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Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals 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. Healthcare professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration and/or supply of

Doxycycline 100mg Capsules

(must be used with metronidazole via separate PGD 0031)

by registered nurses

following an animal or human bite to

Adults and Children aged over 12 years of age

in Powys Teaching Health Board Minor Injury Units

Version number: PGD 0029C

Reference Number: PGD 0029C
Valid from: 16/09/2024
Review date: 31/08/2026
Expiry date: 28/02/2027

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Change history

Version number	Change details	Date
PGD0029	Initial issue	09/03/2006
PGD0029_A	Review issue- in line with NICE guidance July 2015 (Bites-human and animal)	03/05/2018
PGD0029_B	Review issue, new PTHB template, NICE guidelines update and SPC update	16/10/2021
PGD 0029C	Review issue in line with the SPS PGD template ‘supply of doxycycline capsules/dispersible tablets for the treatment of acute bacterial sinusitis (rhinosinusitis) (v1.0)’ and adapted for use for a different indication, using current reference sources. Minor changes to format to promote consistency with other PTHB PGDs. Dose amended as per recommendation by consultant microbiologist.	16/09/2024

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This Powys Teaching Health Board (PTHB) PGD is based on a template developed on behalf of the Specialist Pharmacy Service (SPS), for the supply of doxycycline capsules/dispersible tablets for the treatment of acute bacterial sinusitis (rhinosinusitis) (v1.0). The SPS template had been peer reviewed by the national Upper Respiratory Tract Infection (URTI) antimicrobial PGD Short Life Working Group in accordance with their Terms of Reference. It had been approved by The Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection (APRHAI) to the Department of Health and Social Care (England) in November 2023.

The SPS template has been adapted for use for a different indication in PTHB.

Acknowledgements:

Name	Designation
Dr Diane Ashiru-Oredope	Lead Pharmacist, HCAI, Fungal, AMR, AMU & Sepsis Division, UK Health Security Agency
Dr Imran Jawaid	GP and RCGP AMR representative
Dr Jeeves Wijesuriya	GP and Clinical Advisor to NHS England Primary Care Team and Vaccination and Screening Team
Jackie Lamberty	Medicines Governance Consultant Lead Pharmacist UK Health Security Agency
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, Medicines Use and Safety Division, Specialist Pharmacy Service
Liz Cross	Advanced Nurse Practitioner QN
Dr Martin Williams	Consultant in Microbiology and Infectious Diseases
Temitope Odetunde	Head of Medicines Management
Nigel Gooding	Consultant Paediatric Pharmacist. Neonatal and Paediatric Pharmacist Group (NPPG) representative.
Kieran Reynolds (SLWG co-ordinator) *	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety Division, Specialist Pharmacy Service
Laura Whitney*	NHS England Regional Antimicrobial Stewardship lead for the London region
Ms Wendy Smith	Consultant ENT Surgeon
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Ravijyot Saggu	Medicines Optimisation Lead – Central London Community Healthcare, Chair - UKCPA Respiratory Committee

*Core group members

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PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	9/12/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	Signed by: Jacqui Seaton 71E8089DE3634C4...	9/13/2024
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	9/12/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	9/23/2024

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012

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(HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

Practitioners and organisations must check that they are using the current version of the PGD.

[1] This includes any relevant amendments to legislation.

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Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners must also be a registered healthcare professional with the following body: • Nurses currently registered with the Nursing and Midwifery Council (NMC) and working in a Minor Injury Unit in PTHB Current contract of employment with PTHB. Practitioners must also fulfil the Additional requirements listed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
	• The administration and supply of doxycycline capsules and knowledge of its uses, contraindications and adverse effects The registered healthcare professional authorised to operate under this PGD must have: • undertaken appropriate training and successfully achieved competency to undertake clinical assessment of individuals • undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training eLfH PGD eLearning programme. PTHB staff to access via ESR. Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • competency in the use of PGDs (see NICE Competency framework for health professionals using patient group directions). Individuals operating under this PGD must be assessed as competent (see Appendix A) • undertaken training appropriate to this PGD as required by local policy • Individuals operating under this PGD must be familiar with the product and alert to changes in the BNF and the Summary of Product Characteristics (SPC). • Individuals operating under this PGD must have access to the PGD and associated online resources.

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Initial training	• required training (including updates) in safeguarding vulnerable adults and children or a minimum of level 2 safeguarding or the equivalent. • Individuals operating under this PGD must have an understanding of NICE CKS- Bites- human and animal. • Individuals operating under this PGD must have completed mandatory sepsis training: 000 NHS Wales RRAILS eLearning programme (acute deterioration). • Individuals operating under this PGD must have received training and be competent in the recognition, management of, and reporting of recognised adverse reactions, including anaphylaxis. • Individuals must be competent in the administration of adrenaline and have up to date Intermediate Life Support (ILS) skills. **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) and complete a self-declaration of competence to operate under this PGD in their Personal Appraisal and Development Review (PADR). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. • Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • Staff operating under this PGD should review their competency using the NICE Competency Framework for health professionals using patient group directions • Evidence of training in ILS, anaphylaxis and safeguarding. • Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly.

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Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation. • Update at least every 2 years, or earlier in response to new local/national guidance, on the use of PGDs, doxycycline and the treatment of human and animal bites. • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, ILS, with evidence of appropriate Continued Professional Development (CPD). • Evidence of appropriate Continued Professional Development (CPD) must be retained and made available on request. • Compliance with all mandatory NHS training including safeguarding at the level relevant to the role. • Evidence of ongoing / refresher training to be submitted to line manager annually. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD. The decision to administer or supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.**

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Prevention and treatment of infection in adults and children from 12 years old and presenting with an animal (cat, dog or other traditional pet bite) or human bite **AND** individual is allergic to penicillin or co-amoxiclav is unsuitable, in accordance with NICE guidance -see Appendix B. **Doxycycline must be used in combination with metronidazole (PGD 0031) for this indication.**

	Notes: • For all bites assess the risk of tetanus, rabies or a bloodborne viral infection and take appropriate action, following MIU guidelines. • If there is discharge (purulent or non-purulent), before cleaning, send a pus or a deep wound swab for culture, state on the form that the swab is from an infected human/animal bite as appropriate. • Topical cleaning, thorough irrigation and debridement should be completed as necessary- follow MIU Guidelines.

Criteria for inclusion	• Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained prior to administration/supply and recorded appropriately. Refer to PTHB Consent to Treatment and Examination Policy
	• Known allergy to penicillin or co-amoxiclav is unsuitable
	• Individuals aged 12 years and over with:
	• **An infected human or animal bite** (traditional pet including cats and dogs) if there are symptoms or signs of infection, such as increased pain, inflammation, fever, discharge or an unpleasant smell
	• **An uninfected human bite**:
	  ○ that has broken the skin and drawn blood
	  ○ that has broken the skin but not drawn blood in a person at risk of a serious wound infection because of a co-morbidity such as diabetes, immunosuppression, asplenia, or decompensated liver disease
	  ○ that has broken the skin but not drawn blood if it is in a high-risk area (includes the hands, feet, face, genitals, skin overlying cartilaginous structures, or an area of poor circulation)
	• **An uninfected cat bite**:
	  ○ that has broken the skin and drawn blood
	  ○ that has broken the skin but not drawn blood if the wound could be deep
	• **An uninfected dog bite or other uninfected traditional pet bite (excluding cat)**:
	  ○ that has broken skin and drawn blood and:
	    ▪ has penetrated bone, joint, tendon or vascular structures or
	    ▪ is deep, is a puncture or crush wound, or has caused significant tissue damage or

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	▪ is deep, is a puncture or crush wound, or has caused significant tissue damage or ▪ is visibly contaminated (for example, if there is dirt or a tooth in the wound) or ▪ is a bite in a high-risk area (e.g. hand, feet, face, genitals, skin overlying cartilaginous structures or near prosthetic joints, or an area of poor circulation) or the patient is considered at high risk of a serious wound infection or systemic infection because of a co-morbidity such as diabetes mellitus, asplenia, immunosuppression, decompensated liver disease, or they have a prosthetic heart valve, or if they are at extremes of age **NB**. If there is a discharge (purulent or non-purulent) from the area of bite, take a swab for microbiological testing. Antibiotics may be administered/supplied via this PGD if appropriate based on inclusion/exclusion criteria however the individual must be informed that treatment may change once the results are received, refer for medical advice. • Medical and drug history taken, no reason for exclusion **Refer to exclusion criteria for wounds that must be referred to hospital.** In case of any doubt, contact medical team or emergency services. **Note.** The individual should also meet the inclusion criteria for metronidazole tablets (PGD 0031) **which must be used in combination with doxycycline for this indication.** Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. **It is the responsibility of the administering/ supplying healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**

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Criteria for exclusion
(Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)
	• Conditions outside of the clinical situations criteria
	• Consent refused and documented in the individual's clinical notes, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if the individual is excluded" or "Action to be taken if the individual/carer/parent/guardian declines treatment".
	• Individuals under 12 years of age– refer to PGD 0180 (Co-trimoxazole)
	• Pregnancy or suspected pregnancy - refer to a prescriber for a suitable alternative.
	• Currently breastfeeding- refer to a prescriber for a suitable alternative.
	• Severely immunosuppressed individuals as defined in Chapter 28a Green book:
	
	Individuals with primary or acquired immunodeficiency states due to conditions including:
	  ◦ *acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who are less than 12 months since achieving cure*
	  ◦ *individuals under follow up for a chronic lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (N.B: this list not exhaustive)*
	  ◦ *immunosuppression due to HIV/AIDS with a current CD4 count of below 200 cells/µl.*
	  ◦ *primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000 lymphocytes/ul) or with a functional lymphocyte disorder*
	  ◦ *those who have received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months*
	  ◦ *those who have received a stem cell transplant more than 24 months ago but have ongoing immunosuppression or graft versus host disease (GVHD)*
	
	Individuals on immunosuppressive or immunomodulating therapy including:
	  ◦ *those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for any indication*

	• *those who are receiving or have received in the previous 6 months immunosuppressive therapy for a solid organ transplant* • *those who are receiving or have received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but for which a 6 month period should be considered immunosuppressive), monoclonal tumor necrosis factor inhibitors (TNFi), T-cell co-stimulation modulators, soluble TNF receptors, interleukin (IL)-6 receptor inhibitors., IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors (N.B: this list is not exhaustive)* ***Individuals with chronic immune mediated inflammatory disease who are receiving or have received immunosuppressive therapy*** • *moderate to high dose corticosteroids (equivalent ≥20mg prednisolone per day) for more than 10 days in the previous month* • *long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months* • *any non-biological oral immune modulating drugs e.g. methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the previous 3 months* • *certain combination therapies at individual doses lower than stated above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months* ***Individuals who have received a short course of high dose steroids (equivalent >40mg prednisolone per day for more than a week) for any reason in the previous month.*** • Immunosuppressed individuals: individuals who are immunosuppressed or are currently taking immunosuppressants (including systemic corticosteroids *) or immune modulators, but who do not meet the definition of severe immunosuppression (see above). [For equivalent doses in children, see Chapter 6 Green Book] * does not include:

	- replacement corticosteroids for individuals with adrenal insufficiency - corticosteroid inhalers or corticosteroids applied topically (e.g. to the skin, ears, eyes, nasal cavity) - intra-articular, -bursal or -tendon corticosteroid injections - Systemically unwell individual or individual who is at risk of a serious wound infection because of a pre-existing medical condition- **refer to hospital** - Known hypersensitivity to doxycycline, any tetracycline or any of the components within the formulation- see spc. **Acceptable sources of allergy information include individual/carer/parent/guardian/Welsh Clinical Portal or GP record.** - Known hypersensitivity to metronidazole or to any of the excipients- see relevant spc (refer to PGD 0031 **metronidazole must be used in combination with doxycycline for this indication**) - Any exclusions to PGD 0031, as **metronidazole must be used in combination with doxycycline for this indication** - Inability to absorb oral medications and/or inability to swallow oral capsules- refer to a prescriber - Current long-term use of doxycycline or another tetracycline antibiotic (e.g. treatment of acne vulgaris, prophylaxis of malaria etc.) - Individuals following a ketogenic diet - Bites with signs suggesting a more serious illness or condition (such as severe cellulitis, abscess, lymphangitis, osteomyelitis, septic arthritis, necrotising fasciitis or sepsis), bites to the eye or orbit, or severe bite injuries with heavy bleeding causing haemodynamic instability, or a penetrating wound involving arteries, joints, nerves, muscles, tendons, bones or the central nervous system. **NB these individuals must be referred to hospital**. - Individual who has developed symptoms or signs of infection after taking prophylactic antibiotics- refer to a prescriber - Bites from a wild or exotic animal (including birds and non-traditional pets), unfamiliar domestic or farm animal because the spectrum of bacteria involved may be different and there may be a risk of other serious non-bacterial infections- seek advice from a microbiologist. - Bites from bats- Urgent treatment required. All individuals should be referred to A&E and Public Health Wales Health protection team or the duty virologist (University Hospital of Wales) contacted. Please see PHE guidance (for advice on Rabies) and refer to patients to PHE PIL

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	• Any individual identified with symptoms of severe/life-threatening infection or systemic sepsis: refer urgently via ambulance. • Infected bite that is not responding to oral antibiotics within 24 hours to 48 hours of starting treatment- refer to a prescriber • Individuals who were bitten in a fight – refer to DGH for exploration/irrigation/IV antibiotics • Individual with NO penicillin / cephalosporin allergy (or NO reason why co-amoxiclav is unable to be taken)- refer to PGD 0028 (Co–amoxiclav). • Known myasthenia gravis • Known systemic lupus erythematosus (SLE) • Known oesophagitis or oesophageal ulceration • Known porphyria • Individuals taking enzyme inducing anti-epileptic medications (carbamazepine, fosphenytoin, phenobarbitone/phenobarbital, primidone, phenytoin) • Individuals unable to separate administration times of interacting medicines (e.g. oral calcium/iron/magnesium/zinc/aluminium/bismuth salts (including some over the counter preparations (e.g. antacids)), lanthanum, sucralfate) and doxycycline by 2-3 hours • Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine • Concurrent use of any interacting medicine as listed in Drug Interactions section of this PGD • For individuals who require INR monitoring due to their coumarin anticoagulant (e.g. warfarin, acenocoumarol, phenindione), the practitioner must check that the patients latest International Normalised Ratio (INR) is up to date and within the target range as stated in the patient’s yellow anti-coagulant record book. A patient with an out of date INR, or whose most recent INR is out of range or unknown is excluded from this PGD and must be referred to a prescriber.

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Cautions including any relevant action to be taken	• Consider referral or seeking specialist advice if the bite is in an area of poor circulation • Discuss with appropriate medical/ independent non-medical prescriber if the individual has multiple allergies, or any medical condition or medication of which the healthcare professional is unsure or uncertain. • Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products (Refer to BNF/SPC for full list) • Caution should be exercised when administering/ supplying doxycycline to individuals taking the following medicine(s): **Coumarin anticoagulants (e.g. warfarin, acenocoumarol, phenindione):** rises in INR reported. The practitioner must check the patients latest INR– if the latest INR is up to date and within the target range (as stated in their yellow anticoagulant record book) then the patient may be administered/ supplied with doxycycline **but must** be advised to contact their usual anti-coagulant clinic to inform them that they have been prescribed a course of antibiotics and have their INR monitored while on treatment with doxycycline, and should be counselled re: seeking medical attention if any episode of bleeding develops while taking. • Caution should be exercised when administering/supplying doxycycline capsules to individuals who should avoid the following excipients: **Lactose, sucrose, fructose and sorbitol:** Individuals with rare hereditary problems of galactosaemia, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption, sucrase-isomaltase deficiency, fructose-1,6-bisphosphatase deficiency (also known as hereditary fructose intolerance): check the individual list of excipients available in the SPC before administering/supplying. **Aspartame:** Individuals with phenylketonuria (PKU) must not use medicines containing aspartame. Check the individual list of excipients available in the SPC before administering/supplying. • Patients with facial dog bites should be referred to MaxFax at DGH

	• See NICE CKS for patients that should be referred to secondary care (urgency depending on clinical judgement)
	• Discuss the following patients with a doctor:
	  ○ Patients with hepatic impairment or those receiving potentially hepatotoxic drugs.
	  ○ Patients who are alcohol dependant, as alcohol may decrease the half-life of doxycycline
	
	Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub:
	• to generic email address: PowysTHB.Safeguarding@wales.nhs.uk
	and
	• Central Safeguarding number: 01686 252806
	• Out of hours: 0845 0544847.
	Advice can also be sought from local Safeguarding leads.

Action to be taken if the individual is excluded	• The first line alternative choice of oral antibiotics for adults and young people over 12 years who are allergic to penicillins are doxycycline (PGD 0029) **in combination with** metronidazole (PGD 0031). If the individual is excluded from either of these antibiotics, refer to microbiologist. • Record reasons for exclusion in the appropriate clinical records and seek medical advice. **Refer urgently to a prescriber for further assessment if:** • Individual is severely immunosuppressed or immunosuppressed • Individual is systemically unwell, but not showing signs or symptoms of sepsis **Refer urgently to A&E for further assessment if:** • Signs of a more serious illness or condition • Signs of intracranial complications such as swelling over the frontal bone, symptoms or signs of meningitis, severe frontal headache or focal neurological signs.

	If sepsis is suspected refer the individual urgently to A&E • If appropriate refer to GP / DGH /out of hours service, offer alternative management if appropriate. • Explain reason to individual/ carer. • Bites from bats- Urgent treatment required. All individuals should be referred to A&E and Public Health Wales Health protection team or the duty virologist (University Hospital of Wales) contacted. Please see PHE guidance (for advice on Rabies) and refer individual to PHE PIL
Action to be taken if the individual/ carer/ parent/ guardian declines treatment	Explain consequences of refusing treatment. Advise individual/carer/parent/guardian of alternative treatment (DGH or GP as appropriate). Offer alternative management if appropriate. The patient information leaflet should be available to inform consent. Document refusal and any advice given. Complete a Discharge Against Advice Form if appropriate. Refer to a prescriber if appropriate /follow local procedures as appropriate. Where appropriate, complete the letter on the WPAS system and send to the GP.
Arrangements for referral for medical advice	• Refer to the appropriate medical practitioner in the care pathway- contact GP or microbiologist for advice or refer to DGH if applicable. Document advice given.

Description of treatment

Name, strength and formulation of drug	Doxycycline 100mg capsules
Legal category	POM
Route/method of administration	Oral. Swallowed whole with plenty of water while sitting or standing well before (at least one hour before) bedtime.

	If gastric irritation occurs, doxycycline can be taken with food or milk.
Indicate any off-label use	Yes, when used prophylactically for bite wounds at high risk of infection- its use is in line with NICE guideline recommendations. **Temperature variations** Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the pharmacist must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by a pharmacist in accordance with national or specific product recommendations/manufacturer advice as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with the pharmacist. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/carer/parent/guardian that the drug is being offered in accordance with national guidance but this is outside the product license.
Dose and frequency of administration	**Children 12-17 years and adults:** For treatment: 200 mg (TWO 100mg capsules) as a single dose **once daily** for **5 days.** For prophylaxis: 200 mg (TWO 100mg capsules) as a single dose **once daily** for **3 days.** **NB.** Doxycycline is to be taken in combination with Metronidazole 400 mg three times a day (PGD 0031)
Duration of treatment	• treatment of infected bite for 5 days • prophylaxis of infection for 3 days **Medication should be started immediately, and the full course completed.**

Quantity to be administered and/or supplied	**Children 12-17 years and adults:** ONE appropriately labelled pack of 14 doxycycline 100mg capsules should be supplied for individuals requiring 200mg daily for 3 or 5 days. The quantity must be given as stated above to ensure appropriate labelling of the pack. The individual's name and the date of supply should be written on the label. Complete any gaps on the label to indicate the number of capsules, number of times per day, and number of days treatment. **MUST be supplied with Metronidazole (PGD 0031).**
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk.
Drug interactions	Where it is known an individual is concurrently taking one of the following medicines, doxycycline must not be supplied under this PGD and the individual referred to a prescriber: • Ciclosporin • Acitretin, alitretinoin, isotretinoin, tretinoin • Lithium • Typhoid vaccine (oral): see Criteria for exclusion This list is not exhaustive. See BNF for all drugs that can interact with doxycycline. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk. All concomitant medications should be checked for interactions. Refer to a prescriber if any concern of a clinically significant drug interaction and document advice given. Also refer to cautions and exclusions.

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Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk. The following side effects are listed in the product SPC or BNF as **common** with doxycycline (but may not reflect all reported side effects): • Diarrhoea • Hypersensitivity reactions • Headache • Nausea, vomiting • Photosensitivity skin reactions • Rash including maculopapular, erythematous rashes and Henoch-Schonlein purpura • Urticaria • Hypotension • Pericarditis • Tachycardia • Dyspnoea • Peripheral oedema **Photosensitivity reactions:** advise individuals to avoid exposure to direct sunlight or ultraviolet light (including sunbeds and sun lamps) while taking doxycycline. If exposure to sunlight is unavoidable, advise individuals to protect their skin by: • Wearing clothes that cover them up, • Wearing a hat and sunglasses, • Using a high factor (minimum SPF 30) sunscreen or sunblock. **Gastric irritation**: If individuals experience nausea or vomiting while taking doxycycline, advise them to take it with food or milk. Severe adverse reactions are rare, but anaphylaxis (delayed or immediate) has been reported and requires immediate medical treatment. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD 0017 and anaphylaxis policy

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	• Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO DOXYCYCLINE** and the reaction that occurred. • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system In the event of a severe adverse reaction, the individual must be advised to stop treatment immediately and seek urgent medical advice.

Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals/carers/parents/guardians are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported. Guidance on the yellow card system is available at the back of the BNF, or using the above link. • Record all adverse drug reactions (ADRs) in the individual's clinical record and report any suspected adverse reactions to a doctor. • Report and document in accordance with organisation incident policy. All significant adverse drug reactions should be reported via the Once for Wales Reporting System. • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
Written or other information to be given to individual/ carer/ parent/ guardian	• Provide marketing authorisation holder's information leaflet (PIL) provided with the product. • Give any additional information in accordance with the local service specification. • Complete the pre-printed medication label, to include individual's name and date of supply. Complete any gaps on the label to indicate the number of capsules, number of times per day, and number of days treatment. Instruct the individual/carer about the dose and course length (i.e. 3 or 5 days, as appropriate).

Individual advice / follow up treatment	• Explain the dose, frequency and method of administration. The individual/carer/parent/guardian should be advised to read the PIL. • Where applicable, inform individual/carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed in the product's SPC. • Refer to MIU guidelines. • Advise individual/carer/parent/guardian to seek medical advice if individual develops any red flag symptoms (e.g. intraorbital (within the eye) or periorbital (around the eye) complications: such as periorbital oedema (swelling) or cellulitis, displaced eyeball, double vision, ophthalmoplegia (paralysis/weakness of the eye muscles), or newly reduced visual acuity (reduced vision), intracranial complications such as swelling over the frontal bone, symptoms or signs of meningitis, severe frontal headache or focal neurological signs). • Advise individual/carer/parent/guardian to seek immediate medical attention (by calling 999 or going to A&E) if the individual develops signs or symptoms of sepsis. • Inform individual/carer/parent/guardian of possible side effects and their management, including advice to swallow whole with plenty of water while sitting or standing well before (at least one hour before) bedtime. • Advise individual/carer/parent/guardian to take/give the medication at regular intervals (ideally the same time each day) and to finish the course. • Advise individual/carer/parent/guardian that if the individual experiences nausea or vomiting while taking doxycycline, they can take it with food. • Advise individual/carer/parent/guardian not to take antacids or preparations containing calcium/iron/magnesium/zinc/aluminium/bismuth salts (including some bought over the counter) within 2-3 hours of taking doxycycline. *Note: if these interacting medicines are contained within a medicines compliance aid (MCA or "blister pack"), the individual should be referred to a prescriber or their pharmacist* • Advise individual/carer/parent/guardian to avoid exposure to direct sunlight or ultraviolet light (including sunbeds and sun lamps) while taking doxycycline. • The individual/carer/parent/guardian should be advised

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	to seek medical advice in the event of an adverse reaction or if any other new symptoms develop or if there is any other cause for concern. • If given for prophylaxis, advise individual/carer to check for signs of infection- if these develop advise individual to attend urgently for review. • Advise to seek urgent medical review if: o symptoms or signs of infection develop or worsen rapidly or significantly at any time, or do not start to improve within 24 to 48 hours of starting treatment o the individual becomes systematically unwell, or if the boundaries of the soft tissue infection continue to expand o there is no improvement or if the presenting complaint/infection worsens or if they feel increasingly unwell (a 5-day course is appropriate for treating infection following most human or animal bites, but course length can be increased to 7 days (with review) based on clinical assessment of the wound by a clinician). o the condition has not completely cleared towards the end of the treatment course o there is severe pain that is out of proportion to the infection o wound was infected, individual should be advised to contact their GP for review at 24 and 48 hours to ensure infection is responding to treatment. • If a dose is missed, advise to refer to PIL supplied with the product • Advise individual to complete the full course even if the wound looks better • Advise individual/carer/parent/guardian to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet. • About appropriate oral pain relief Additionally, if applicable: • If a swab has been taken, the individual/carer will be contacted once the results are received. The GP/prescriber will also be contacted to review the choice of antibiotic based on the swab results. • For individuals taking **oral anti-coagulants** such as warfarin, acenocoumarol (nicoumalone) or phenindione, advise them to contact their usual anti-coagulant clinic to inform them that they have been prescribed a course of antibiotics. Individuals should

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	be advised to seek medical advice if they experience any bruising or bleeding. • Women taking oral hormonal contraception should be advised about the importance of correct contraceptive practice if they experience vomiting or diarrhoea (see the sections on vomiting or diarrhoea in the CKS topics on Contraception - combined hormonal methods and Contraception - progestogen-only methods.)

Records	Record consultation details as required by local procedures. Appropriate records must include the following: • That valid informed consent has been given. Record name of representative who gave consent if appropriate. • Individual's name, address and date of birth • Name of GP individual is registered with or record where an individual is not registered with a GP • Printed name and signature of registered healthcare professional operating under the PGD • Specify how the individual has/has not met the criteria of the PGD. Include any reasons for referral, including arrangements made and advice given. • Relevant past and present medical history and medication history • Name/dose/form/route/quantity and expiry date of medicine administered and/or supplied • Date and time of administration and/or supply • Documentation of cautions as appropriate • Advice given and actions taken if individual excluded or declines treatment • Details of any ADRs/allergy status and actions taken • That the medication was administered and/or supplied via PGD, record PGD version number. • Any safety incidents, such as medication errors, near misses and suspected adverse events • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any additional requirements in accordance with the service specification • GP to be notified of administration/supply via usual communication channels • All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners. • Examination or microbiology finding/s where relevant. **Records must be signed and dated (or a password controlled e-records).** **All records must be clear, legible and contemporaneous.** The record must be kept securely for a defined period in line with local policy. **A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.**

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Key references (last accessed November 2023)

- Electronic Medicines Compendium http://www.medicines.org.uk/
- Electronic BNF https://bnf.nice.org.uk/
- Electronic BNF for Children https://bnfc.nice.org.uk/
- Reference guide to consent for examination or treatment https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- UK Sepsis Trust. Sepsis e-learning resources. https://sepsistrust.org/professional-resources/sepsis-e-learning/
- NICE guideline [NG184] - Human and animal bites: antimicrobial prescribing, published: 04 November 2020
- NICE CKS Prescribing information: Doxycycline | Prescribing information | Bites - human and animal | CKS | NICE – accessed 03/07/2024
- All Wales Medicines Strategy Group Primary Care Antimicrobial Guidelines March 2022 – accessed 03/07/2024

Appendix A Staff accredited to use this Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the PGD to work under it.

The authorising manager must use the competency checklist (below).

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of registered health professional	Signature of registered health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB for 25 years after the PGD expires. The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in "comments"	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) ________________________________			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.

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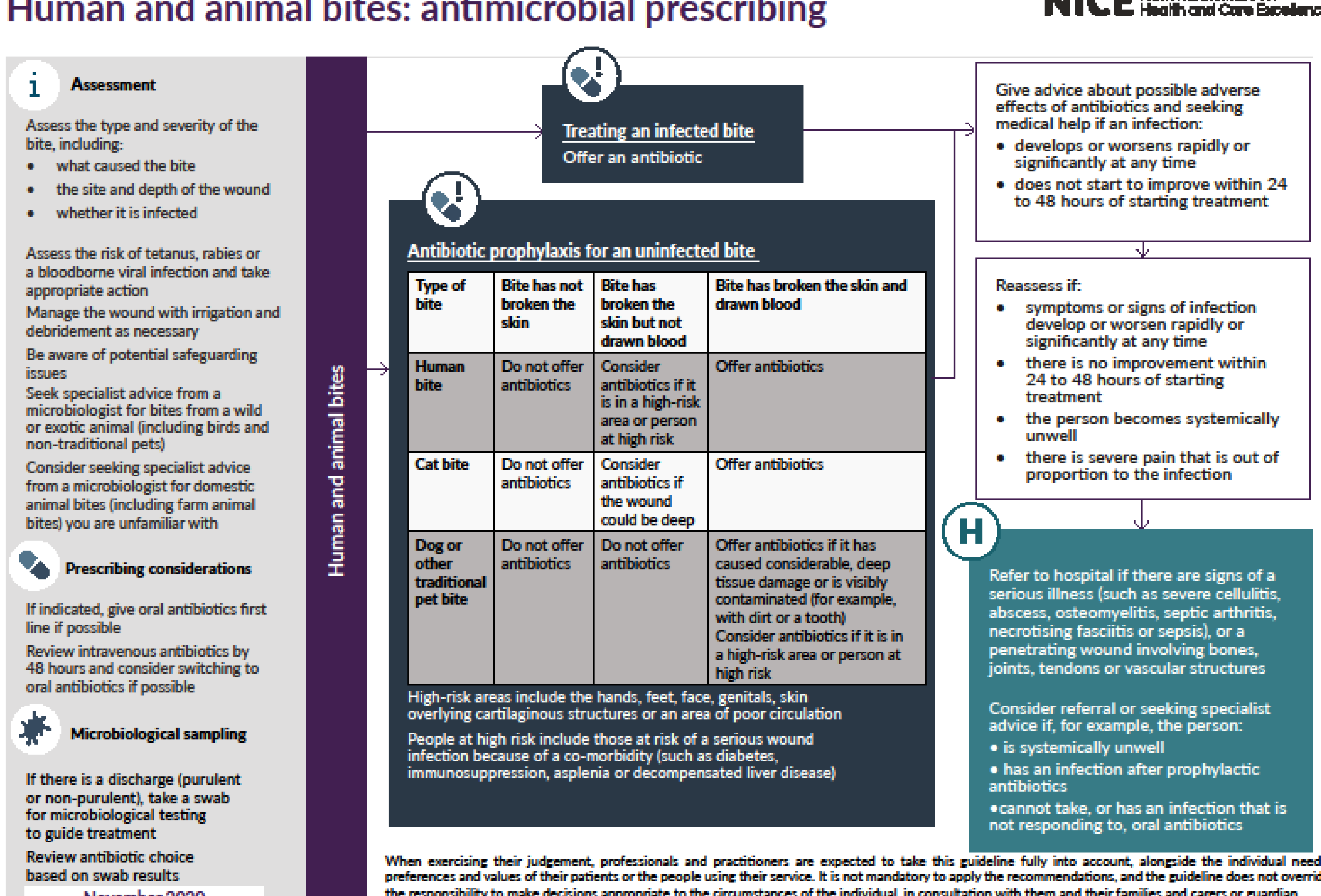
Appendix B



Human and animal bites: antimicrobial prescribing

NICE National Institute for Health and Care Excellence

Assessment

Assess the type and severity of the bite, including:

- what caused the bite
- the site and depth of the wound
- whether it is infected

Assess the risk of tetanus, rabies or a bloodborne viral infection and take appropriate action

Manage the wound with irrigation and debridement as necessary

Be aware of potential safeguarding issues

Seek specialist advice from a microbiologist for bites from a wild or exotic animal (including birds and non-traditional pets)

Consider seeking specialist advice from a microbiologist for domestic animal bites (including farm animal bites) you are unfamiliar with

Prescribing considerations

If indicated, give oral antibiotics first line if possible

Review intravenous antibiotics by 48 hours and consider switching to oral antibiotics if possible

Microbiological sampling

If there is a discharge (purulent or non-purulent), take a swab for microbiological testing to guide treatment

Review antibiotic choice based on swab results

November 2020

Human and animal bites

Treating an infected bite

Offer an antibiotic

Antibiotic prophylaxis for an uninfected bite

Type of bite	Bite has not broken the skin	Bite has broken the skin but not drawn blood	Bite has broken the skin and drawn blood
Human bite	Do not offer antibiotics	Consider antibiotics if it is in a high-risk area or person at high risk	Offer antibiotics
Cat bite	Do not offer antibiotics	Consider antibiotics if the wound could be deep	Offer antibiotics
Dog or other traditional pet bite	Do not offer antibiotics	Do not offer antibiotics	Offer antibiotics if it has caused considerable, deep tissue damage or is visibly contaminated (for example, with dirt or a tooth) Consider antibiotics if it is in a high-risk area or person at high risk

High-risk areas include the hands, feet, face, genitals, skin overlying cartilaginous structures or an area of poor circulation

People at high risk include those at risk of a serious wound infection because of a co-morbidity (such as diabetes, immunosuppression, asplenia or decompensated liver disease)

Give advice about possible adverse effects of antibiotics and seeking medical help if an infection:

- develops or worsens rapidly or significantly at any time
- does not start to improve within 24 to 48 hours of starting treatment

Reassess if:

- symptoms or signs of infection develop or worsen rapidly or significantly at any time
- there is no improvement within 24 to 48 hours of starting treatment
- the person becomes systemically unwell
- there is severe pain that is out of proportion to the infection

Refer to hospital if there are signs of a serious illness (such as severe cellulitis, abscess, osteomyelitis, septic arthritis, necrotising fasciitis or sepsis), or a penetrating wound involving bones, joints, tendons or vascular structures

Consider referral or seeking specialist advice if, for example, the person:

- is systemically unwell
- has an infection after prophylactic antibiotics
- cannot take, or has an infection that is not responding to, oral antibiotics

When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

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Human and animal bites: antimicrobial prescribing

Choice of antibiotic for prophylaxis and treatment: adults aged 18 years and over

Prophylaxis and treatment	Antibiotic, dosage and course length for prophylaxis (3 days) and treatment (5 days)
First-choice oral antibiotic	**Co-amoxiclav**: 250/125 mg or 500/125 mg three times a day
Alternative first-choice oral antibiotics for penicillin allergy or if co-amoxiclav is unsuitable	**Doxycycline**: 200 mg on first day, then 100 mg or 200 mg daily With **Metronidazole**: 400 mg three times a day
Alternative first-choice oral antibiotics in pregnancy for penicillin allergy or if co-amoxiclav is unsuitable	Seek specialist advice
First-choice intravenous antibiotic (if unable to take oral antibiotics or severely unwell)	**Co-amoxiclav**: 1.2 g three times a day
Alternative first-choice intravenous antibiotics for penicillin allergy or if co-amoxiclav is unsuitable If a cephalosporin is not appropriate, seek specialist advice	**Cefuroxime** (caution in penicillin allergy): 750 mg three times a day (increased to 750 mg four times a day or 1.5 g three or four times a day if infection is severe) With **Metronidazole**: 500 mg three times a day **Ceftriaxone** (caution in penicillin allergy) 2 g once a day With **Metronidazole**: 500 mg three times a day

See the BNF and summary of product characteristics for appropriate use and dosing in specific populations, for example, for hepatic or renal impairment, in pregnancy, when breastfeeding and when administering intravenous (or, if appropriate, intramuscular) antibiotics.
A 5-day course is appropriate for treating most human or animal bites, but course length can be increased to 7 days (with review) based on clinical assessment of the wound, for example, if there is significant tissue destruction or it has penetrated bone, joint, tendon or vascular structures.

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Human and animal bites: antimicrobial prescribing

Choice of antibiotic for prophylaxis and treatment: children and young people under 18 years

Prophylaxis and treatment	Antibiotic, dosage and course length for prophylaxis (3 days) and treatment (5 days)
Choice for children under 1 month	Seek specialist advice
First-choice oral antibiotic for children aged 1 month and over	**Co-amoxiclav**: 1 month to 11 months: 0.25 ml/kg of 125/31 suspension three times a day 1 year to 5 years: 0.25 ml/kg or 5 ml of 125/31 suspension three times a day 6 years to 11 years: 0.15 ml/kg or 5 ml of 250/62 suspension three times a day 12 years to 17 years: 250/125 mg or 500/125 mg three times a day Co-amoxiclav 400/57 suspension may also be considered to allow for twice-daily dosing
Alternative first-choice oral antibiotic for children under 12 years for penicillin allergy or if co-amoxiclav is unsuitable	**Co-trimoxazole** (off-label use; see the BNF for Children for information on monitoring): 6 weeks to 5 months: 120 mg or 24 mg/kg twice a day 6 months to 5 years, 240 mg or 24 mg/kg twice a day 6 years to 11 years, 480 mg or 24 mg/kg twice a day For off-label use, follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's good practice in prescribing and managing medicines and devices for information.
Alternative first-choice oral antibiotics for young people aged 12 to 17 years for penicillin allergy or if co-amoxiclav is unsuitable	**Doxycycline**: 200 mg on first day, then 100 mg or 200 mg daily **With metronidazole**: 400 mg three times a day
Alternative first-choice oral antibiotics in pregnancy for penicillin allergy or if co-amoxiclav unsuitable	Seek specialist advice
First-choice intravenous antibiotic (if unable to take oral antibiotics or severely ill)	**Co-amoxiclav**: 1 month to 2 months: 30 mg/kg twice a day 3 months to 17 years: 30 mg/kg three times a day (maximum per dose 1.2g)
Alternative first-choice intravenous antibiotics for penicillin allergy or if co-amoxiclav is unsuitable If a cephalosporin is not appropriate, seek specialist advice	**Cefuroxime** (caution in penicillin allergy): 1 month to 17 years: 20 mg/kg three times a day (maximum 750 mg per dose), which can be increased to 50 mg/kg to 60 mg/kg three or four times a day (maximum per dose 1.5 g) **With metronidazole**: 1 month: loading dose 15 mg/kg, then (after 8 hours) 7.5 mg/kg three times a day 2 months to 17 years: 7.5 mg/kg three times a day (maximum per dose 500 mg) **Ceftriaxone** (caution in penicillin allergy): 1 month to 11 years (up to 50 kg): 50 mg/kg to 80 mg/kg once a day (maximum 4 g per day) 9 years to 11 years (50 kg and above) and 12 years to 17 years: 1 g to 2 g once a day **With metronidazole**: 1 month: loading dose 15 mg/kg, then (after 8 hours) 7.5 mg/kg three times a day 2 months to 17 years: 7.5 mg/kg three times a day (maximum per dose 500 mg)

See the BNF for Children and summary of product characteristics for appropriate use and dosing in specific populations, for example, for hepatic or renal impairment, in pregnancy, when breastfeeding and when administering intravenous (or, if appropriate, intramuscular) antibiotics.
A 5-day course is appropriate for treating most human or animal bites, but course length can be increased to 7 days (with review) based on clinical assessment of the wound, for example, if there is significant tissue destruction or it has penetrated bone, joint, tendon or vascular structures