1. WHAT DOXYCYCLINE IS AND WHAT IT IS USED FOR

Doxycycline belongs to a group of medicines called tetracycline antibiotics. It is also known as a broad-spectrum antibiotic and may be used to treat a wide range of infections caused by bacteria, these include:

- Respiratory tract infections.
- Urinary tract infections.
- Sexually transmitted diseases.
- Skin infections such as Acne.
- Infections of the eye.
- Infections of the ear.
- Bacterial infections such as Clostridium.
- Periodontal and gingival infections.

Doxycycline capsules are not recommended for use in children under 12 years of age as it can cause permanent discoloration of tooth enamel and affect bone development.

Children and adolescents

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Doxycycline capsules contain the colouring agent sunset yellow (E110) which may cause allergic reactions.

Important information about some of the ingredients of Doxycycline

- If you are allergic to doxycycline, other similar antibiotic (such as minocycline or tetracycline) or any of the other ingredients of this medicine or any of the other listed ingredients.
- If you have any further questions, ask your doctor or pharmacist.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOXYCYCLINE

• Travellers diarrhoea - 200mg on the first day of travel followed by 100mg a day throughout the duration of the stay.
• Prevent infection with scrub typhus - 200mg as a single dose.
• Malaria - 200mg a day for at least 7 days, should be given with other drugs such as quinine.
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4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the capsules immediately and seek urgent medical advice if:

- you notice that your skin is very sensitive to light (you may get a skin rash, itching, redness or severe sunburn when out in sunlight or after using a sun bed).

Contact your doctor at once if the following reaction happens:

- swollen tongue, watery diarrhoea, fever and cramps (pseudo-diarrhoea/nontyphoidal colitis), soreness and itching around the tongue and/or of the gullet and/or the mouth.

• signs of inflamed skin (erythema multiforme) (reddening, peeling and swelling that resembles burns).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed.

- Glucose and hormones: dissociation of thyroid tissue (does not affect thyroid function).

- Central nervous system: headache, increased pressure in the skull (severe headaches, blurred and/or double vision, loss of vision, permanent loss of vision, bulging fontanelles (soft spot on head) in infants.

- Gastrointestinal tract: stomach pain, loss of appetite, feeling or being sick, heartburn, diarrhoea, difficulty in swallowing, sore or painful tongue or mouth, inflammation and/or ulcers of the gullet, discoloration and underdevelopment of teeth.

- Liver: changes in liver function tests.

- Skin: detachment of the nail from the nail bed.

- Muscles and bones: muscle or joint pain.

- Kidneys: an increase in urea in the blood.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOXYCYCLINE

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions. Do not use Doxycycline after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Doxycycline contains

• The active substance (the ingredient that makes the capsule work) is doxycycline hyclate. Each Doxycycline 50 mg Capsule contains 50 mg of the active substance doxycycline.

• The other ingredients are microcrystalline cellulose, talc, magnesium stearate, colloidal anhydrous silica and sodium lauryl sulphate. The capsule shell is made of gelatin. The colouring agents used in the capsule shell are titanium dioxide (E171), quinoline yellow (E104) and sunset yellow (E110).

• The active substance (the ingredient that makes the capsule work) is doxycycline hyclate. Each Doxycycline 100 mg Capsule contains 100 mg of the active substance doxycycline.

• The other ingredients are microcrystalline cellulose, talc, magnesium stearate, colloidal anhydrous silica and sodium lauryl sulphate. The capsule shell is made of gelatin. The colouring agents used in the capsule shell are titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132).

What Doxycycline looks like and the contents of the pack

Doxycycline 50 mg Capsules are white and yellow.

They are available in the following pack sizes: 8, 16 and 28 capsules. Not all pack sizes may be marketed.

Doxycycline 100 mg Capsules are white and blue.

They are available in the following pack sizes: 8, 16, 28 and 50 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder and manufacturer is Chernelle Medical, Loughrea, Co. Galway, Ireland.

The distributor is Chernelle Medical U.K., Ltd.

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