

**Importance Ratings and Summary of**

**Antibacterial Uses in Human and Animal Health in Australia**

**June 2018**

**Australian Strategic and Technical Advisory Group   
on Antimicrobial Resistance (ASTAG)**

**Importance Ratings and Summary of Antibacterial Uses in Human and Animal Health in Australia, Version 1.0 (2018)**

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The Antibacterial Importance Ratings capture the knowledge of national and international experts with backgrounds in human and animal medicine and is based upon the best available evidence at the time of completion. Readers should not rely solely on the information contained within this document.

Antibacterial Importance Ratings is not intended to be a substitute for advice from other relevant sources including, but not limited to, the advice from a health professional. Clinical judgment and discretion may be required in the interpretation and application of this information.

The information in this publication is not treatment advice in either human or animal health and must never be used for treatment without advice from a qualified medical or veterinary professional.

# Foreword

Antimicrobial resistance is one of the most significant human and animal health threats facing our generation and the ones to come. Antimicrobial resistance occurs when microorganisms, such as bacteria, that cause infection, become resistant to the medicine used to treat it.

The main cause of antimicrobial resistance is antimicrobial use. Antimicrobial use, specifically antibacterial use, applies selective pressure by killing susceptible bacteria and allowing resistant bacteria to survive and multiply. Inappropriate use of antibacterials across human health, animal health and agriculture globally is responsible for accelerating the development of antimicrobial resistance.

If resistance emerges to an antibacterial agent used to treat a specific infection for which there are no treatment alternatives, the consequences to health outcomes are significant and potentially life threatening.

As such, it is important that antibacterials are used appropriately in order to effectively respond to the threat of antimicrobial resistance in Australia, particularly given that the development of new antibacterials is minimal. As a result, it is essential that we preserve the effectiveness of our existing antibacterials.

The Antibacterial Importance Ratings aim to provide information to inform decision making about the registration and use of antibacterial medicines in Australia.

For more information about antimicrobial resistance and Australia’s *first National Antimicrobial Resistance Strategy* 2015-2019, visit [www.amr.gov.au](http://www.amr.gov.au).

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| *The term ‘antibacterial’ is used in this document as the more common term ‘antimicrobial’ technically includes agents with other antimicrobial properties (e.g. antifungals), and such agents are not discussed here.* |

Contents

[Foreword 4](#_Toc514404325)

[Version control 6](#_Toc514404326)

[History of this document 6](#_Toc514404327)

[About this document 7](#_Toc514404328)

[Purpose 8](#_Toc514404329)

[Other potential uses of this document 8](#_Toc514404330)

[Ratings explained 10](#_Toc514404331)

[Background 11](#_Toc514404332)

[Regulation of antibacterial medicines in Australia 11](#_Toc514404333)

[Other reference material 11](#_Toc514404334)

[Legend 12](#_Toc514404335)

[Table: Summary of Antibacterial Uses in Human and Animal Health in Australia and Importance to Human Health 13](#_Toc514404336)

# Version control

The *Importance Ratings and Summary of Antibacterial Uses in Human and Animal Health in Australia* (the “Antibacterial Importance Ratings”) has been reviewed as per the table below.

|  |  |  |
| --- | --- | --- |
| **Version** | **Reviewed by** | **Date** |
| 1.0 | Australian Strategic and Technical Advisory Group on AMR (ASTAG) | Xx 2018 |

## History of this document

The Antibacterial Importance Ratings was first developed in 2002 by the Expert Advisory Group on Antimicrobial Resistance of the National Health and Medical Research Council.

In 2014, the document underwent revision by the Antimicrobial Resistance Standing Committee of the Australian Health Protection Principal Committee, and in 2015 was further updated by the then newly created Australian Strategic and Technical Advisory Group on Antimicrobial Resistance (ASTAG). The ASTAG develops and provides expert advice on AMR-related issues and includes representatives from across the fields of human health, animal health, food, agriculture and the environment.

The Antibacterial Importance Ratings have undergone significant revision and have been renamed. Changes made since the previous version of the Antibacterial Importance Ratings include:

* consolidation of information on antibacterials registered in Australia and antibacterials not registered in Australia for any purpose into a single table;
* updating of all table information to ensure currency;
* brief comments on the use of antibacterials in animals, including those about off-label use and relevant label restraints;
* comments on the potential for the use of certain antibacterials in animals, which are not used in humans, to select for cross resistance to human medicines;
* an expanded explanation of the Low, Medium and High Importance ratings categories; and
* a revised front section, including Foreword, History of the Document, Background and other information relevant to the use of this document.

# About this document

The Antibacterial Importance Ratings provides brief comments on the ways in which registered antibacterials are currently used in human and animal health. The ratings will change over time as resistance levels change, new antibacterials are introduced, and optimum antibacterial choices for therapy and prophylaxis alter because of new evidence relevant to Australia. Consequently the table will be reviewed by ASTAG at regular intervals. Updates will be issued as appropriate.

The Antibacterial Importance Ratings has been revised with an awareness of international documents with a similar purpose including:

* the World Health Organization’s (WHO) [*Critically Important Antimicrobials for Human Medicine*, 5th Revision (2016)](http://www.who.int/foodsafety/publications/antimicrobials-fifth/en/); and
* the World Organisation for Animal Health’s (OIE) [*List of Antimicrobial Agents of Veterinary Importance* (2015)](https://www.oie.int/doc/ged/D9840.PDF).

While care has been taken to consider these international lists, this document does differ in some circumstances as the local context is taken into account, including Australian surveillance data and available alternative antibacterials.

The WHO *Critically Important Antimicrobials for Human Medicine* list represents a global list providing a ranking of antimicrobial agents according to their importance in human health, which could be used, especially by countries with limited resources, for risk prioritisation of non-human use of antimicrobial agents. It is noted in the document that implementation of the WHO’s list at national levels may vary when national considerations are taken into account.

Please note that the macrolides such as erythromycin and the penicillins such as ampicillin are listed as **critically important** on the WHO *Critically Important Antimicrobials for Human Medicine* list but as **low** importance on the Australian Antibacterial Importance Ratings. The difference in importance rating reflects the relatively low reliance on these antibacterial agents in Australia because resistance is widespread in many human pathogens causing infection in Australia or that some of the pathogens of interest to WHO are less important in Australia.

To ensure that the Australian context is taken into account, this document has precedence above other lists including the WHO Critically Important Antimicrobials for Human Medicine list.

The WHO recognises that implementation at the national level requires that national considerations be taken into account and may vary from country to country[[1]](#footnote-1).

# Purpose

The main purpose of this document is to provide information to regulators and users of antibacterials on their importance in the treatment of infections in animals and humans, and the seriousness of the consequences should resistance emerge or be amplified.

The document provides information on antibacterials used in:

* humans alone;
* animals alone; and
* those agents used in both humans and animals.

This information is important as it provides a comprehensive picture of antibacterial use across all sectors in Australia, and the potential for resistance and cross-resistance to develop. It also helps to identify areas that might require close monitoring and/or intervention.

All agents with significant antibacterial activity are included in this document, even if their primary use is not for treating or preventing bacterial infections. For example, pyrimethamine, a dihydrofolate reductase inhibitor, whose main role is treatment of malaria and toxoplasmosis, has antibacterial activity similar to that of trimethoprim, and therefore has the potential to select for resistance to this class.

This document is relevant to the “severity of impact” of antibacterial resistance, which is an important element to overall risk characterisation. Ratings in this document do not affect other parts of risk assessment including hazard, exposure or probability of disease as a result of exposure.

## Other potential uses of this document

This document may also be used:

* As a resource for the education of human health, animal health and pharmacy professionals
* To inform risk assessments for the registration of new antibacterial agents and extensions of indications of currently registered antibacterials
* To inform changes to regulatory arrangements for currently registered antibacterials
* To assist animal sectors in determining the appropriate use of antibacterials
* To direct responses to protect the effectiveness of antibacterials with ‘High’ importance ratings
* To inform the development of stewardship initiatives, alternative therapies and prescribing guidelines
* To raise the profile of the importance of appropriate antibacterial use generally
* To ensure that surveillance programs include the collection of data relevant to antibacterials of highest importance
* To inform areas for further research and development
* To inform advice provided by ASTAG in relation to the risk to human and animal health posed by exposure to either antibacterials or bacteria that are resistant to them. Such advice may be provided to:
  + the Australian Pesticides and Veterinary Medicines Authority (APVMA)
  + Therapeutic Goods Administration (TGA)
  + Advisory Committee on Medicines Scheduling (ACMS)
  + Advisory Committee on Chemicals Scheduling (ACCS) and
  + the Pharmaceutical Benefits Advisory Committee (PBAC).

# Ratings explained

The Antibacterial Importance Ratings table categorises each antibacterial as either of ‘High’, ‘Medium’ or ‘Low’ Importance for the mitigation of antibacterial resistance.

**Low Importance:** There are a reasonable number of alternative antibacterials in different classes available to treat or prevent most human infections even if antibacterial resistance develops.

**Medium Importance:** There are some alternative antibacterials in different classes available to treat or prevent human infections, but less than for those rated as Low Importance.

**High Importance:** These are essential antibacterials for the treatment or prevention of infections in humans where there are few or no treatment alternatives for infections. These have also been termed “last resort” or “last line” antibacterials.

The potential for ALL antibacterials to select for resistance is recognised, not just to the agent itself, but also cross-resistance (to agents from the same or similar classes), and the co-selection of resistance (linked resistances in the same bacterial strain to unrelated antibacterial classes). Cross-resistance is more immediate and a primary consideration for antibacterial classes that might be shared between human and animal health.

In general, it is expected that antibacterials with a High rating would have restricted in animals producing food for human consumption (which includes cattle, pigs, poultry, sheep, and some horses).

There are currently a small number of antibacterials in the High category that have been, and remain legitimately, registered by the APVMA. The use of antibacterials with High ratings in animals will be considered appropriate when national stewardship guidelines are available, or in ‘exceptional circumstances’. For the purposes of this document exceptional circumstances are defined as:

* *Based on culture and susceptibility testing, there are no effective alternate agents and the animal is not destined for human consumption*.

It is important that all antibacterials are used appropriately regardless of their importance rating because, when resistance emerges to Low and Medium Importance agents, High Importance agents will be required more often. This will accelerate the development of resistance in these agents. All antibacterials are important and efforts must be applied to ensure the prudent and appropriate use of all agents regardless of rating.

# Background

## Regulation of antibacterial medicines in Australia

The majority of antibacterial medicines used in human and animal health in Australia are Schedule 4 medicines, which means that they are available by prescription only.

Before an antibacterial medicine can be supplied in Australia for human use it must be included on the [Australian Register of Therapeutic Goods (](https://www.tga.gov.au/australian-register-therapeutic-goods)ARTG) or approved for use under the Special Access Scheme. All antibacterial medicines on the ARTG are subject to TGA evaluation criteria for safety, quality and efficacy, including risk assessment for the development of resistance. Many antibacterials are subsidised through the Australian Government’s Pharmaceutical Benefits Scheme (PBS), which supports affordable access to these important medicines. Varying levels of restriction apply to antibacterials on the PBS, and subsidies are available for specific indications to encourage appropriate use.

Antibacterial medicines for animal use are evaluated and registered by the APVMA under the [*Agricultural and Veterinary Chemicals Code Act 1994*](https://www.legislation.gov.au/Details/C2016C00999). Each antibacterial is evaluated for quality, safety to humans, the environment and the target host animal, efficacy and trade implications. The safety evaluation includes the management of risks associated with the development of antibacterial resistant organisms in animals that may be transferred to humans. The APVMA is responsible for the regulating the manufacture and the supply of antibacterial veterinary chemical products up to the point of sale. State and territory government agencies are responsible for regulating the supply and use from the point of sale, including the prescription of antibacterial medicines by veterinarians in their respective jurisdictions.

## Other reference material

The Antibacterial Importance Ratings should be used in conjunction with other important reference documents, including:

* *Therapeutic Guidelines: Antibiotic,* version 15, Therapeutic Guidelines Ltd (2014)available at [www.tg.org.au](http://www.tg.org.au)
* *Veterinary Use of Antimicrobials Critical to Human Health,* Fact Sheet, Australian Veterinary Association (2017) available at [www.ava.com.au/amr](http://www.ava.com.au/amr)
* *Critically Important Antimicrobials for Human Medicine,* 5th Revision, World Health Organization, (2017) available at [www.who.int/foodsafety/publications/antimicrobials-fifth/en](http://www.who.int/foodsafety/publications/antimicrobials-fifth/en)

# Legend

**Human health uses**

The following codes reflect the current use of these antibacterials in Australia in human medicine.

**P: prophylactic use**

0 = not recommended for prophylactic use; 1 = rarely used; 2 = moderate use; 3 = frequent or major use.

**T: therapeutic use**

0 = not used for treatment; 1 = infrequently used for listed indications; 2 = moderate use for listed indications; 3 = used frequently for listed indications.

**R = Restriction on use (Pharmaceutical Benefits Scheme or hospitals)**

1 = readily available;

2 = some extra rules on use e.g. ‘Restricted benefit’ in the Pharmaceutical Benefits Scheme (PBS) or not listed on the PBS and therefore not subsidised;

3 = higher level of restriction e.g. needs an ‘Authority required’ prescription on the PBS or not listed on the PBS and therefore not subsidised; often restricted use in hospitals;

4 = use severely restricted (e.g. not available for prescription under PBS, available in major hospitals but only with permission from a microbiologist or infectious diseases consultant, or in a special clinic);

5 = not TGA registered but imported under the Special Access Scheme.

# Table: Summary of Antibacterial Uses in Human and Animal Health in Australia and Importance to Human Health

| Antibacterial class and antibacterial | Australian Importance Rating1 | Human health uses P, T, R | Brief comments on human use2 | APVMA registered | Brief comments on animal use5 | Not registered in Australia by TGA or APVMA for any purpose |
| --- | --- | --- | --- | --- | --- | --- |
| **ß-lactamase inhibitor combinations** | | | | | | |
| Amoxicillin with clavulanic acid | Medium | P1, T3, R1 | Second line agent for respiratory tract infections; role in certain types of skin/soft tissue infections and mixed staphylococcal/Gram-negative infections and aerobic/anaerobic infections. | Yes | Amoxicillin combination with clavulanic acid approved for use in cattle (intramammary only), dogs and cats. | Ampicillin-sulbactam  Cefoperazone with sulbactam  Ceftazidime with avibactam |
| Piperacillin with tazobactam,  Ticarcillin with clavulanic acid | High | P1, T2, R2 | Valuable agents for a range of severe mixed aerobic-anaerobic infections including intra-abdominal infections, aspiration pneumonia, skin/soft tissue infections.  Primary agents for *Pseudomonas aeruginosa* neutropenic sepsis. | No | Not registered for use in animals. |
| Ceftolozane with tazobactam | High | P0, T1, R4 | Multi-resistant Gram-negative infections. | No | Not registered for use in animals. |
| **Aminoglycosides / Aminocyclitols** | | | | | | |
| Neomycin | Low | P1, T2, R1 | Topical agent for skin infection and gut suppression. | Yes | Approved for use in cattle, sheep, pigs, meat chickens (broilers), replacement pullets, horses, dogs and cats. | Arbekacin  Bekanamycin  Dibekacin  Isepamicin  Kanamycin  Netilmicin  Ribostamycin  Sisomicin  Streptoduocin |
| Framycetin | Low | P1, T2, R1 |  | Yes | Approved for topical ocular and aural use in cattle, sheep, horses, dogs and cats. |
| Gentamicin, tobramycin | Medium | P2, T3, R1 | Standard agents in combination for serious and pseudomonal infection.  Gentamicin used in combination for endocarditis. | Yes (Gentamicin) | Gentamicin only: approved for use in horses, dogs and cats.  All gentamicin products are not for use in animals that may be used for human consumption, which may include horses.  Tobramycin is not registered for use in animals. |
| Amikacin | High | P0, T2, R4 | Reserve agents for Gram-negatives resistant to gentamicin and tobramycin, and the drug-resistant *Mycobacterium tuberculosis* infection. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| Spectinomycin3 | Medium | P0, T2, R5 | Spectinomycin only used for gonorrhoea (infrequently). | Yes | Approved for use singly or in combination with lincomycin in pigs, meat chickens (broilers), layers, ornamental birds, dogs and cats. |
| Streptomycin3 | Low | P0, T1, R5 | Rare use in treatment of TB and enterococcal endocarditis. | Yes | Approved for use in pigs, meat chickens (broilers), layers, dogs, cats and ornamental birds.  Note: The differences between streptomycin and dihydrostreptomycin are considered by the APVMA to be small. |
| Dihydrostreptomycin | Low | Not used in humans | Not used in humans. | Yes | Used in cattle in combination with novobiocin and neomycin for intramammary treatment.  (Dihydro)streptomycin/penicillin combination products are available under APVMA permits issued to veterinarians for control of leptospirosis in cattle, sheep and pigs, campylobacteriosis in bulls and for live cattle for export to countries which require (dihydro)streptomycin injection prior to shipment. Approved for use in dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Paromomycin3 | Low | P0, T1, R5 | Used for *Cryptosporidium, Entamoeba histolytica* and *Dientamoeba* infection. Has antibacterial activity. | No | Not registered for use in animals. |
| Apramycin | Medium | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, pigs and meat chickens (broilers).  For use in animals with bacterial infection and enteritis associated with *E. coli* and/or *Salmonella* species.  Not used in humans but has potential to select for cross resistance to gentamicin and tobramycin. |
| **Amphenicols** | | | | | | |
| Chloramphenicol | Low | P0, T2, R1 | Usage largely as topical eye preparation. Occasional need for the treatment of bacterial meningitis. | Yes | Approved for use in dogs and cats.  Not for use in livestock species. | Azidamfenicol  Thiamphenicol |
| Florfenicol | Low | Not used in humans | Not used in humans. | Yes | Approved for use in cattle and pigs and for topical aural use in dogs.  Not used in humans but has potential to select for cross resistance to human medicines. |  |
| **Antileprotics** | | | | | | |
| Clofazimine | High | P0, T3, R4 | Usage predominantly for treatment of leprosy. | No | Not registered for use in animals. | Acedapsone |
| Dapsone | High | P0, T3, R4 | Usage predominantly for treatment of leprosy. | No | Not registered for use in animals. |
| **Antimycobacterials** | | | | | | |
| Isoniazid | High | P2, T3, R4 | Primary agent for treatment and prevention of tuberculosis (TB). | No | Not registered for use in animals. | Ethionamide  Calcium aminosalicylate  Morinamide  Sodium aminosalicylate  Terizadone  Tiocarlide  Bedaquiline  Delamanid |
| Ethambutol | High | P1, T3, R4 | Primary agent for treatment of TB. | No | Not registered for use in animals. |
| Pyrazinamide | High | P1, T3, R4 | Primary agent for treatment of TB. | No | Not registered for use in animals. |
| Cycloserine | High | P0, T1, R4 | Reserve agents for complicated or resistant TB. | No | Not registered for use in animals. |
| p-aminosalicylic acid | High | P0, T1, R5 | Reserve agents for complicated or resistant TB. | No | Not registered for use in animals. |
| Prothionamide | High | P0, T1, R5 | Reserve agents for complicated or resistant TB. | No | Not registered for use in animals. |
| Capreomycin | High | P0, T1, R5 | Rare use in TB. | No | Not registered for use in animals. |
| **Arsenicals** | | | | | | |
| Roxarsone, 3-nitro-4-hydroxyphenylarsonic acid, sodium arsanilate | Low | Not used in humans | Not used in humans. | Yes | Roxarsone approved for growth promotion in meat chickens (broilers) and turkeys.  Sodium arsanilate approved for injection in horses and dogs, but not as an antibacterial agent.  No cross resistance with human medicines. |  |
| **Bambermycins** | | | | | | |
| Flavophospholipol (bambermycin) | Low | Not used in humans | Not used in humans. | Yes | Approved for growth promotion in cattle, pigs, meat chickens (broilers), layers and turkeys.  No cross resistance with human medicines. |  |
| **Bicozamycins** | | | | | | |
| Bicozamycin (bicyclomycin) | Low | Not used in humans | Not used in humans. | No | Not registered for use in animals.  No cross resistance with human medicines. | Bicozamycin |
| **Coumermycins** | | | | | | |
| Novobiocin | Low | Not used in humans | Not used in humans. | Yes | Approved for use in cattle. Currently available in an intramammary preparation (with neomycin and dihydrostreptomycin).  No cross resistance with human medicines. | Coumermycin  Clorobiocin |
| **Carbapenems** | | | | | | |
| Imipenem, meropenem | High | P0, T3, R4 | Very broad-spectrum reserve agents for multi-resistant and serious Gram-negative and mixed infections. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. | Biapenem  Panipenem  Razupenem  Tebipenem |
| Ertapenem | High | P0,T3, R4 | Broad-spectrum reserve agent for multi-resistant and Gram-negative infections. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| **1st Generation Cephalosporins** | | | | | | |
| Cefalexin, cefalotin, cefazolin | Medium | P3, T3, R1 | Treatment of minor and staphylococcal infections in penicillin allergic patients.  Prophylaxis in orthopaedic and other surgery. | Yes (Cefalexin) | Cefalexin only: approved for use in dogs and cats.  Cefalotin and cefazolin are not registered for use in animals. | Cefacetrile  Cefadroxil  Cefatrizine  Cefazedone  Ceforanide  Cefroxadine  Ceftazafur  Ceftezole  Cephaloglycin  Cephaloridine  Cephradine |
| Cephapirin | Medium | Not used in humans | Not used in humans. | Yes | Approved as an intra-uterine treatment of metritis in cows.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Cephalonium | Medium | Not used in humans | Not used in humans. | Yes | Approved as a dry cow intramammary product and as an ophthalmic ointment in cattle and dogs.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| **2nd Generation Cephalosporins** | | | | | | |
| Cefaclor, cefuroxime-axetil | Medium | P0, T2, R1 | Treatment of respiratory infections in penicillin-allergic patients. | Yes (Cefuroxime) | Cefuroxime: Approved as an intramammary treatment in lactating cows.  Cefaclor is not registered for use in animals. | Cefamandole  Cefonicid  Cefotiam  Cefprozil  Cefroxadine  Ceftezole  Loracarbef |
| **3rd Generation Cephalosporins** | | | | | | |
| Ceftriaxone | High | P2, T3, R2 | Major agent in severe pneumonia and meningitis. Used in selected cases for treatment of gonorrhoea and alternative for prophylaxis of meningococcal infection. | No | Not registered for use in animals.  Used in dogs and cats in exceptional circumstances∞. | Cefcapene  Cefdinir  Cefditoren  Cefetamet  Cefixime  Cefmenoxime  Cefodizime  Cefoselis  Cefazopran  Cefpiramide  Cefpodoxime  Ceftizoxime  Ceftibuten  Latamoxef |
| Cefotaxime | High | P0, T3, R2 | Major agent in severe pneumonia and meningitis. | No | Not registered for use in animals.  Used in dogs and cats in exceptional circumstances∞. |
| Ceftiofur | High | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, dogs and horses.  **Label restraints:**   * Do not use for mass medication; individual animal treatment only. * Do not use by intramammary, topical or oral route in food producing animals. * Do not use for the treatment of mastitis in dairy cattle.   Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Cefovecin | High | Not used in humans | Not used in humans. | Yes | Approved for use in dogs and cats.  **Label restraints:**   * Do not use in food producing species of animal or guinea pigs. For use only in dogs and cats where indicated by antibiotic sensitivity testing according to the principles of prudent use.   Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| **4th Generation Cephalosporins** | | | | | | |
| Ceftazidime and cefepime | High | P1, T3, R3 | Restricted role in pseudomonal infection and neutropenic sepsis. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. | Cefsulodin  Cefoperazone  Cefpirome  Cefquinome |
| **Anti-MRSA Cephalosporins** | | | | | | |
| Ceftaroline | High | P1, T1, R3 | Restricted role in MRSA infection. | No | Not registered for use in animals. | Ceftobiprole |
| **Cephamycins** | | | | | | |
| Cefoxitin | Medium | P3, T1, R2 | Useful anti-anaerobic activity, major role in surgical prophylaxis. | No | Not registered for use in animals. | Cefbuperazone  Cefmetazole  Cefminox  Cefotetan  Flomexef |
| **Fosfomycins** | | | | | | |
| Fosfomycin | High | P0,T1,R5 | Multi-resistant Gram-negative infections, especially UTI. | No | Not registered for use in animals. |  |
| **Fusidanes** | | | | | | |
| Sodium fusidate | High | P0, T3, R2 | Used in combination therapy with rifampicin for MRSA. | Yes4 | Approved as a topical treatment of skin infections in dogs and eye infections in dogs and cats.  Only appropriate in exceptional circumstances∞. |  |
| **Glycopeptides** | | | | | | |
| Vancomycin | High | P2, T3, R2 | Drug of choice for serious methicillin-resistant staphylococcal infections.  Reserve agent for enterococcal infection when there is resistance or penicillin allergy. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. | Avoparcin  Dalbavancin  Oritavancin  Norvancomycin  Ramoplanin  Telavancin |
| Teicoplanin | High | P1, T1, R4 | Substitute for vancomycin if intolerance or outpatient IV therapy. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| **Glycylcyclines** | | | | | | |
| Tigecycline | High | P0, T1, R4 | Reserve agent for multi-resistant Gram-positives and some multi-resistant Gram-negatives. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |  |
| **Ionophores** | | | | | | |
| Lasalocid  Maduramicin  Monensin  Narasin  Salinomycin  Semduramicin | Low | Not used in humans | Not used in humans. | Yes | Maduramicin and semduramicin approved as anticoccidial agents for use in meat chickens (broilers). The other ionophores are approved as anticoccidial agents for meat chickens (broilers), replacement pullets, turkeys and cattle, and as growth promoters in cattle, sheep, pigs and goats.  No cross resistance to human agents. | Laidlomycin |
| **Lantibiotics** | | | | | | |
| Nisin | Low | Food additive | This is a permitted food additive (FSANZ). Not used in human therapeutics. No cross resistance to other classes. | No | Not registered for use in animals. |  |
| **Lincosamides** | | | | | | |
| Clindamycin, lincomycin | Medium | P1, T3, R2 | Reserved for Gram-positive and anaerobic infections in penicillin-allergic patients.  Clindamycin topical used for acne. | Yes | Lincomycin approved for use singly or in combination with spectinomycin in pigs, meat chickens (broilers), layers, ornamental birds, dogs and cats.  Clindamycin approved for use in dogs and cats. | Pirlimycin |
| **Lipopeptides** | | | | | | |
| Daptomycin | High | P0, T1, R4 | Reserve agent for serious MRSA and VRE infections. | No | Not registered for use in animals. |  |
| **Macrocyclic lactones** | | | | | | |
| Fidaxomicin | High | P0, T1, R4 | Reserve agents for refractory *Clostridium difficile* infection. | No | Not registered for use in animals. |  |
| **Macrolides** | | | | | | |
| Azithromycin | Low | P3, T3, R2 | Treatment of *Chlamydia trachomatis* infections. Major agent for treatment and suppression of atypical mycobacterial infection. | No | Not registered for use in animals.  Should not be used off-label except in exceptional circumstances∞ for individual animals. | Dirithromycin  Flurithromycin  Gamithromycin  Josamycin  Midecamycin  Miocamycin  Mirosamycin  Rokitamycin  Telithromycin  Terdecamycin  Tildipirosin  Troleandomycin  Tylvalosin |
| Clarithromycin | Low | P2, T2, R1 | Treatment of minor Gram-positive infections. Major agent for treatment and suppression of atypical mycobacterial infection. | No | Not registered for use in animals.  Should not be used off-label except in exceptional circumstances∞ for individual animals. |
| Erythromycin^, roxithromycin | Low | P1, T3, R1 | Treatment of minor Gram-positive, *Chlamydia* and *Mycoplasma* infections. | Yes (Erythromycin) | Approved for use in cattle, sheep, pigs and meat chickens (broilers).  Roxithromycin is not registered for use in animals. |
| Spiramycin3 | Low | P0,T1,R5 | Treatment of toxoplasmosis in pregnancy. | Yes | Approved for use in dogs and cats |
| Kitasamycin | Low | Not used in humans | Not used in humans. | No | Not registered for use in animals. |
| Oleandomycin | Low | Not used in humans | Not used in humans. | Yes | Approved for use in cows as an intramammary treatment.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Tilmicosin | Low | Not used in humans | Not used in humans. | Yes | Approved for use in pigs and cattle.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Tulathromycin | Low | Not used in humans | Not used in humans. | Yes | Approved for use in pigs and cattle.  Approved for treating only respiratory infections in cattle and pigs.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Tylosin | Low | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, pigs, meat chickens (broilers), replacement pullets and turkeys.  Note: On 29 March, 2018, the APVMA cancelled the approval of the growth promotion claim.  **Label restraints:**   * Prior to prescribing [Name of Product] investigate the use of non-antibiotic options. If [Name of Product] is indicated and selected for use, prudent prescribing practices (appropriate dose, duration and frequency to minimise treatment failure while minimising the emergence of antimicrobial resistance) must be adhered to. * NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL.   Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| **Monobactams** | | | | | | |
| Aztreonam | High | P0, T3, R4 | Reserve agents for resistant Gram-negative infections or patients with severe ß-lactam allergy. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals.. | Carumonam  Norcardicin A  Tigemonam |
| **Nitrofurans** | | | | | | |
| Nitrofurantoin | High | P2, T2, R1 | Treatment and prophylaxis of urinary tract infections only. | No | Not registered for use in animals.  Note: All registrations and approved uses of nitrofurans in food-producing species were cancelled in December 1992. There are no MRLs for nitrofurans. | Furaltadone  Nifurtoinol  Nitrofural |
| Furazolidone3 | High | P0, T1, R5 | Reserve treatment for *Helicobacter pylori* infection. | No | Not registered for use in animals.  Note: All registrations and approved uses of nitrofurans in food-producing species were cancelled in December 1992. There are no MRLs for nitrofurans. |
| Nitrofurazone | High | Not used in humans | Not used in humans. | Yes4 | Approved as a topical treatment of infections of the skin and ear of horses, dogs and cats.  Note: All registrations and approved uses of nitrofurans in food-producing species were cancelled in December 1992. There are no MRLs for nitrofurans.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| **Nitroimidazoles** | | | | | | |
| Metronidazole, tinidazole | Medium | P2, T3, R1 | Major agents for the treatment and prevention of anaerobic infections in hospitals.  Principal agents for the treatment of giardiasis and trichomoniasis. | Yes  (Metronidazole) | Tinidazole is not registered for use in animals.  Metronidazole is approved for use in horses, dogs, cats and ornamental birds. | Ornidazole |
| Dimetridazole | Medium | Not used in humans | Not used in humans. | Yes | Approved for use only in breeder caged birds, breeder pigeons and breeder game birds.  DO NOT USE in birds intended for human consumption.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Ronidazole | Medium | Not used in humans | Not used in humans. | Yes | Approved for use in ornamental birds and pigeons.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| **Orthosomycins** | | | | | | |
| Avilamycin | Low | Not used in humans | Not used in humans. | Yes | Approved for use in broiler chickens.  No cross resistance with human medicines. |  |
| **Oxazolidinones** | | | | | | |
| Linezolid | High | P0, T1, R4 | Treatment of multi-resistant Gram-positive infections, especially MRSA and VRE. | No | Not registered for use in animals. | Tedizolid |
| **Antistaphylococcal penicillins** | | | | | | |
| Flucloxacillin, dicloxacillin | Medium | P3, T3, R1 | Standard treatment for *Staphylococcus aureus* infections (not MRSA).  Surgical prophylaxis, especially orthopaedics. | No | Not registered for use in animals. | Nafcillin  Oxacillin |
| Cloxacillin | Medium | Not used in humans in Australia | Not used in humans. | Yes | Approved for ocular use in cattle, sheep, horses, dogs and cats and for intramammary use in lactating and dry cows.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| **Moderate-spectrum penicillins** | | | | | | |
| Amoxicillin, ampicillin^ | Low | P2, T3, R1 | Principal role in respiratory tract infections. Widespread IV hospital use in combination for a range of moderate and serious infections.  Surgical and endocarditis prophylaxis. | Yes | Amoxicillin approved for use in cattle, sheep, pigs, meat chickens (broilers), replacement pullets, turkeys, horses, dogs and cats. Ampicillin - approved as an intramammary infusion for both dry and lactating cows. | Aspoxicillin  Azidocillin  Bacampicillin  Clometocillin  Epicillin  Hetacillin  Metampicillin  Penamecillin  Pivampicillin  Propicillin  Sultamicillin  Talampicillin  Temocillin  Tobicillin |
| **Narrow-spectrum penicillins** | | | | | | |
| Benzylpenicillin (pen G), phenoxymethylpenicillin (pen V) | Low | P2, T3, R1 | Primary agents in pneumococcal and streptococcal infection. | Yes  (Benzyl-penicillin) | Approved for use in pigs, cattle, sheep, horses, dogs and cats. | Phenoxyethylpenicillin (phenethicillin) |
| Procaine penicillin | Low | P2, T3, R1 | Intramuscular – occasional substitute for benzylpenicillin. | Yes | Approved singly or in combination with benzathine penicillin for use in cattle, sheep, pigs, horses, dogs and cats. |
| Benzathine penicillin | Low | P3, T3, R1 | Intramuscular – syphilis treatment and rheumatic fever prophylaxis. | Yes | Approved in combination with procaine penicillin for use in cattle, sheep, pigs, horses, dogs and cats. |
| Penethamate hydriodide | Low | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, sheep, pigs and horses.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| **Broad-spectrum penicillins** | | | | | | |
| Piperacillin | Medium | P1, T2, R4 | *Pseudomonas aeruginosa* infections | No | Not registered for use in animals. | Azlocillin  Carbenicillin  Carindacillin  Mecillinam  Mezlocillin Pivmecillinam  Sulbenicillin  Temocillin  Ticarcillin |
| **Pleuromutilins** | | | | | | |
| Tiamulin | Low | Not used in humans | Not used in humans | Yes | Approved for use in pigs and meat chickens (broilers).  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. | Valnemulin  Lefamulin |
| Retapamulin | Low | P0, T1, R4 | Skin infections. | No | Not registered for use in animals. |  |
| **Polymyxins** | | | | | | |
| Polymyxin B | High | P0, T2, R1 | Topical agent with Gram-negative activity. | Yes4 | Approved for topical ocular and aural use in cattle, sheep, horses, dogs and cats. Only appropriate in exceptional circumstances∞. |  |
| Colistin | High | P0, T1, R4 | Reserve agent for very multi-resistant Gram-negative infection (both inhaled and intravenous). | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| **Polypeptides** | | | | | | |
| Bacitracin, gramicidin | Low | P0, T2, R1 | Topical agents with Gram-positive activity. | Yes  (Bacitracin) | Bacitracin - Approved as an infeed premix for use in meat chickens (broilers) and layers.  Approved for topical ocular and aural use in cattle, sheep, horses, dogs and cats.  Gramicidin is not registered for use in animals. | Enramycin |
| Thiostrepton | Low | Not used in humans | Not used in humans. | Yes | Approved for dermal and aural use in dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| **Pseudomonic acids** | | | | | | |
| Mupirocin | Medium | P1, T3, R1 | Topical treatment of skin infections and clearance of *S. aureus* nasal carriage (including MRSA). | No | Not registered for use in animals.  Should not be used off-label except in exceptional circumstances∞ for individual animals. |  |
| **Quinolones** | | | | | | |
| Norfloxacin | High | P1, T3, R2 | Treatment and prevention of complicated UTI. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. | Cinoxacin  Danofloxacin  Difloxacin  Enoxacin  Fleroxacin  Flumequine  Garenoxacin  Gemifloxacin  Grepafloxacin  Lomefloxacin  Miloxacin  Nalidixic acid  Oxolinic acid  Pazufloxacin  Pefloxacin  Pipemidic acid  Piromidic acid  Prulifloxacin  Rosoxacin  Rufloxacin  Sarafloxacin  Sitafloxacin  Sparfloxacin  Temafloxacin  Trovafloxacin |
| Ciprofloxacin | High | P2, T3, R3 | Major oral agent for the treatment of Gram-negative infections resistant to other agents. Minor role in meningococcal prophylaxis. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| Moxifloxacin | High | P0, T3, R4 | Restricted role in the management of serious respiratory infections, especially pneumonia in patients with severe penicillin allergy. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| Ofloxacin | High | P0, T2, R3 | Topical treatment of severe eye infections. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| Levofloxacin3 | High | P0, T1, R5 | Reserve treatment for *Helicobacter pylori* infection. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| Enrofloxacin  Enrofloxacin+Silver Sulfadiazine | High | Not used in humans | Not used in humans. | Yes | Approved for use in dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans.  **Label restraints:**   * Do not use in food producing animals. * For use in companion animals where culture and sensitivity testing indicate no suitable alternative.   Only appropriate in exceptional circumstances∞. |
| Ibafloxacin | High | Not used in humans | Not used in humans. | Yes | Approved for use in dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans.  **Label restraints:**   * Do not use in food producing animals. * For use in dogs animals where culture and sensitivity testing indicate no suitable alternative.   Only appropriate in exceptional circumstances∞. |
| Marbofloxacin | High | Not used in humans | Not used in humans. | Yes | Approved for use in dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans.  **Label restraints:**   * Do not use in food producing animals * For use in dogs and cats where culture and sensitivity testing indicate no suitable alternative.   Only appropriate in exceptional circumstances∞. |
| Orbifloxacin | High | Not used in humans | Not used in humans. | Yes | Approved for use in dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans.  **Label restraints:**   * Not for use in food producing species.   Only appropriate in exceptional circumstances∞. |
| Pradofloxacin | High | Not used in humans | Not used in humans. | Yes | Approved for use in dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans.  **Label restraints:**   * Do not use for any purpose, or in a manner, contrary to this label. * For use only in dogs and cats which have responded poorly to other classes of antimicrobials and where culture and sensitivity testing indicate no suitable alternative.   Only appropriate in exceptional circumstances∞. |
| **Quinoxalines** | | | | | | |
| Carbadox, Olaquindox | Low | Not used in humans | Not used in humans. | Yes (Olaquindox) | Approved for use in pigs (olaquindox only).  No evidence for cross resistance to human agents.  Carbadox is not registered for use in animals. |  |
| **Rifamycins** | | | | | | |
| Rifampicin (Rifampin) | High | P3, T3, R2 | Meningococcal and *H. influenzae* type b prophylaxis.  Standard part of TB regimens.  Important oral agent in combination for MRSA infections. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. | Rifapentine  Rifamycin |
| Rifabutin | High | P3, T2, R4 | Treatment and prophylaxis of *Mycobacterium avium* complex infections. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| Rifaximin | High | P1, T0, R4 | Prevention of hepatic encephalopathy. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| **Sulfonamides and dihydrofolate reductase inhibitors** | | | | | | |
| Sulfadiazine3 | Low | P0, T3, R5 | Treatment of acute toxoplasmosis. | Yes | Approved for use in cattle, sheep, pigs, meat chickens (broilers), turkeys, horses, dogs and pigeons in combination with trimethoprim. Also approved for use in aquarium fish when combined with sulfadimidine and sulfamerazine. | Baquiloprim  Brodimoprim  Iclaprim  Ormetoprim  Pyrimethamine  Sulfachlorpyridazine  Sulfadimerazin  Sulfadimethoxazole  Sulfadimethoxine  Sulfafurazole = sulfisoxazole  Sulfaguanidine  Sulfaisomidine  Sulfalene  Sulfamazone  Sulfamethazine  Sulfamethizole  Sulfamethoxazole (alone)  Sulfamethoxine  Sulfamethoxypyridazine  Sulfametomidine  Sulfamethoxydiazine  Sulfametrole  Sulfamonomethoxine  Sulfamoxole  Sulfanilamide  Sulfaperin  Sulfaphenazole  Sulfapyridine  Sulfathiourea  Tetroxaprim  Ormosulfathiazole |
| Silver sulfadiazine | Low | P3, T1, R1 | Prevention of wound infections, especially in burns. | Yes | Approved for aural use in dogs in combination with enrofloxacin (High, refer to enrofloxacin entry). |
| Trimethoprim | Low | P2, T3, R1 | Treatment and prophylaxis of UTI. | Yes | Approved for use in cattle, sheep, pigs, meat chickens (broilers), turkeys, horses, dogs and pigeons in combination with other sulphonamides, which all rate as Medium. |
| Sulfamethoxazole-trimethoprim (co-trimoxazole) | Medium | P2, T3, R1 | Minor infections, especially treatment and prophylaxis of UTI. Standard for treatment and prophylaxis of *Pneumocystis jiroveci* infection and nocardiasis.  Important for community-acquired MRSA infections. | No | Not registered for use in animals. |
| Sulfadoxine-pyrimethamine | Medium | P1, T1, R3 | Treatment and prophylaxis of malaria. | No | Not registered for use in animals. |
| Sulfadoxine-trimethoprim | Medium | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, sheep, pigs, goats, horses, dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Sulfadiazine-trimethoprim | Medium | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, sheep, pigs, broiler chickens, turkeys, pigeons, horses, dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Sulfadimidine-trimethoprim | Medium | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, sheep, pigs, broiler chickens, horses, dogs and cats.  Sulfadimidine alone is approved for use in aquarium fish and ornamental caged birds.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Proguanil | Low | P2, T1, R3 | Malaria prophylaxis. | No | Not registered for use in animals. |
| Pyrimethamine | Low | P0, T3, R1 | Treatment of toxoplasmosis. | No | Not registered for use in animals. |
| Sulfacetamide | Low | Not used in humans | Not used in humans. | Yes | Approved for ocular and aural use in horses, dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Sulfadimidine | Low | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, sheep, pigs, meat chickens (broilers), horses, dogs, cats and ornamental birds in combination with trimethoprim. Also approved for use in aquarium fish when combined with sulfadiazine and sulfamerazine.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Sulfaquinoxaline | Low | Not used in humans | Not used in humans. | Yes | Approved as an anticoccidial agent for use in meat chickens (broilers).  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Sulfamerazine | Low | Not used in humans | Not used in humans. | Yes | Approved for use in ornamental birds when combined with sulfadimidine and sulfathiazole and for use in aquarium fish when combined with sulfadimidine and sulfadiazine.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Sulfathiazole | Low | Not used in humans | Not used in humans. | Yes | Approved for use in ornamental birds when combined with sulfadimidine and sulfamerazine.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Phthalylsulfathiazole | Low | Not used in humans | Not used in humans. | Yes | Approved for use in dogs and cats.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Sulfathiazole | Low | Not used in humans | Not used in humans. | Yes | Approved for use in ornamental birds when combined with sulfadimidine and sulfamerazine.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| **Streptogramins** | | | | | | |
| Quinupristin with dalfopristin | High | P0, T1, R5 | Multidrug-resistant Gram-positive infections, especially those caused by *E. faecium* | No | Not registered for use in animals. |  |
| Pristinamycin3 | High | P0, T1, R5 | As for quinupristin-dalfopristin as well as MRSA. | No | Not registered for use in animals and should not be used off-label except in exceptional circumstances∞ for individual animals. |
| Virginiamycin | High | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, sheep, meat chickens (broilers) and horses.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans.  **Label restraints:**   * Not to be used for any purpose, or in a manner, contrary to this label. * Do not feed to laying birds. * Do not use in horses that may be slaughtered for human consumption. * Prudent use: Prior to using [virginiamycin] investigate the use of non-antibiotic options. If virginiamycin is indicated and selected for use, prescription must be consistent with the AVA *Code of Practice for Prescription and Use of Products which Contain Antimicrobial Agents*. Dosage regimens should be designed for each situation with an appropriate duration and frequency to minimise treatment failure while minimising the emergence of resistance. Review farm records on the use of product containing virginiamycin to ensure compliance with prescribing instructions. |
| **Tetracyclines** | | | | | | |
| Tetracycline, doxycycline, minocycline | Low | P2, T3, R1 | Major agents for minor respiratory tract infections and acne.  Supportive role in pneumonia for treating *Mycoplasma* and *Chlamydia pneumoniae.*  Malaria prophylaxis (doxycycline). | Yes | Tetracycline approved for use in ornamental birds and aquarium fish.  Doxycycline approved for use in dogs, cats, ornamental birds and pigeons.  Minocycline is not registered for use in animals. | Clomoclocycline  Demeclocyline  Lymecycline  Metacycline  Minocycline  Penimepicycline  Rolitetracycline |
| Chlortetracycline | Low | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, pigs, meat chickens (broilers), layers, dogs, cats and ornamental birds.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |
| Oxytetracycline | Low | Not used in humans | Not used in humans. | Yes | Approved for use in cattle, sheep, goats, pigs, meat chickens (broilers), horses, dogs, cats, bees and ornamental birds.  Not used in humans but has potential to select for cross resistance to antibacterials used in humans. |

Abbreviations:

MRSA methicillin-resistant *Staphylococcus aureus*

TB tuberculosis

UTI urinary tract infections

VRE vancomycin-resistant *Enterococcus* species

1. *Critically Important Antimicrobials for Human Medicine,* 5th Revision, World Health Organization, (2017) available at [www.who.int/foodsafety/publications/antimicrobials-fifth/en](http://www.who.int/foodsafety/publications/antimicrobials-fifth/en) [↑](#footnote-ref-1)