

INFORMATION FOR THE PATIENT

Please read this leaflet carefully before you use this medication. This leaflet provides some useful information for you on DOXYTAB (doxycycline hyclate). If you have any questions about this medication or your condition, please ask your doctor or pharmacist.

REMEMBER: This medication is for YOU. Never give it to others. It may harm them even if their symptoms are the same as yours.

What is DOXYTAB?

The name of this medication is DOXYTAB. Each tablet (DOXYTAB) contains 100 mg of the active ingredient doxycycline (as hyclate). Each tablet also contains the inactive ingredients microcrystalline cellulose, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide, FD&C Yellow No. 6, purified water, and carnauba wax.

DOXYTAB are available as light orange, round, biconvex, film-coated tablet, engraved PRO over 100 on the score side, the other side is plain.

What is DOXYTAB used for?

DOXYTAB may be prescribed by your doctor to treat bacterial infections.

When should DOXYTAB not be used?

Do not take DOXYTAB if:

- You are allergic to DOXYTAB, other tetracyclines, or to any of the inactive ingredients listed at the beginning of this leaflet
- you have myasthenia gravis (a chronic autoimmune neuromuscular disease which cause muscle weakness)

Before taking DOXYTAB

You should tell your doctor if:

- you are pregnant, or planning to become pregnant
- you are breastfeeding your child. DOXYTAB is not recommended in women who are breastfeeding. Tetracycline is excreted in human breastmilk.
- DOXYTAB is prescribed for a child, and your child is under 8 years old. DOXYTAB is not recommended for children under 8 years of age.
- you have or have had any other health problems especially:
 - you have difficulty swallowing, or medical conditions such as the narrowing or obstruction of your esophagus (passage from your mouth to stomach)
 - you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket, or health food store.

Taking DOXYTAB with other medicines

DOXYTAB should not be taken with alcohol, barbiturates, phenytoin, carbamazepine and methoxyflurane*

* Methoxyflurane is not marketed in Canada

Some medicines and DOXYTAB may interfere with each other and your doctor may wish to change dosage or directions for the following medications or may recommend other medications:

- oral anticoagulants
- penicillin
- bismuth subsalicylate
- antacids containing aluminum, calcium or magnesium reduce DOXYTAB absorption and should not be given to patients taking DOXYTAB
- iron-containing products should be taken at a different time than DOXYTAB
- use of DOXYTAB may reduce the effectiveness of oral contraceptives

How should you take DOXYTAB?

Antibacterial drugs including DOXYTAB should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). Although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by DOXYTAB or other antibacterial drugs in the future.

Follow your doctor's instructions carefully about how much DOXYTAB to take and when to take it.

DOXYTAB should be swallowed, preferably with food.

How long should you take DOXYTAB?

DOXYTAB should be taken with or after a meal. This should be swallowed with a full glass of water to avoid potential irritation or ulceration of the esophagus (passage from mouth to stomach). Remain in an upright position for a time and do not go to bed right away (at least 1-2 hours), to avoid direct irritation of the esophagus.

What should you do if you forget to take your medication?

If you should forget to take your tablet or your capsule at the usual time, take it as soon as you remember unless it is time to take the next one. Continue with the remaining doses as before. Do not take more than one dose at a time.

What if you take too many tablets or capsules?

Do not take more tablets or capsules than your doctor has told you to.

If you take too many tablets or capsules by accident, call your doctor, pharmacist, **local poison control centre or hospital emergency department** immediately, even if there are not symptoms.

While taking DOXYTAB

- Follow your doctor's instructions carefully,
- Stop taking DOXYTAB immediately if you become pregnant and consult your doctor.
- Tell your doctor and pharmacist that you are taking DOXYTAB if you are about to start taking any new medicines.
- Do not stop taking your medicine until your doctor tells you to, even if you are feeling better.
- Do not use DOXYTAB to treat any other medical complaints unless your doctor tells you to.

Are there any side effects with DOXYTAB?

DOXYTAB may cause side effects. If they occur, they are likely to be minor and temporary. However, some may be serious and need medical attention. DOXYTAB may cause side effects such as nausea, vomiting, diarrhea, loss of appetite, abdominal pain, pain or difficulty in swallowing, tooth discolouration and rash.

Use of DOXYTAB may increase the incidence of vaginal candidiasis (infection) and benign intracranial hypertension (high blood pressure in the brain).

Sensitivity to sunlight and development of a sunburn reaction have occurred with some individuals taking tetracyclines. If you plan to be exposed to direct sunlight, preventative use of a sunscreen or other physical measures are recommended. Avoid excessive sunlight or artificial ultraviolet exposure. Discontinue use if phototoxicity develops (e.g. skin eruption...).

Tell your doctor or pharmacist right away if you suffer from any of the following side effects while taking this medication:

- if you develop diarrhea, watery diarrhea, bloody stools, with or without stomach cramps and fever, contact your doctor as soon as possible.

Tell your doctor or pharmacist right away, and stop taking DOXYTAB, if you suffer any of the following side effects while taking this medication

- You develop a hypersensitivity (allergic) reaction which may include symptoms such as difficulty in breathing, fast heartbeat, dizziness, itching, rash, and skin blistering .
- You develop symptoms such as swelling of the hands and feet, muscle and joint pain, and rash, as these may be signs of an auto-immune reaction.

Check with your doctor or pharmacist right away if you have any problems while taking DOXYTAB, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

How to store DOXYTAB

Store at room temperature 15-30°C (59-86°F). Protect from Light

You should not use your medication after the expiration date printed on the carton and label.

Keep all medications out of the reach of children. This medication could harm them.

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-Free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-234-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

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