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Dispense with Patient Information available at: https://torrentpharma.com/pi/usa/products/

#### PATIENT INFORMATION MINOCYCLINE HYDROCHLORIDE (Mi-no-svk-lin hi-droh-clor-ride) TABLETS, USP 50 mg, 75 mg and 100 mg Rx only

Read the Patient Information that comes with minocycline hydrochloride tablets, USP before you or a family member starts taking it and each time you get a refill. There may be new information. This Patient Information leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

#### What are minocycline hydrochloride tablets, USP?

Minocycline hydrochloride tablets. USP are a tetracycline-class antibiotic medicine. Minocycline hydrochloride tablets, USP are used to treat certain infections caused by bacteria. These include infections of the skin, respiratory tract, urinary tract, some sexually transmitted diseases, and others. Minocycline hydrochloride tablets, USP may be used along with other treatments for severe acne.

Sometimes other germs, called viruses, cause infections. The common cold is a virus. Minocycline hydrochloride tablets, USP, like other antibiotics, does not treat viruses.

#### Who should not take minocycline hydrochloride tablets. USP?

#### Do not take minocycline hydrochloride tablets, USP if you are allergic to minocycline or other tetracycline antibiotics.

Ask your doctor or pharmacist for a list of these medicines if you are not sure. See the end of this Patient Information leaflet for a complete list of ingredients in minocycline hydrochloride tablets, USP.

Minocycline hydrochloride tablets. USP are not recommended for pregnant women or children under 8 years of age because:

- 1. Minocycline hydrochloride tablets, USP may harm an unborn baby.
- 2. Minocycline hydrochloride tablets, USP may permanently turn a baby's or child's teeth vellow-gray-brown durina tooth **development.** Tooth development happens in the last half of pregnancy and birth to age 8 vears.

What should I tell my doctor before taking minocycline hydrochloride tablets, USP? Before taking minocycline hydrochloride tablets, USP tell your doctor about all of your medical conditions, including if you:

have liver or kidney problems.

- are pregnant or plan to become pregnant. Minocycline hydrochloride tablets, USP may harm your unborn baby. Stop taking minocycline hydrochloride tablets. USP and call your doctor if you become pregnant while taking it.
- are breastfeeding or plan to breastfeed. Minocycline passes into your breast milk and may harm your baby. You and your doctor should decide if you will take minocycline hydrochloride tablets, USP or breastfeed. You should not do both.

#### Tell your doctor about all the medicines you take.

including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using minocycline hydrochloride tablets, USP with other medicines can cause side effects.

#### Especially tell your doctor if you take:

- birth control pills. Minocycline hydrochloride tablets. USP may make your birth control pills less effective
- a blood thinner medicine. The dose of your blood thinner may have to be lowered.
- a penicillin antibiotic medicine. Minocycline hydrochloride tablets, USP and penicillins should not be used together.
- migraine medicines called ergot alkaloids.
- an acne medicine by mouth called isotretinoin.
- antacids that contain aluminum, calcium, or magnesium, or iron-containing products.

Know the medicines you take, keep a list of them to show your doctor and pharmacist each time you get a new medicine.

#### How should I take minocycline hydrochloride tablets. USP?

- Take minocycline hydrochloride tablets, USP exactly as your doctor tells you to take them. Skipping doses or not taking all your minocycline hydrochloride tablets, USP may:
- o Decrease the effectiveness of the treatment.
- o Increase the chance that bacteria will develop resistance to minocycline hydrochloride tablets, USP.
- Take minocycline hydrochloride tablets, USP with a full glass of liquid. Taking minocycline hydrochloride tablets, USP with enough liquid may lower your chance of getting irritation or ulcers in your esophagus. Your esophagus is the tube that connects your mouth to your stomach.
- Minocycline hydrochloride tablets, USP may be taken with or without food. If you forget to take minocycline hydrochloride tablets. USP take it as soon as you remember.

If you take too much minocycline hydrochloride tablets. USP. call your doctor or poison control center right away.

#### What are the possible side effects of minocycline hydrochloride tablets. USP?

Minocycline hydrochloride tablets, USP may cause serious side effects. Stop minocycline hydrochloride tablets, USP and call your doctor if vou have:

- watery diarrhea
- bloody stools
- stomach cramps
- unusual headaches
- blurred vision
- fever
- rash
- joint pain
- feeling very tired
- swollen lymph nodes

Minocycline hydrochloride tablets. USP may also cause:

- central nervous system effects. Symptoms include light-headedness, dizziness, and a spinning feeling (vertigo). You should not drive or operate machines if you have these symptoms.
- sun sensitivity (photosensitivity). You may get a worse sunburn with minocycline hydrochloride tablets, USP. Avoid sun exposure and the use of sunlamps or tanning beds. Protect your skin while out in the sunlight. Stop minocycline hydrochloride tablets, USP and call your doctor if your skin turns red.

These are not all the possible side effects of minocycline hydrochloride tablets. USP. For more information ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store minocycline hydrochloride tablets, USP?

- Store minocycline hydrochloride tablets, USP at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep minocycline hydrochloride tablets, USP away from light, moisture, and excess heat.
- Throw away any minocycline hydrochloride tablets, USP that is outdated or no longer needed.
- Keep minocycline hydrochloride tablets, USP and all medicines out of the reach of children.

#### General information about minocycline hydrochloride tablets. USP

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not take minocycline hydrochloride tablets. USP for a condition for which it was not prescribed. Do not give minocycline hydrochloride tablets, USP to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the

most important information about minocycline hydrochloride tablets, USP. If you would like more information, talk with your doctor. You can ask vour doctor or pharmacist for information about minocycline hydrochloride tablets. USP that is written for health care professionals. For more information, you can also call Torrent Pharmaceuticals Inc. at 1-800-912-9561.

### What are the ingredients in minocycline hydrochloride tablets, USP?

Active ingredient: minocycline hydrochloride, USP, 50 mg, 75 mg and 100 mg Inactive ingredients: colloidal silicon dioxide, crospovidone, hypromellose, iron oxide yellow, lactose monohydrate, magnesium stearate, polyethylene glycol 6000, silicified microcrystalline cellulose, stearic acid, and titanium dioxide.

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Manufactured by: Torrent Pharmaceuticals LTD., India.

#### Manufactured for:

Torrent Pharma INC., Basking Ridge, NJ 07920. 8097674

This Patient information has been approved by the U.S. Food and Drug Administration.

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