

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

DOXYTAB
Doxycycline Hyclate Tablets USP
100 mg doxycycline (as hyclate)

Read this carefully before you start taking DOXYTAB and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about DOXYTAB.

What is DOXYTAB used for?

- DOXYTAB is used to treat infections caused by germs (bacteria).
- DOXYTAB is **NOT** used to treat viral infections (e.g. the common cold).

How does DOXYTAB work?

- DOXYTAB is an antibiotic. It stops the bacteria's ability to make what it needs to grow new cells. This helps get rid of the infection.

What are the ingredients in DOXYTAB?

Medicinal ingredients:

- DOXYTAB: doxycycline hyclate.

Non-medicinal ingredients:

- DOXYTAB: each tablet contains 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 comes in the following dosage forms:

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

Do not use DOXYTAB if you:

- are allergic to this drug.
- are allergic to any of the ingredients in these products. See also "What are the ingredients in DOXYTAB" above.
- are allergic to tetracycline drugs (a class of antibiotics).
- have myasthenia gravis (a muscle disease).
- are taking isotretinoin (e.g. Accutane). See the next section, "To help avoid side effects and ensure proper use".

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DOXYTAB. Talk about any health conditions or problems you may have, including if you:

- are pregnant or plan to become pregnant.
- are breastfeeding or planning to breastfeed. Some of this drug may pass to your baby.

- DOXYTAB are not recommended for women who are breastfeeding.
- have trouble swallowing.
- have health problems that affect or block the tube that carries food from your mouth to your stomach (esophagus).

DOXYTAB should not be used in children under 8 years of age.

Tetracyclines such as DOXYTAB may cause a serious side effect, benign intracranial hypertension (pressure around the brain) with symptoms such as headache, nausea, vomiting and vision loss. If this occurs, contact your doctor immediately. Do not use DOXYTAB and isotretinoin together as they both can cause this effect.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Do not take DOXYTAB with:

- alcohol.
- barbiturates (drugs that help you sleep).
- phenytoin (a drug that controls epilepsy).
- carbamazepine (a drug that controls epilepsy).
- methoxyflurane (an anaesthetic).

Some drugs can make DOXYTAB not work as well as it should. These include:

- drugs to thin the blood (oral anticoagulants).
- penicilin, a drug to treat infections.
- drugs to treat upset stomach that contain bismuth subsalicylate.
- drugs to treat heartburn that contain aluminum, calcium or magnesium.
- products that contain iron.

Do not take these drugs at the same time of day as DOXYTAB.

Birth control pills may not work if you are on them while taking DOXYTAB. You should use other birth control while taking these products and for 7 days after stopping.

How to take DOXYTAB:

- Take this medicine exactly as your doctor has told you to.
- Do not skip doses.
- Stop taking DOXYTAB right away if you become pregnant.
- Tell your doctor if you become pregnant.
- Do not use DOXYTAB to treat any other medical problems unless your doctor tells you to.
- This medicine has been prescribed for you only. Do not share it with others. It may harm them, even if their symptoms are the same as yours.
- Do not stop taking this medicine until you have taken all of it, even if you feel better.
- Stopping this medicine early may:
 - increase the risk that bacteria will become resistant to it.
 - make this product not work as well in the future.

Usual dose:

- Take your medicine when your doctor tells you.
- Take the amount of medicine your doctor tells you.
- Take your medicine with or after a meal.

- Take your medicine with a glass of water.
- Take your medicine while standing or sitting.
- After taking your medicine, wait at least 1 to 2 hours before lying down.

Overdose:

If you think you have taken too much DOXYTAB, call your doctor, pharmacist, hospital, or Poison Control Centre right away. Do this even if there are no symptoms.

Missed Dose:

- If you forget to take DOXYTAB take it as soon as you remember unless it is time to take the next dose.
- Continue taking the rest of the doses as your doctor has told you to.
- Do not take more than one dose at a time.

What are possible side effects from using DOXYTAB?

These are not all the possible side effects you may feel when taking DOXYTAB. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

Clostridium difficile is a kind of bacteria that can be found in the bowel (gut). It can cause severe diarrhea and bowel inflammation (colitis) for some patients on antibiotics like DOXYTAB. Symptoms are:

- bloody or watery diarrhea with or without fever.
- stomach cramps.
- stomach pain.

If this occurs, stop taking DOXYTAB and contact your healthcare professional right away.

Other side effects that may occur while using DOXYTAB:

- change in tooth colour.
- diarrhea.
- loss of appetite.
- nausea.
- stomach pain.
- vomiting.

If these become bothersome, contact your doctor.

- You may be sensitive to the sun when taking DOXYTAB.
- You could get a sunburn.
- If you will be in direct sunlight protect your skin, use sunscreen.
- Avoid excessive sunlight.
- Avoid tanning beds.
- Stop using DOXYTAB if you become sensitive to the sun. Symptoms of sun sensitivity include rash, blisters or skin break outs.

Serious side effects and what to do about them

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	

UNKNOWN

Pain or difficulty swallowing	√		
Rash	√		
Yeast infection		√	
Hypersensitivity (allergic) reaction. Symptoms are: - difficulty breathing. - fast heartbeat. - dizziness. - itching. - rash. - skin blistering.			√
Autoimmune adverse drug reactions. Symptoms are: - swelling of hands and feet. - muscle and joint pain. - rash.			√
Benign intracranial hypertension (high blood pressure in the brain). Symptoms are: - headache. - nausea. - vomiting. - visual disturbances (e.g. blurred vision, double vision, blank spots).			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program

Health Canada, Postal Locator 0701E Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature 15°C to 30°C. Protect from light

Keep out of reach and sight of children.

If you want more information about DOXYTAB:

- Please contact your doctor, pharmacist or other healthcare professional.
- This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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