SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name	:	**Doxyleb Capsule**
1.2 Generic Name	:	Doxycycline Capsules BP 100 mg
1.3 Strength	:	Doxycycline 100mg/cap.
1.4 Pharmaceutical Form	:	Capsule

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each hard gelatin capsule contains:

Doxycycline Hyclate	BP
eq. to anhydrous Doxycycline	100 mg.
Approved colors used in the shell	

3. PHARMACEUTICAL FORM

Capsule

Green/Green colored hard gelatin intact capsule of Size “3”.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Doxyleb Capsule (Doxycycline) is indicated in Susceptible infections (e.g. chlamydia, rickettsia, and mycoplasma), Acne, Rosacea, Early syphilis, Late latent syphilis, Neurosyphilis, Uncomplicated genital chlamydia, Non-gonococcal urethritis, Pelvic inflammatory disease, Lyme disease, Anthrax (treatment or post-exposure prophylaxis), Prophylaxis of malaria, Adjunct to quinine in the treatment of Plasmodium falciparum malaria.

4.2 Posology and method of administration

- **Susceptible infections (e.g. chlamydia, rickettsia, and mycoplasma):**
  Child 12–17 years: Initially 200 mg daily for 1 dose, then 100 mg daily; 200 mg daily, the increased dose used for severe infections including refractory urinary-tract infections. **Adult:** Initially 200 mg daily for 1 dose, then 100 mg daily; 200 mg daily, the increased dose used for severe infections including refractory urinary-tract infections.
- **Acne:**
  Child 12–17 years: 100 mg daily. Adult: 100 mg daily.
- **Rosacea:**
  Adult: 100 mg daily
- **Early syphilis:**
  Child 12–17 years: 100 mg twice daily for 14 days. **Adult:** 100 mg twice daily for 14 days.
- **Late latent syphilis:**
  Child 12–17 years: 100 mg twice daily for 28 days. **Adult:** 100 mg twice daily for 28 days.
- **Neurosyphilis:**
  Adult: 200 mg twice daily for 28 days.
- **Uncomplicated genital Chlamydia, Non-gonococcal urethritis:**
  Child 12–17 years: 100 mg twice daily for 7 days. **Adult:** 100 mg twice daily for 7 days.
- **Pelvic inflammatory disease:**
  Child 12–17 years: 100 mg twice daily for 14 days. **Adult:** 100 mg twice daily for 14 days.
- **Lyme disease:**
  Child 12–17 years: 100 mg twice daily for 10–14 days (for 28 days in Lyme arthritis). **Adult:** 100 mg twice daily for 10–14 days (for 28 days in Lyme arthritis).
- **Anthrax (treatment or post-exposure prophylaxis)**:
  Child 12–17 years: 100 mg twice daily. **Adult:** 100 mg twice daily.
- **Prophylaxis of malaria:**
  Child 12–17 years: 100 mg once daily, to be started 1–2 days before entering the endemic area and continued for 4 weeks after leaving, can be used for up to 2 years. **Adult:** 100 mg once daily, to be started 1–2 days before entering the endemic area and continued for 4 weeks after leaving, can be used for up to 2 years.
- **Adjunct to quinine in the treatment of Plasmodium falciparum malaria:**
  Child 12–17 years: 200 mg daily for 7 days. **Adult:** 200 mg daily for 7 days.

4.3 Contraindications

Doxycycline is contraindicated in patients who have shown hypersensitivity to doxycycline or any tetracyclines. Doxycycline is contraindicated in children under the age of 12 years (deposition in growing bone and teeth, by binding to calcium, causes staining and occasionally dental hypoplasia).

4.4 Special warnings and special precautions for use:

Doxycycline should be used with caution in patients with Myasthenia gravis (muscle weakness may be increased), Systemic lupus erythematosus (may be exacerbated). Alcohol may decrease the half-life of doxycycline. Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines, including doxycycline.

4.5 Interaction with other FPPs and Other forms of Interaction

Carbamazepine, Fosphenytoin, Phenobarbital accelerates the metabolism of Doxycycline. Dairy products reduce the absorption of Tetracyclines (except Doxycycline), increase the risk of Methotrexate toxicity when given with Doxycycline. The absorption of Doxycycline may be impaired by concurrently administered antacids containing aluminum, calcium, magnesium, or other drugs containing these cations; oral zinc, iron salts, or bismuth preparations. Dosages should be maximally separated.

4.6 Pregnancy and lactation

When travel to malarious areas is unavoidable during pregnancy, Doxycycline can be used for malaria prophylaxis if other regimens are unsuitable, and if the entire course of Doxycycline can be completed before 15 weeks gestation. Tetracyclines should not be given to pregnant women; effects on skeletal development have been documented in the first trimester in animal studies. Administration during the second or third trimester may cause discoloration of the child's teeth, and maternal hepatotoxicity has been reported with large parenteral doses. Tetracyclines should not be given to women who are breastfeeding (although absorption and therefore discoloration of teeth in the infant is probably usually prevented by chelation with calcium in milk).

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Doxycycline may show anorexia, anxiety, dry mouth, flushing, fungal superinfection (when used for periodontitis), and tinnitus. Tetracycline rarely shows anaphylaxis, angioedema, blood disorders exfoliative dermatitis, hepatotoxicity, hypersensitivity, reactions, pancreatitis, pericarditis, photosensitivity (particularly with demeclocycline), rash, Stevens-Johnson syndrome, urticaria & Benign intracranial hypertension.

4.9 Overdose

Acute overdosage with antibiotics is rare. In the event of overdosage discontinue the medication. Gastric lavage plus appropriate supportive treatment is indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterial

Mechanism of action:

Doxycycline is lipophilic and can pass through the lipid bilayer of bacteria. It reversibly binds to the 30S ribosomal subunits and possibly the 50S ribosomal subunit, blocking the binding of aminoacyl tRNA to the mRNA and inhibiting bacterial protein synthesis.

5.2 Pharmacokinetic properties

Doxycycline is completely absorbed after oral administration. Absorption is rapid (effective concentrations are attained from the first hour), and the peak serum concentration occurs after 2 to 4 hours. It shows >90% of protein binding. They are concentrated by the liver in the bile and excreted in the urine and faeces at high concentrations in a biologically active form.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Starch (Maize)	BP
02.	Lactose	BP
03.	Purified Talc (Talcum)	BP
04.	Magnesium Stearate	BP
05.	E. H. G. Capsule Size “3” Green/Green	IH

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Protect from light. Keep away from moisture. Keep out of reach of children. Keep container tightly closed. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of a container

10 blisters of 10 capsules packed in an inner carton. (10’s x 10)

1000 capsules packed in a white-colored HDPE jar. (1000’s).

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER
AMD/12/2002 & AMD/6/2002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
a) Date of first authorization: 21/01/1989.
b) Date of latest renewal: 01/01/2018.

10. DATE OF REVISION OF THE TEXT
01/01/2023