

# Antibiotic prescriptions for Oral Diseases in India: Pattern and Practices

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## Research Article

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## Abstract

**Introduction:** The key objective of this research was to describe the prescription rate of various antibiotics for dental problems in India and to study the relevance of the prescriptions by analysing antibiotic type associated with different dental diagnoses, using a large scale nationally representative dataset.

**Methods:** We used a 12-month period (May 2015 to April 2016) medical audit dataset from IQVIA (formerly IMS Health). We coded the dental diagnosis provided in the medical audit data to International Statistical Classification of Diseases and Related Health Problems (ICD-11) and the prescribed antibiotics for the diagnosis to Anatomic Therapeutic Chemical (ATC) -2020 classification of World Health Organization. The primary outcome measure was the medicine prescription rate per 1,000 persons per year (PRPY<sub>1000</sub>).

**Results:** Our main findings were – 403 prescriptions per 1,000 persons per year in the year 2015 -2016 for all dental ailments. Across all ATC level 1 classification, 'Diseases of hard tissues' made up the majority of the prescriptions. 'Beta-lactam', 'Penicillin', and 'Cephalosporins' were the most commonly prescribed antibiotics for dental diagnoses followed by 'Macrolides' and 'Quinolones'. 'Dental caries', 'Discoloration of tooth', and 'Toothache' were the most common reasons for 'Beta-Lactams' and 'Penicillin' prescriptions.

**Conclusion:** To conclude our study reports first ever country (India) level estimates of antibiotic prescription by antibiotic classes, age groups, and ICD-11 classification for dental ailments.

## Knowledge Transfer Statement

In today's world, combating Antimicrobial Resistance and Antibiotic Stewardship are global aspirations. Ours is the first study which analyses a nationally representative dataset from India and showcases that most antibiotic prescriptions for oral disorders are inappropriate and unnecessary. The paper highlights the need to strengthen our health systems by developing evidence based standard treatment guidelines for oral diseases and build capacity of health professionals for adhering to these guidelines.

## 1.0 Introduction

Although modern medicine with its discovery of drugs (Fleming 1929) and other technological advances has been hailed for significantly reducing mortality and morbidity worldwide, the problem of Antimicrobial Resistance (AMR) has emerged as one of the principal public health problems of the 21st century (Prestinaci et al. 2015). A growing challenge for health systems across the world is the "*Rational Use of Drugs*" which is defined as prescribing of an appropriate dose of medicines according to a patients' clinical diagnosis, well-being, amenability and cost (WHO 2002). In the Nairobi Declaration of 1985 (WHO 1985) rational drug use was identified as a global issue, relevant to both developing and developed countries. In developed countries, health professionals in many countries face the issues of selecting from a multitude of drugs available together with a tidal wave of information, and having to deal with commercial influences from drug promotions. The rational use of drugs has also been discussed by the World Health Organization through "*The International Network for Rational Use of Drugs* (INRUD) (WHO 1989) in 1989; "*Policy Perspectives on Medicines*" (WHO 2002) in 2002; and during the 60th World Health Assembly in 2007 (WHO 2007).

Dental providers are not immune to irrational prescription of drugs including antibiotics (Öcek et al. 2008; Poveda Roda et al. 2007; Stein et al. 2018; Yingling et al. 2002). India is considered to be a major consumer of antibiotics in the world, and this appears to be expanding further (Farooqui et al. 2019). Although several studies highlight the prescription practices of doctors in India (Balamurugan and Ganesh 2011; Dineshkumar et al. 1995; Greenhalgh 1987; Patel et al. 2005; Rishi et al. 2003), studies on dental providers are few, involving either interview data or small-scale surveys, and have limited generalisability across the country (Doshi et al. 2017; Garg et al. 2014; Naveen et al. 2015). In an effort to address this gap, we, therefore, aim to describe the prescription rate of various antibiotics for dental problems in India and then to investigate the appropriateness of the prescriptions by analysing antibiotic type associated with a range of dental diagnoses, using a large scale nationally representative dataset.

## 2.0 Methods

### 2.2 Data source and Setting

We analysed the IQVIA medical audit data (formerly IMS Health) for a 12-month period (May 2015 to April 2016). These data were collected from a panel comprising of 4600 health professionals from the private allopathic sector selected through a multi-stage stratified random sampling, including General Practitioners e.g. MBBS (Bachelor of Medicine Bachelor of Surgery), Non-MBBS General Practitioners, and other Medical Specialties (Dentists, Paediatricians, Gynaecologists, and others) from 23 metropolitan areas (population more than 1 million), 128 class 1 towns (population more than 100,000) and 1A towns (population less than 100,000) in India. These outpatient data were then extrapolated to reflect the prescription pattern of these professionals. Data relevant to dental diagnoses for the current analysis were extracted from the parent data set.

The IQVIA dataset contains 75 distinct dental diagnoses and 1196 drugs, including combinations of oral solids and liquids. We classified all the drugs prescribed by providers into 14 broad categories according to the Anatomical Therapeutic Chemical (ATC) 2020 (WHO 2021) – Level 1 classification, given by World Health Organisation (WHO), while the remaining unidentified drugs and/or entities were treated as "Others" (Supplementary Table 1). We coded the dental diagnoses based on the International Statistical Classification of Diseases and Related Health Problems, (ICD-11) 11th Revision (WHO 2022). Any diagnoses in the dataset not included in the ICD-11 classification were grouped and labelled as "Not Defined" (Supplementary Table 2). The primary outcome measure was the medicine prescription rate per 1,000 persons per year (PRPY<sub>1000</sub>) that measures the annual utilisation of drugs. We then estimated age-specific, gender-specific, and disease-specific drug prescriptions patterns for the year 2015–2016.

## 2.3 Statistical Analysis

The population estimates were obtained from the report of the technical group on population projections constituted by the National Commission on Population, Government of India (MoHFW 2019). Age-groups were determined by the classification already provided in the medical audit data.

Prescription rate per 1000 persons per year was calculated as below:

$$PRPY_{1000} = \left( \frac{n}{P} \right) * \frac{1000}{t}$$

Where,  $PRPY_{1000}$  = Prescription rate per 1000 persons per year

n = number of prescriptions

P = population, t = number of years

All the statistical analyses were performed in STATA (version-13.0, Stata Corp LP) software, Parallel Edition (Stata 2020).

## 3.0 Results

The total number of prescriptions in the year 2015–2016 for all dental ailments was 520,241,570, or 403 prescriptions per 1,000 persons per year. The drugs prescription rates for different age groups '30–39 years,' '40–49 years,' and '50–59 years' were 53.9, 65.5, and 76.6 per 1,000 persons per year, respectively. The highest prescription rate was estimated for the age group '60–64 years' (120.7 per 1,000 persons per year). The prescription rate for 'males' (407.8 per 1,000 persons per year) was found to be marginally higher than that of 'females' (398.4 per 1,000 persons per year), as shown in Table 1. The out-patient antibiotic prescription rate for dentists and/or general practitioners was estimated to be 89.2 per 1,000 persons per year (i.e. 22.1% for the given sample) for various dental diagnoses (Table 2).

Table 1  
Percentage distribution of outpatient drugs prescriptions by patient demographic characteristics in India

Patient demographic characteristic		%	PRPY1000
<b>Age-Group</b>	<b>Total Prescriptions* (in millions)</b>		
0–4 Years	3.2	0.6	<b>2.3</b>
5–9 Years	14.2	2.7	<b>11.9</b>
10–19 Years	25.7	5.0	<b>10.2</b>
20–29 Years	93.1	17.9	<b>40.2</b>
30–39 Years	102.6	19.7	<b>53.9</b>
40–49 Years	100.7	19.4	<b>65.5</b>
50–59 Years	82.5	15.9	<b>76.6</b>
60–64 Years	46.4	8.9	<b>120.7</b>
65+ Years	51.8	10.0	<b>64.8</b>
<b>Gender</b>			
Female	249.7	48.0	<b>398.4</b>
Male	270.5	52.0	<b>407.8</b>
<b>Total</b>	<b>520.2</b>	<b>100</b>	<b>403.2</b>
*Moving Annual Total (MAT)			
* Prescriptions Per 1000 Persons Per Year (PRPY)			

Table 2

Percentage distribution of outpatient drugs prescriptions by Anatomical Therapeutic Chemical (ATC) Classification in India,

Drugs	Total Prescriptions*	%	PRPY 1000
A: Alimentary tract and metabolism	12,83,93,312	24.68	99.51
B: Blood and blood forming organs	33,06,814	0.64	2.56
C: Cardiovascular system	1,20,301	0.02	0.09
D: Dermatological	9,05,701	0.17	0.70
G:Genito urinary system and sex hormones	2,03,863	0.04	0.16
H:Systemic hormonal preparations excluding sex hormones and insulins	30,79,992	0.59	2.39
J:Anti-infectives for systemic use	11,51,04,511	22.13	89.21
L:Antineoplastic and immunomodulating agents	4,020	0.00	0.00
M:Musculo skeletal system	13,67,02,976	26.28	105.95
N:Nervous system	2,59,01,869	4.98	20.08
P:Antiparasitic products insecticides and repellents	1,63,38,346	3.14	12.66
R:Respiratory system	14,04,604	0.27	1.09
S:Sensory organs	97,256	0.02	0.08
V:Various	48,52,824	0.93	3.76
Not defined	8,38,25,181	16.11	64.97
<b>Total</b>	<b>52,02,41,570</b>	<b>100</b>	<b>403.21</b>
<b>*Moving Annual Total (MAT)</b>			
<b>* Prescriptions Per 1000 Persons Per Year (PRPY 1000)</b>			

Across all ATC level 1 classification, 'Diseases of hard tissues' made up the majority of the prescriptions. For antibiotics (J), the highest prescriptions were dispensed for 'Disease of hard tissues of teeth' (39.9%), 'Disease of Pulp or periapical tissues' (26.6%), 'Certain specified orders of teeth and support structures' (14%) and 'Periodontal diseases' (9.2%). A significant percentage of 'Systemic hormonal preparations excluding sex hormones and insulins' (H) was prescribed for 'Diseases of the hard tissues' (36.5). Similarly, medications for 'Blood and Blood forming organs' (B) was prescribed for 'Certain specified disorders of teeth or supporting structures' (40.25%) as shown in Fig. 1.

'Beta-Lactams' and 'Penicillin' were particularly used for categories 'Diseases of hard tissues of teeth' (60.4%) and 'Disorders of tooth development or eruption' (61.4%), shown in (Table 3).

Table 3  
Percentage distribution of diagnosis (ICD11) by ATC (J: Anti-infective for systemic use) classification, (2015–2016)

<b>J:Antiinfectives for systemic use</b>									
<b>ICD-11 Classification</b>	<b>Tetracycline</b>	<b>Amphenicols</b>	<b>Beta-Lactams, Penicillin</b>	<b>Beta-Lactams, Cephalosporins</b>	<b>Sulfonamides &amp; Trimethoprim</b>	<b>Macrolides &amp; Lincosamides</b>	<b>Aminoglycosides</b>	<b>Quinolones</b>	<b>Otr</b>
Diseases of hard tissues of teeth	2.70	0.00	60.49	25.32	0.06	2.65	0.00	0.05	8.7
Diseases of pulp or periapical tissues	2.65	0.00	55.37	32.78	0.24	4.10	0.00	0.05	4.8
Certain specified disorders of teeth or supporting structures	3.12	0.00	58.66	27.33	0.18	2.89	0.00	0.14	7.6
Gingival diseases	16.71	0.01	46.58	24.85	0.77	4.58	0.00	0.02	6.4
Periodontal disease	10.74	0.00	51.10	26.64	0.29	4.09	0.00	0.15	6.9
Certain specified disorders of gingival or edentulous alveolar ridge	1.38	0.00	59.02	32.18	0.00	3.62	0.00	0.01	3.7
Fracture of skull or facial bones	1.16	0.00	49.62	22.23	0.01	4.57	0.00	0.08	22.
Disorders of tooth development or eruption	2.54	0.00	61.46	28.83	0.02	2.35	0.00	0.07	4.7
Others	6.33	0.06	32.12	39.65	0.58	8.47	0.06	0.62	12.
<b>Total</b>	<b>43,45,775</b>	<b>3,048</b>	<b>6,55,24,003</b>	<b>3,26,26,556</b>	<b>1,95,952</b>	<b>39,46,464</b>	<b>952</b>	<b>91,038</b>	<b>83,</b>

Whereas 'Beta-lactam', 'Penicillin,' and 'Cephalosporins' were the most commonly prescribed antibiotics for dental diagnoses followed by 'Macrolides' and 'Quinolones' (Table 4). On the other hand, the antimicrobials 'Beta-Lactams' and 'Cephalosporins' were the most commonly used prescriptions for 'Diseases of pulp or periapical tissues' (32.7%) (Table 3). 'Tetracyclines' were also found to be prescribed for 'Disorders of tooth development or eruption' (2.5%), 'Discoloration of teeth' (12.8%), and 'Abrasion' (7.5%), as shown in (Table 3 and Table 4). More detailed breakdown of larger categories of dental diagnosis showed that 'Dental caries' (60.3%), 'Discoloration of tooth' (61.2), and 'Toothache' (51.0%), were the most common reasons for 'Beta-Lactams' and 'Penicillin' prescriptions.

Table 4  
Percentage distribution of antibiotic prescriptions by top 15 dental diagnoses in India

Dental Diagnoses	Tetracycline	Amphenicols	Beta-Lactams, Penicillin	Beta-Lactams, Cephalosporins	Sulphonamides & Trimethoprim	Macrolides and Lincosamides	Aminoglycosides	Quinolones	Others
Abrasion of teeth	7.45	0.00	58.09	28.36	0.00	2.51	0.00	0.03	3.57
Dental abscess	2.35	0.00	54.16	34.13	0.17	3.66	0.00	0.05	5.64
Gingivitis	17.43	0.01	45.91	24.89	0.76	4.57	0.00	0.02	6.41
Periodontitis	7.76	0.00	54.77	27.25	0.21	3.70	0.00	0.11	6.96
Pulpitis	2.00	0.00	58.16	32.39	0.01	3.93	0.00	0.00	3.59
Others	6.21	0.04	39.59	37.25	0.28	5.41	0.01	0.48	10.27
Root canal	2.89	0.00	57.27	30.61	0.35	4.01	0.00	0.07	4.89
Dental caries	2.01	0.00	60.31	25.45	0.06	2.74	0.00	0.05	9.47
Oral prophylaxis	17.16	0.00	50.21	20.34	0.09	4.06	0.00	0.19	7.35
Fracture of tooth	1.16	0.00	49.62	22.23	0.01	4.57	0.00	0.08	22.43
Extraction	2.69	0.00	59.74	27.24	0.13	3.15	0.00	0.14	6.05
OSMF/ leucoplakia	7.76	0.00	29.16	39.44	1.24	9.66	0.29	0.45	12.70
Toothache	4.61	0.01	50.99	31.27	0.39	2.04	0.00	0.04	10.35
Discoloration tooth	12.79	0.00	61.15	17.76	0.05	2.42	0.00	0.00	5.91
Loss of teeth	2.92	0.00	73.47	19.72	0.13	2.41	0.00	0.00	1.76
<b>Total</b>	<b>4,345,775</b>	<b>3,048</b>	<b>65,524,003</b>	<b>32,626,556</b>	<b>195,952</b>	<b>3,946,464</b>	<b>952</b>	<b>91,038</b>	<b>8,341</b>

## 4.0 Discussion

To the best of our knowledge, this is the first study using a nationally representative dataset to evaluate the estimates of outpatient antibiotic prescription rates for dental ailments and patterns with antibiotic prescription rates across age groups by diagnosis (ICD-11 classification) and antibiotic classification (ATC classification) in India. Our estimated antibiotic prescription rate for dental ailments was approximated to be 89.21 prescriptions per 1,000 persons per year which is much higher than the prescription rate of 77.5 prescriptions per 1,000 persons for the United States (Roberts et al. 2017). The results also suggest that most antibiotics prescribed for infection prophylaxis in dental ailments in India are irrational – a finding consistent with findings from other countries (Poveda Roda et al. 2007; Suda et al. 2019).

The overall prescription rate of antibiotics for any ailment in India was estimated to be 412 prescriptions per 1,000 persons per year, in a previous study published in 2019 using the same dataset (Farooqui et al. 2019). The estimates are much less compared to the UK (555 prescriptions per 1,000 persons) (Holstiege et al. 2014) and Greece (1,100 antibiotics per 1000 person) (Kourlaba et al. 2015).

Excessive prescription of antibiotics for dental ailments in India is problematic for several reasons. Firstly, most oral health conditions commonly leading to pain, abscess formation, and/or tooth loss (Hescot 2015) can be successfully treated with clinical intervention rather than antibiotics (Öcek et al. 2008; Palmer et al. 2000; Yingling et al. 2002). Secondly, most practitioners do not know the type of micro-organism present in the suppuration, so their prescriptions lack specificity and are based on assumptions (Poveda Roda et al. 2007). The situation regarding the irrational use of antibiotics in India is not usual, as shown in previous reviews showing dentists prescribe a wide variety of antibiotics for various clinical and non-clinical indications (Dar-Odeh et al. 2010; Stein et al. 2018). Our study also shows that Indian practitioners commonly prescribe antibiotics such as Tetracyclines (J01A) for disorders of tooth development or eruption, which can accumulate in the developing teeth and bone, with side effects such as discoloration of teeth at an early age. Other side effects such as gastro-intestinal, haematological, neurological, dermatological, and allergic reactions are also associated with such irrational antibiotic use.

Within national guidelines governing the use of antibiotics in India, oral health applications are not mentioned in any of the national guidelines such as the National Policy for Containment of Antimicrobial Resistance, Establishment of the National Programme on AMR Containment under the Twelfth Five Year Plan (2012–2017) (Government of India 2013; MoHFW 2010; 2017), National Action Plan for Anti-Microbial Resistance in India and the Treatment Guidelines for Antimicrobial Use in Common Syndromes (ICMR) (ICMR 2017).

There is a lack of a comprehensive standard treatment prescription guidelines for oral diseases in India. The current standard treatment guideline for oral health in India was last released in 2010 (MoHFW 2010), which focuses on only the two most common dental ailments; Dental Caries and Periodontitis (Supplementary Table 3). These guidelines recommend that 'Beta-lactam,' its derivatives (Amoxicillin), and analgesics (Brufen and Paracetamol) are the

antibiotics of choice for common dental ailments. The guideline, however, fails to elaborate on other dental conditions. Rationally, conditions like pulpitis with moderate or severe symptoms with/without acute periodontitis do not require antibiotic coverage (Agnihotry et al. 2019). However, in our study, 58.16% of prescriptions had Beta-Lactams, Penicillin for the said diagnosis. Similarly, diagnoses such as toothache, discoloration tooth, halitosis were also treated with Beta-Lactams, Penicillin (J01C) and Beta-Lactams, Cephalosporins (J01D).

To summarize, the current study identifies the current state of antibiotic prescribing practices among health professionals. The paper highlights the need to develop a health-care workforce that displays a deeper range of skills, better understanding of AMR, and greater attention to evidence base practices.

#### **Strengths and Limitations:**

To the best of our knowledge, this is the first study to evaluate the estimates of outpatient antibiotic prescription rates for dental ailments and patterns with antibiotic prescription rates across age groups by diagnosis (ICD-11 classification) and antibiotic classification (ATC classification) in India. The data used in the presented study has some inherent limitations. The diagnosis available in the data set was not charted to ICD 11 classification. Therefore, manual coding based on available diagnosis may have led to certain inaccuracies in the allocation of codes. The data collected was based on the panel stockist's data, with inherent limitations such as lack of motivation of recording the data and its validation. The analysis had to rely on the total project population taken from the National Commission on Population to determine prescription rates. Using prescription rates also ignored many factors that play a role in the outcome, such as the underlying condition of the patient; how sick the patient was; and the length of time of the measurement. We also had limited information on whether the prescriptions for the data set "Oral Cavity" were explicitly written only by a Dental Practitioner and not by any other General Practitioner.

## **5.0 Conclusion**

Through our analysis of a nationally representative dataset, we have highlighted the irrational use of antibiotics for oral diseases in India. The impact of irrational use of antibiotics is constantly increasing the burden of the disease with antibiotic resistance, drug dependence, side effects, morbidity, mortality, and financial loss. We need to strengthen our health systems by developing evidence based standard treatment guidelines for oral diseases and build capacity of health professionals for adhering to these guidelines. Further research is also needed to understand the factors (both from the prescriber as well as the consumer perspective) that promote antibiotic prescriptions by health professionals for oral diseases and whether antibiotics are used mainly for urgent care or routine oral health care. Integrating oral health services in overall health systems has been the call for action in the recently global policy discourse and appropriate use of antibiotics for oral diseases is one firm step in this direction.

## **Declarations**

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**Conflicting Interest:** We declare no conflicting interest.

**Availability of Datasets:** The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Author Contributions:** Manu Raj Mathur led the conception, design, data acquisition and interpretation. Led the drafting and critically revision of the manuscript ; Deepti Nagrath contributed to drafting, data analysis and revisions of the manuscript ; Vijay Kumar Mishra performed statistical analyses and contributed to revisions to the manuscript; Rebecca Harris contributed to the discussion section and critical revisions to the manuscript; Syed Saif helped with literature review and drafting of the background and discussion sections; Sakthivel Selvaraj, Aashna Mehta and Habib Hasan Farooqui helped with data acquisition and contributed to conception, design, and critically revisions to the manuscript. All authors gave their final approval and agree to be accountable for all aspects of the work.

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## Figures



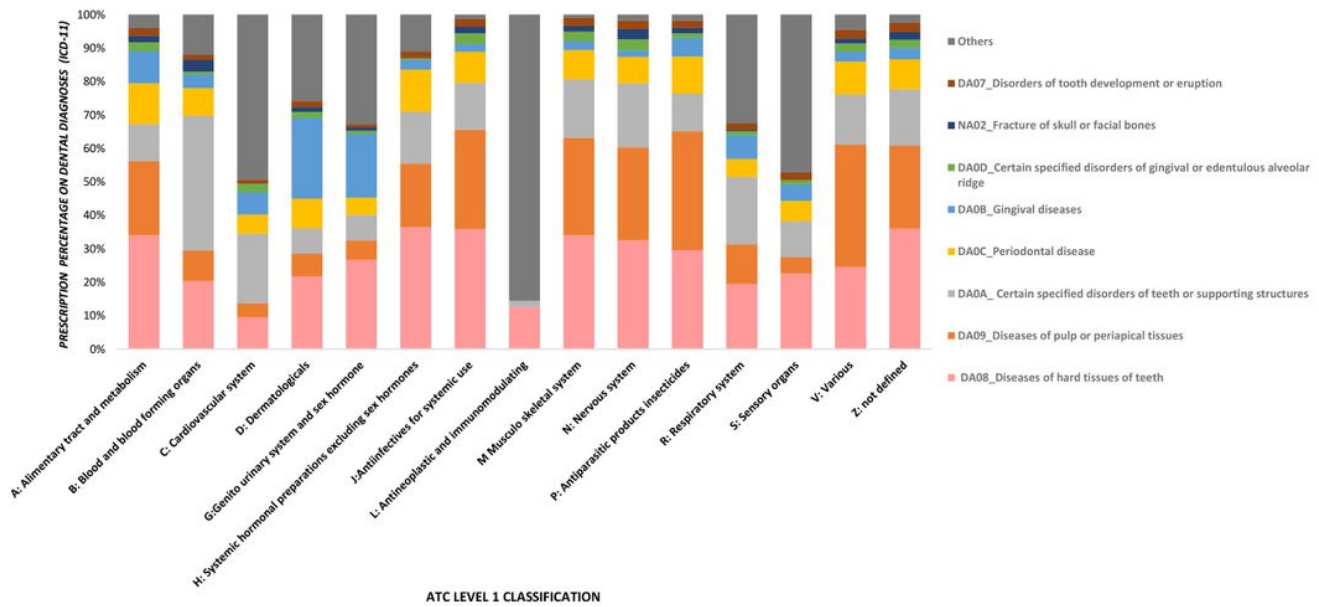


Figure 1

Percentage distribution of diagnosis (ICD 11) by Anatomical Therapeutic Chemical (ATC) Classification

Note: A:Alimentary tract and metabolism, B: Blood and blood forming organs, C:Cardiovascular system, D:Dermatologicals, G:Genito urinary system and sex hormones, H:Systemic hormonal preparations excluding sex hormones and insulins, J:Antiinfectives for systemic use, L:Antineoplastic and immunomodulating agents, M:Musculo skeletal system, N:Nervous system, P:Antiparasitic products insecticides and repellents, R:Respiratory system, S:Sensory organs, V:Various, Z: not defined

## Supplementary Files

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