Public Assessment Report
UKPAR

Doxycycline 50 mg and 100 mg Capsules
(doxycycline hyclate)

UK Licence Nos: PL 30684/0241-2

Dawa Limited
LAY SUMMARY

Doxycycline 50 mg and 100 mg Capsules
(doxycycline hyclate)

This is a summary of the Public Assessment Report (PAR) for Doxycycline 50 mg and 100 mg Capsules (PL 30684/0241-2). For ease of reading, this medicinal product will be referred to as Doxycycline Capsules in the remainder of this Lay Summary.

This summary explains how Doxycycline Capsules were assessed and their authorisations recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

For practical information about using Doxycycline Capsules, patients should read the package leaflet or contact their doctor or pharmacist.

What are Doxycycline Capsules and what are they used for?
Doxycycline Capsules are “generic medicines”. This means that they are similar to ‘reference medicines’ already authorised in the UK called Vibracina 50 mg and 100 mg Capsules (PL 00057/0238 and PL 00057/5059R: Pfizer Limited).

Doxycycline Capsules are used to treat many different types of infections including:
- Chest, lung, or nasal infections e.g. acute worsening of chronic bronchitis, pneumonia, sinusitis
- Urinary tract infections (the passage through which urine passes) e.g. cystitis urethritis
- Acne (a skin condition)
- Eye infection
- Sexually transmitted disease e.g. gonorrhoea, syphilis, chlamydia
- Fevers associated with louse or tick bites
- Malaria, when chlorouine is not effective

Doxycycline Capsules are also used to prevent certain infections developing, these are scrub typhus (a disease carried by small insects) travellers’ diarrhoea, malaria and leptospirosis (a bacterial infection).

A doctor may want the patient to take Doxycycline Capsules to treat another infection not listed above. The patient may also be prescribed an additional medicine to take with Doxycycline Capsules to treat the infection. Patients must talk to a doctor if they do not feel better or if feel worse.

How are Doxycycline Capsules used?
Doxycycline Capsules are taken by mouth. The whole capsule should be swallowed with plenty of water.

It is best to take the capsules at the same time(s) each day, when sitting or while standing. It is important not to lie down for at least thirty minutes after taking Doxycycline Capsules, so that the capsule can move as swiftly as possible into the stomach and prevent irritation of the throat or oesophagus (canal taking food from the mouth to the stomach).

For the treatment of infections, this medicine can be taken with or without food.

For the treatment of acne, it is recommended to take Doxycycline Capsules with food or a drink.

If Doxycycline Capsules upsets patient’s stomach it is recommended that they take it with food or milk.
The recommended doses are shown in the list below. These are the different doses that a doctor may prescribe depending on the infections being treated.

- **Usual dose (chest, lung or nasal, urinary tract, eye and other infections)** is 200 mg on the first day, then 100 mg daily. The length of treatment is dependent on the infection being treated.

- **Acne**
  50mg daily for 6-12 weeks, with food and a drink.

- **Sexually Transmitted Diseases**
  100mg twice daily for 7-10 days

- **Primary and Secondary Syphilis**
  200mg twice daily for 2 weeks. A doctor will continue to monitor the patient after the treatment has stopped.

- **Fevers associated with louse or tick bites**
  Single dose of 100 mg or 200 mg depending on severity.

- **Treatment of malaria, when chloroquine is not effective**
  200 mg daily for at least 7 days.

- **Prevention of malaria**
  100mg daily from 1-2 days before travelling to a malarial area until 4 weeks after returning.

- **Prevention of scrub typhus**
  Single dose of 200 mg

- **Prevention of travellers’ diarrhoea**
  100mg twice daily on the first day of travel, followed by 100 mg daily throughout the stay in the area. If the patient is planning to take these capsules for more than 21 days he/she must consult a doctor.

- **Prevention of leptospirosis**
  20 mg once each week during the stay in the area; 200mg on completion of the trip. If the patient is planning to take these capsules for more than 21 days he/she must consult a doctor.

The patient must start to feel better within a few days. If the patient is given Doxycycline capsules for acne it may be a few weeks before he/she starts to see an improvement. If the infection gets worse or the patient do not start feeling better within a few days (except for acne), or a new infection develops, the patient should go back and see a doctor.

**Children aged 8 years to less than 12 years:**
Doxycycline for the treatment of acute infections in children aged 8 years to less than 12 should be used in situations where other drugs are not available or are not likely to be effective. In such circumstances, the usual doses are:

**For children 45 kg or less:**
First day: 4.4 mg for each kg of body weight (in single or 2 divided doses) then 2.2 mg for each kg of body weight (in single or 2 divided doses) from the second day. The length of treatment is dependent on the infection being treated. In more severe infections, up to 4.4 mg for each kg of body weight should be given throughout treatment.
For children, over 45 kg – Dose administered for adults should be used:
200 mg on the first day, then 100 mg daily. The length of the treatment is dependent on the infection being treated.

Adults and children aged 12 years to less than 18 years:
200 mg on the first day, then 100 mg daily. The length of treatment is dependent on the infection being treated.

This medicine can only be obtained on prescription from a doctor.

For further information on how Doxycycline Capsules are used, please see the Summaries of Product Characteristics and package leaflet available on the MHRA website.

How do Doxycycline Capsules work?
Doxycycline Capsules contains the active ingredient doxycycline. Doxycycline is an antibiotic belonging to a group of medicines called tetracyclines. It treats infections by preventing the growth and spread of bacteria. It also treats acne by killing the bacteria that infects pores and decreasing a certain natural oily substance that causes acne.

How have Doxycycline Capsules been studied?
Because Doxycycline Capsules are generic medicines, studies in patients have been limited to tests to determine that they are bioequivalent to the reference medicines, Vibracina 50 mg and 100mg Capsules. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Doxycycline Capsules?
As Doxycycline Capsules are generic medicines of the reference medicines, Vibracina 50 mg and 100 mg Capsules, their benefits and risks are taken as being the same as those for the reference medicines.

Why are Doxycycline Capsules approved?
It was concluded that, in accordance with EU requirements, Doxycycline Capsules have been shown to have comparable quality and to be bioequivalent to Vibracina 50 mg and 100 mg Capsules. Therefore, the view was that, as for the reference products, the benefits outweigh the identified risks.

What measures are being taken to ensure the safe and effective use of Doxycycline Capsules?
A risk management plan has been developed to ensure that Doxycycline Capsules are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics and the package leaflet for Doxycycline Capsules, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Doxycycline Capsules
Marketing Authorisations were granted in the UK on 1 February 2019.

The full PAR for Doxycycline Capsules follows this summary.

This summary was last updated in March 2019.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th></th>
<th>Introduction</th>
<th>Page 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>II</td>
<td>Quality aspects</td>
<td>Page 8</td>
</tr>
<tr>
<td>III</td>
<td>Non-clinical aspects</td>
<td>Page 9</td>
</tr>
<tr>
<td>IV</td>
<td>Clinical aspects</td>
<td>Page 10</td>
</tr>
<tr>
<td>V</td>
<td>User consultation</td>
<td>Page 12</td>
</tr>
<tr>
<td>VI</td>
<td>Overall conclusion, benefit/risk assessment and recommendation</td>
<td>Page 12</td>
</tr>
</tbody>
</table>

Table of content of the PAR update | Page 35
I INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Dawa Limited, Marketing Authorisations for the medicinal products Doxycycline 50 mg and 100 mg Capsules (PL 30684/0241-2) on 1 February 2019. These products are prescription-only medicines (POM).

Doxycycline Capsules has been found clinically effective in the treatment of a variety of infections caused by susceptible strains of Gram-positive and Gram-negative bacteria and certain other microorganisms.

**Respiratory tract infections** Pneumonia, acute exacerbation of chronic bronchitis, sinusitis.

**Urinary tract infections** caused by susceptible strains of Klebsiella species, Enterobacter species, *Escherichia coli, Streptococcus faecalis* and other organisms.

**Sexually transmitted diseases** Infections due to *Chlamydia trachomatis* including uncomplicated urethral, endocervical or rectal infections. Non-gonococcal urethritis caused by *Ureaplasma urealyticum* (T-mycoplasma). Doxycycline Capsules is also indicated in chancroid, granuloma inguinale and lymphogranuloma venereum. Doxycycline Capsules is an alternative drug in the treatment of gonorrhoea and syphilis.

**Skin infections** Acne vulgaris, when antibiotic therapy is considered necessary.

Since Doxycycline is a member of the tetracycline series of antibiotics, it may be expected to be useful in the treatment of infections which respond to other tetracyclines, such as:

**Ophthalmic infections** Due to susceptible strains of gonococci, staphylococci and *Haemophilus influenzae*. Trachoma, although the infectious agent, as judged by immunofluorescence, is not always eliminated. Inclusion conjunctivitis may be treated with oral Doxycycline Capsules alone or in combination with topical agents.

**Rickettsial infections** Rocky Mountain spotted fever, typhus group, Q fever, *Coxiella endocarditis* and tick fevers.

**Other infections** Psittacosis, brucellosis (in combination with streptomycin), cholera, bubonic plague, louse and tick-borne relapsing fever, tularaemia glands, melioidosis, chloroquine-resistant falciparum malaria and acute intestinal amoebiasis (as an adjunct to amoebicides).

Doxycycline Capsules is an alternative drug in the treatment of leptospirosis, gas gangrene and tetanus.

Doxycycline Capsules is indicated for prophylaxis in the following conditions: Scrub typhus, travellers’ diarrhoea (enterotoxigenic *Escherichia coli*), leptospirosis and malaria. Prophylaxis of malaria should be used in accordance to current guidelines, as resistance is an ever changing problem.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

These applications were submitted as abridged national applications, according to Article 10(1) of Directive 2001/83/EC, as amended, claiming to be generic medicinal products. The applicant has cross-referred to Vibramycin 50mg Capsules and Vibramycin 100mg Capsules, which were originally authorised to Pfizer Limited (PL 00057/0238 and PL 00057/5059R) on 18 December 1984.
October 1990. The reference product used to which bioequivalence has been demonstrated by bioavailability studies, is Vibracina 100mg Capsules (Invicta Farma S.A. Group Pfizer, Spain).

Doxycycline is primarily bacteriostatic and is believed to exert its antimicrobial effect by the inhibition of protein synthesis. Doxycycline is active against a wide range of Gram-positive and Gram-negative bacteria and certain other micro-organisms.

No new non-clinical studies were conducted, which is acceptable given that these applications were based on being generic medicinal products of originator products that have been licensed for over 10 years.

A major objection was raised relating to the bioequivalence of the proposed product with the reference product. The application was referred to Commission on Human Medicines (CHM) on 19/20 July 2018. The applicant conducted a new BE study with the 100mg strength, and bioequivalence of this formulation with the reference product was accepted. The criteria for the biowaiver are met, the study results can be extrapolated to the 50 mg strength.

This study compared the applicant’s test product, Doxycycline 100mg capsules, and the reference formulation Vibracina 100mg Capsules (Invicta Farma S.A. Group Pfizer, Spain) in normal healthy, adult, human subjects under fasting conditions. The applicant has stated that the bioequivalence study was carried out in accordance with Good Clinical Practice (GCP).

With the exception of the bioequivalence study, no new clinical data were submitted, which is acceptable given that these applications were based on products being generic medicinal products of the originator products that have been in clinical use for over 10 years.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product type at all sites responsible for the manufacturing and assembly of these products. Evidence of compliance with GMP has been provided for the named manufacturing and assembly sites.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications, and these are satisfactory.

No new or unexpected safety concerns arose during the review of information provided by the Marketing Authorisation Holder and it was, therefore, judged that the benefits of taking Doxycycline 50 mg and 100 mg Capsules outweigh the risks and Marketing Authorisations were granted.
II QUALITY ASPECTS

II.1 Introduction
The product is presented as a capsule and contain 50 mg or 100 mg of doxycycline (as hyclate), as active substance. The excipients present are hypromellose, sodium lauryl sulphate, microcrystalline cellulose, magnesium stearate making up the capsule content. The capsule shell is made up of gelatin and titanium dioxide (E171).

All the excipients used in the manufacture of the product comply with their respective European Pharmacopoeia monographs with the exception of gelatin complies with the United States Pharmacopeia (USP). Satisfactory Certificates of Analysis have been provided for all excipients showing compliance with their proposed specifications.

With the exception of gelatin, none of the excipients contain materials of animal or human origin. The suppliers of gelatin have provided Certificates of Suitability from the European Directorate for the Quality of Medicines (EDQM) to show that they are manufactured in-line with current European guidelines concerning the minimising of risk of transmission of Bovine Spongiform Encephalopathy/transmissible Spongiform Encephalopathies (BSE/TSE). Confirmation has also been given that the magnesium stearate used in the capsules is of vegetable origin.

This product does not contain or consist of genetically modified organisms (GMO).

The finished product is packaged either in aluminium- polyvinylchloride (PVC)/ aluminium blister with pack sizes of 8, 10, 14, 20, 28, 30, 50, 56, 60, 84 & 90 Capsules.

Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2 Drug Substance
INN: Doxycycline hyclate
Chemical Name: Hydrochloride hemiethanol hemihydrate of (4S,4aR,5S,5aR,6R,12aS)-4-(dimethylamino)-3,5,10,12,12a- pentahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11,12aoctahydrotetracene- 2-carboxamide.

![Structure of Doxycycline](image)

Molecular formula: C_{22}H_{24}N_{2}O_{8}·HCl·\(\frac{1}{2}\)C_{2}H_{6}O·\(\frac{1}{2}\)H_{2}O
Molecular weight: 512.9 g/mol
Appearance: A yellow, crystalline powder.
Solubility: Freely soluble in water and in methanol, sparingly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides and carbonates.
Doxycycline hyclate is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, doxycycline hyclate, are covered by European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificates of Suitability.

II.3 Medicinal Product
Pharmaceutical development
The objective of the development programme was to formulate a safe, efficacious, capsule containing 50 mg or 100 mg of doxycycline hyclate per capsule, that are generic versions of the reference products Vibracina 50 mg and 100mg Capsules (Pfizer Limited).

Comparative dissolution profiles have been presented for the proposed and reference products.

Manufacture of the products
Satisfactory batch formulae have been provided for the manufacture of the products, together with an appropriate account of the manufacturing processes. The manufacturing processes have been validated at pilot scale batch size and has shown satisfactory results. The manufacturing processes have been validated at production scale and has shown satisfactory results.

Finished Product Specifications
The finished product specifications are acceptable. The test methods have been described and have been adequately validated. Batch data have been provided that complies with the release specification. Certificates of Analysis have been provided for all working standards used.

Stability of the product
Stability studies were performed in accordance with current guidelines on batches of the finished product, packed in the packaging proposed for marketing. The data from the studies support a shelf-life of 3 years, with no special storage conditions.

Suitable post approval stability commitments have been provided.

II.4 Discussion on chemical, pharmaceutical and biological aspects
The grant of Marketing Authorisations is recommended.

III NON-CLINICAL ASPECTS
III.1 Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of doxycycline hyclate are well-known, no new non-clinical studies are required, and none have been provided. An overview based on the literature review is, thus, appropriate.

The applicant’s non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology data.

III.2 Pharmacology
Not applicable for these product type. Refer to section ‘III.1; Introduction’ detailed above.

III.3 Pharmacokinetics
Not applicable for these product type. Refer to section ‘III.1; Introduction’ detailed above.
III.4 Toxicology
Not applicable for these product type. Refer to section ‘III.1; Introduction’ detailed above.

III.5 Environmental Risk Assessment (ERA)
Since Doxycycline 50 mg and 100 mg Capsules are intended for generic substitution, this will not lead to an increase of the environmental exposure. An environmental risk assessment is therefore not deemed necessary.

III.6 Discussion on the non-clinical aspects
No new non-clinical studies were conducted, which is acceptable given that the applications were based on being generic medicinal products of the originator products that have been licensed for over 10 years. There are no objections to the approval of these applications from a non-clinical point of view.

IV CLINICAL ASPECTS

IV.1 Introduction
The clinical pharmacology doxycycline hyclate is well-known. With the exception of data from the bioequivalence study detailed below, no new clinical studies are provided or are required for these applications.

A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of doxycycline hyclate.

Based on the data provided, Doxycycline 50 mg and 100mg capsules can be considered bioequivalent to Vibracina 50 mg and 100mg Capsules (Invicta Farma S.A. Group Pfizer, Spain).

IV.2 Pharmacokinetics
In support of these applications, the Marketing Authorisation holder has submitted the following bioequivalence study under fasting conditions:

STUDY
A randomised, open label, balanced, two treatment, two period, two sequence, single dose, two-way crossover, bioequivalence study of Doxycycline 100mg capsules and Vibracina 100mg Capsules (Invicta Farma S.A. Group Pfizer, Spain) in normal healthy, adult, human subjects under fasting conditions.

A single dose of one capsule of either test product (T) or reference product (R) containing Doxycycline hyclate 100mg were administered orally in each period.

Blood samples were collected before dosing and up to and including 72 hours after drug administration. The study periods were separated by a wash-out period of 14 days.

Results
Bioequivalence results for log-transformed test/reference ratio with 90% Confidence Intervals (N=27)

<table>
<thead>
<tr>
<th>Pharmacokinetic parameters (units)</th>
<th>Geometric Mean Ratio Test/Ref (%)</th>
<th>90% Confidence Intervals</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>LnCmax</td>
<td>98.51</td>
<td>90.25-107.54</td>
<td>19.00</td>
</tr>
<tr>
<td>LnAUC0-72</td>
<td>96.28</td>
<td>91.48-101.34</td>
<td>11.04</td>
</tr>
</tbody>
</table>
Conclusion
The 90% confidence intervals of the test/reference formulations for $C_{\text{max}}$ and AUC(0-72) values lie within the acceptable limits of 80.00% to 125.00%, in line with the ‘Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1/Corr**). Bioequivalence has been shown for the test formulation (Doxycycline 100mg capsules), and the reference formulation Vibracina 100mg Capsules (Invicta Farma S.A. Group Pfizer, Spain) under fasting conditions.

As the 50 mg and 100 mg strength test products meet the biowaiver criteria specified in the current bioequivalence guidance, the results and conclusions of the bioequivalence study with the 100 mg capsule strength can be extrapolated to the 50 mg strength capsule.

IV.3 Pharmacodynamics
No new pharmacodynamics data are required for these applications and none have been submitted.

IV.4 Clinical efficacy
No new clinical efficacy data are required for these applications and none have been submitted.

IV.5 Clinical safety
With the exception of the safety data collected during the bioequivalence study, no new safety data have been provided. No new or unexpected safety issues have arisen from the safety data from the bioequivalence study.

IV.6 Risk Management Plan (RMP)
The Marketing Authorisation holder has submitted an RMP, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Doxycycline 50 mg and 100 mg Capsules.

A summary of safety concerns as approved in the RMP, is listed below:
Routine pharmacovigilance and routine risk minimisation are proposed for all safety concerns.

IV.7 Discussion on the clinical aspects
The grant of Marketing Authorisations is recommended for these applications.

V User consultation
The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC, as amended. The language used for the purpose of user testing the PIL was English. The results show that the package leaflet meets the criteria for readability as set out in the guideline on the readability of the label and package leaflet of medicinal products for human use.

VI Overall conclusion, benefit/risk assessment and recommendation
The quality of the products is acceptable, and no new non-clinical or clinical concerns have been identified. The data provided by the applicant showed that the proposed products are bioequivalent to the authorised reference products. The benefit-risk assessment is, therefore, considered to be positive.
Summary of Product Characteristics, Patient Information Leaflet & Labels
In accordance with Directive 2012/84/EU, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

The current approved labelling is provided below:
Each hard gelatin capsule contains 50 mg of doxycycline (as hydrate).

Keep out of the sight and reach of children.

For oral use only.
Each hard gelatin capsule contains 50mg of doxycycline (as hyclate). Read the package leaflet before use. This medicinal product does not require any special storage conditions. Keep out of the sight and reach of children.
Each hard gelatin capsule contains 50 mg of doxycycline (as hyclate).

Read the package leaflet before use.
This medicinal product does not require any special storage conditions.

Keep out of the sight and reach of children.

30 capsules
Doxycycline 50 mg
Capsules

For oral use only.

Marketing Authorisation Holder:
Dawa Limited,
5 Sandridge Close, Harnas,
Middlesex, HA5 1XD, U.K.

PL 30684/0241
Each hard gelatin capsule contains 50 mg of doxycycline (as hydrite).

Read the package leaflet before use.

This medicinal product does not require any special storage conditions.

Keep out of the sight and reach of children.

50 capsules
Doxycycline 50 mg Capsules

50 capsules
Doxycycline 50 mg Capsules

For oral use only.

Marketing Authorisation Holder:
Dama Ltd, Ltd.,
S Sandefjord Cross, Harrow,
Middlesbrough, TS1 1XG, UK
PL 20484/0241

POM
Each hard gelatin capsule contains 50mg of doxycycline (ashydrate).

Read the package leaflet before use.

This medicinal product does not require any special storage conditions.

Keep out of the sight and reach of children.

For oral use only.

Marketing Authorisation Holder:
DAWA Limited,
2 Grandridge Close, Harrow,
Middlesex, HA2 8HD, UK
Ph: 0208906241
Each hard gelatin capsule contains 100 mg of doxycycline (as tetracycline).

Read the package leaflet before use.

This medicinal product does not require any special storage conditions.

Keep out of the sight and reach of children.

8 capsules
Doxycycline 100 mg Capsules

For oral use only

Marketing Authorization Holder: Dawa Limited,
5 Sandridge Close, Harrow,
Middlesex, HA1 1XD, UK
PL 30684/0242

POM
Each hard gelatin capsule contains 100mg of doxycycline (as hyclate).

Read the package leaflet before use.
This medicinal product does not require any special storage conditions.

Keep out of the sight and reach of children.
Each hard gelatin capsule contains 100mg of doxycycline (as hydrate).

Read the package leaflet before use. This medicinal product does not require any special storage conditions. Keep out of the sight and reach of children.

20 capsules
Doxycycline 100 mg Capsules
For oral use only

Marketing Authorization Holder: Dawa Limited, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD, UK
PL 30684/0242

POM

50301114524225
Each hard gelatin capsule contains 100mg of doxycycline (as hydolate).
Read the package leaflet before use.
This medicinal product does not require any special storage conditions.
Keep out of the sight and reach of children.

28 capsules
Doxycycline 100 mg Capsules

For oral use only

Marketing Authorisation Holder: Dawa Limited,
5 Sandridge Close, Harrow,
Middlesex, HA1 1XO, UK
PL 30684/0242
POM
Each hard gelatin capsule contains 100mg of doxycycline (as hyclate).
Read the package leaflet before use.
This medicinal product does not require any special storage conditions.
Keep out of the sight and reach of children.

56 capsules
Doxycycline 100 mg
Capsules
For oral use only

Marketing Authorisation Holder: Dawa Limited,
5 Sandridge Close, Hatfield,
Middlesex, HA3 1XD, UK
PL 30684/024.2
POM
Each hard gelatin capsule contains 100mg of doxycycline (as hyclate).
Read the package leaflet before use.
This medicinal product does not require any special storage conditions.
Keep out of the sight and reach of children.
Each hard gelatin capsule contains 100mg of doxycycline (as hydrous).
Read the package leaflet before use.
This medicinal product does not require any special storage conditions.
Keep out of the sight and reach of children.

84 capsules
Doxycycline 100 mg Capsules
For oral use only

Marketing Authorization Holder: Dawa Limited, 1, Sainsbury Close, Hemel Hempstead, Hertfordshire, HP1 3DQ, UK
PL 30684/242
POM
Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitment)

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>