosage, frequency of administration and maximum total dosage

This is administered as 100mg twice a day for maximum of 7 days. If the patient misses one dose they can double up the next dose.

4.3. Quantity to be supplied

14 x 100mg capsules

4.4. Route of administration

Oral

4.5. Minimum or maximum period over which the medicine should be administered

The capsules are to be taken regularly for seven days.

4.6. Patient advice and relevant warnings

- Give patient information leaflet
- The nurse should check the following:
 - ◆ That the patient has read the chlamydia fact sheet and understands the following:
 - If asymptomatic it could have been present for months or even years
 - It is often asymptomatic especially in women
 - The main complications of **untreated** chlamydia are pelvic inflammatory disease, ectopic pregnancy and infertility in women. Therefore treatment of women is very important. Treatment of men is equally important to prevent infection of female sexual partners.
 - Importance of complying fully with treatment.
 - Interaction between doxycycline and combined oral contraceptive pill (COC). The patient should continue straight on with her next packet of pills and miss the week free interval. The COC pill becomes effective one week after finishing Doxycycline
 - The importance of their sex partner(s) being evaluated and treated
 - Advised to abstain from sexual intercourse until they **and** their partner have completed therapy.
 - ◆ That the patient understands the potential side effects associated with doxycycline and its efficacy:
 - Advice re antacids – at least 2 hours apart from doxycycline
 - Side effects: Doxycycline can cause gastro-intestinal upset including nausea, abdominal discomfort, vomiting and diarrhoea. If diarrhoea is prolonged or severe the patient should consult their GP. It is best taken with plenty of fluid after food whilst sitting or standing.
 - Effectiveness: It is believed that the medication is over 95% effective in treating chlamydia. This means that less than one person in twenty will need re-treatment.
 - Avoid exposure of skin to direct sunlight or sunlamps
 - The course must be completed. If the patient misses one dose they can double up the next dose.

4.7. Potential adverse reactions and their management

- Doxycycline can cause gastro-intestinal upset including nausea abdominal discomfort, vomiting and diarrhoea.
- Photosensitivity may occur. This is manifested by an exaggerated sunburn reaction. For patients routinely exposed to this a strong sun block is recommended. The patient should be advised to discontinue therapy at the first evidence of skin erythema.
- Very occasionally allergic reactions such a rash may occur. If this happens the patient should be discussed with one of your GPs

4.8. The Case Report File must be completed.

Checklist for the administration of Doxycycline

Doxycycline maybe contra-indicated in cases where a patient gives a positive answer to ANY of the following questions. Please ensure that the patient's response is negative to all the following questions before administering the drug. If any answers are in the positive please refer to the practice GP or use a recommended alternative.

		Yes	No
1	Does the patient suffer from liver disease		
2	Does the patient suffer from myasthenia gravis		
3	Is the patient allergic to tetracyclines		
4	Is the patient taking any of the following: (a) Anticoagulant such as Warfarin or Heparin (b) Antiepileptics e.g. Carbamazepine, Phenytoin, Barbiturates (c) Antibiotics – Penicillin, Amoxycillin (d) Antacids (see patient advice section) (e) Oral zinc or iron salts (see patient advice section) (f) Bismuth preparations (see patient advice section)		
5	Is the patient pregnant or breast feeding		
6	If the patient is female, is she at risk of pregnancy		

In addition to the preceding questions, please check the following have been discussed with the patient

		Yes	No
1	Have the side effects of doxycycline been discussed?		
2	Has the patient read the Chlamydia fact sheet and have outstanding questions been discussed?		
3	Has partner notification been discussed and has the importance of abstaining from sexual intercourse until their partner has been treated been understood?		
4	If taking combined oral contraceptive, has patient been informed of reduced efficacy?		
5	If taking antacids, should be at least 2 hours apart from doxycycline. Has patient been informed of this?		
6	Has the patient been informed of possibility of photosensitivity?		
7	It is advised to take medication after food with plenty of fluid, has the patient been informed of this?		
8	Have the patients details been recorded in Case Report File?		

I have read *the Doxycycline drug protocol for the ClaSS Chlamydia screening Study, Version 4 dated 07/03/2001*, and confirm that the details relating to dosage, contraindications, side effects and patient information comply with current statutory regulations.

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Erythromycin for the treatment of genital tract *Chlamydia trachomatis* infection identified during the ClaSS Chlamydia screening study in women at risk of pregnancy, pregnant or breast feeding.

1. Medicine

Erythromycin

2. Clinical Condition or Situation

2.1. Definition of clinical condition/situation and eligibility for inclusion

Patients identified as having lower genital tract infection with chlamydia as part of the ClaSS project and unable to be prescribed azithromycin because of risk of pregnancy/pregnancy and or breast-feeding.

2.2. Exclusion criteria and circumstances in which further advice should be sought from doctor

- Patient suffers from liver disease or myaesthesia gravis
 - Previous known allergy to erythromycin, azithromycin or clarithromycin (macrolide antibiotics)
 - Patient is taking any of the following:
 - Antihistamines including (*Astemizole*, *Terfenadine* (Triludan))
 - Anti-epileptics (Carbamazepine, Phenytoin, Valproate)
 - Anti-retrovirals (HIV)
 - *Cisapride*
 - Combined oral contraceptive pill (see patient advice section)
 - Cyclosporin, Tacrolimus
 - Anti-arythmics: Disopyramide or quinidine
 - *Ergot derivatives* (Ergotamine, Cafegot, Lingraine, Migranal, Migril)
 - *Pimozide*, clozapine
 - Reboxitine
 - Statin Cholesterol-lowering agents
 - Theophylline
 - Tolteridine
 - Warfarin, acenocoumarol
 - Zopiclone
- Underlined and italics = contraindicated*

2.3. Action following exclusion or refusal

The patient should be discussed with one of your GPs. They can seek advice from your GUM clinic consultant if necessary.

3. Authorised staff

3.1. Class of health professional who are authorised

Registered nurses employed as practice nurses, nurse practitioners or treatment room nurses in general practice

3.2. Additional required qualifications, training, experience and competences

Nurses have attended the ClaSS Chlamydia Screening Study training course or have had individual training by one of ClaSS study research personnel

3.3. Requirements for on-going training/education

To attend update training courses for ClaSS study when and where applicable

4. Treatment

4.1. Names and legal status of medicines for administration and/or supply

Erythromycin (enteric coated) – prescription only medicine

4.2. Appropriate dosage, frequency of administration and maximum total dosage

This is administered as 500mg twice a day for maximum 14 days.

4.3. Quantity to be supplied

Sufficient for 14-day course of 250mg tablets. (56 tablets)

4.4. Route of administration

Oral

4.5. Minimum or maximum period over which the medicine should be administered

The tablets are to be taken regularly for fourteen days.

4.6. Patient advice and relevant warnings

- Give patient information leaflet
- The nurse should check the following:
 - ◆ That the patient has read the chlamydia fact sheet and understands the following:
 - If asymptomatic it could have been present for months or even years
 - It is often asymptomatic especially in women
 - The main complications of **untreated** chlamydia are pelvic inflammatory disease, ectopic pregnancy and infertility in women. Therefore treatment of women is very important. Treatment of men is equally important to prevent infection of female sexual partners.
 - Importance of complying fully with treatment.
 - Interaction between erythromycin and combined oral contraceptive pill (COC). The patient should continue straight on with her next packet of pills and miss the week free interval. The COC pill becomes effective one week after finishing erythromycin
 - The importance of their sex partner(s) being evaluated and treated
 - Advised to abstain from sexual intercourse until they **and** their partner have completed therapy.
 - ◆ That the patient understands the potential side effects associated with erythromycin and its efficacy: It is best taken with food
 - Side effects: Erythromycin can cause gastro-intestinal upset including nausea abdominal discomfort, vomiting and diarrhoea. If diarrhoea is prolonged or severe the patient should consult their GP.
 - Effectiveness: It is less than 95% effective in treating chlamydia. The patient should have a repeat test at least 2 weeks after completing therapy.

4.7. Potential adverse reactions and their management

Erythromycin can cause gastro-intestinal upset including nausea abdominal discomfort, vomiting and diarrhoea. Very occasionally allergic reactions such a rash may occur. If this happens the patient should be discussed with one of your GPs

4.8. The Case Report File must be completed.

Checklist for the administration of Erythromycin

Erythromycin maybe contra-indicated in cases where a patient gives a positive answer to ANY of the following questions. Please ensure that the patient's response is negative to all the following questions before administering the drug. If any answers are in the positive please refer to the practice GP or use a recommended alternative.

		Yes	No
1	Does the patient suffer from liver disease		
2	Is the patient allergic to erythromycin, azithromycin or clarithromycin (macrolide antibiotics)		
3	Is the patient taking any of the following: (a) Antihistamines including (Astemizole, Terfenadine (Triludan) (b) Antiepileptics e.g. Carbamazepine, Phenytoin, Valporate (c) Anti-retrovirals (HIV) (d) Cisapride (e) Cyclosporin, Tacrolimus (f) Anti-arythmics (g) Ergot derivatives (Ergotamine, Cafergot, Lingraine, Migranal, Migril) (h) Pimozide, clozapine (i) Reboxitine (j) Theophylline (k) Tolteridine (l) Warfarin, acenocoumarol (m) Zopiclone		

In addition to the preceding questions, please check the following have been discussed with the patient

		Yes	No
1	Have the side effects of erythromycin been discussed?		
2	Has the patient read the Chlamydia fact sheet and have outstanding questions been discussed?		
3	Has partner notification been discussed and has the importance of abstaining from sexual intercourse until their partner has been treated been understood?		
4	If taking combined oral contraceptive, has patient been informed of reduced efficacy?		
5	Has the patient been informed of possibility of photosensitivity?		
6	It is advised to take medication after food with plenty of fluid, has the patient been informed of this?		
7	Have the patients details been recorded in Case Report File?		

I have read the *Erythromycin drug protocol for the ClaSS Chlamydia screening Study, Version 4 dated 07/03/2001*, and confirm that the details relating to dosage, contraindications, side effects and patient information comply with current statutory regulations.

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