

## Consumer Medicine Information

# Tiberal<sup>®</sup>

Ornidazole

500mg film-coated tablets

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### What is in this leaflet

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This leaflet answers some common questions about TIBERAL tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TIBERAL against the benefits expected for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What TIBERAL is used for

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TIBERAL contains the active ingredient ornidazole.

TIBERAL is used to treat people who have certain types of vaginal, urinary tract and intestinal infections, or some specific infections that are in the body. These infections may be caused by anaerobic bacteria (bacteria that do not use oxygen) or amoeba (single celled parasites). TIBERAL is also used to guard against the possibility of these types of infections during surgery (prophylaxis).

TIBERAL belongs to a group of medicines called antiprotozoals. These medicines work by targeting the bacteria or amoeba in your body, and killing them.

Your doctor, however, may have prescribed TIBERAL for another purpose.

**Ask your doctor if you have any questions about why TIBERAL has been prescribed for you.**

This medicine is available only with a doctor's prescription.

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### Before you take TIBERAL

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#### ***When you must not take it***

Do not take TIBERAL if:

1. **you have had an allergic reaction to TIBERAL, other nitroimidazole derivatives such as metronidazole (Flagyl<sup>®</sup>), Rozex<sup>®</sup>, Trichazole<sup>®</sup>), or any ingredients listed at the end of this leaflet**



**2. the package is torn or shows signs of tampering**

**3. the expiry date printed on the pack has passed**

If you take this medicine after the expiry date has passed, it may not work as well.

**If you are not sure if you should be taking TIBERAL, talk to your doctor.**

### ***Before you start to take it***

**Tell your doctor if:**

**1. you are pregnant or plan to become pregnant**

It is not known whether TIBERAL is harmful to an unborn baby when taken by a pregnant woman. TIBERAL is not recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

**2. you are breast-feeding or plan to breast-feed**

It is not known whether TIBERAL passes into breast milk. Your doctor will discuss the risks and benefits of using TIBERAL if you are breast-feeding.

**3. you have any other health problems, especially the following:**

- epilepsy
- multiple sclerosis
- liver disease

**4. you are allergic to any other medicines, foods, dyes or preservatives**

**If you have not told your doctor about any of the above, tell them before you start taking TIBERAL.**

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop.**

Some medicines and TIBERAL may interfere with each other. These include:

- warfarin (Coumadin<sup>®</sup>, Marevan<sup>®</sup>), a blood-thinning agent
- vecuronium bromide (Norcuron<sup>®</sup>), a muscle relaxant

These medicines may be affected by TIBERAL, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking TIBERAL.

**Ask your doctor or pharmacist if you are not sure about this list of medicines.**

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## **How to take TIBERAL**

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**Follow all directions given to you by your doctor and pharmacist carefully.**

They may differ from the information contained in this leaflet.

### ***How much to take***

**Take TIBERAL exactly as your doctor has prescribed.**

Your doctor will tell you how many TIBERAL tablets to take each day.

The usual dose of TIBERAL for adults and children weighing over 35kg is three 500mg tablets taken in the evening for one to three days depending on the type of infection you have. Alternatively the dose may be split into one or two 500mg tablets in the morning and in the evening for three to ten days, again depending on the type of infection you have.

If you are having haemodialysis, your dose may be increased.

For prophylaxis during surgery the usual dose is three 500mg tablets 12 hours before the surgery, and then one 500mg tablet every 12 hours for three to five days after the surgery.

The usual dose for children weighing 35kg or less is from 25mg per kg bodyweight to 40mg per kg bodyweight given as one dose per day for up to 10 days, again depending on the type of infection.

### ***How to take it***

**Swallow tablets whole with a glass of water.**

### ***When to take it***

**Take TIBERAL during or immediately after a meal, at about the same time(s) each day.**

If you take TIBERAL on an empty stomach, it may cause a stomach upset.

### ***How long to take it***

**Continue taking TIBERAL until your doctor tells you to stop.**

Treatment with TIBERAL is a short-term treatment, usually from one to ten days.

### ***If you forget to take it***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise take it as soon as you remember and then go back to taking it as you would normally.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering your dose, ask your pharmacist for some hints.**

### ***In case of an overdose***

**Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much TIBERAL. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

**Keep telephone numbers for these places handy.**

**If you are not sure what to do, contact your doctor or pharmacist.**

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## **While you are taking TIBERAL**

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### ***Things you must do***

**Tell all doctors, dentists and pharmacists who are treating you that you are taking TIBERAL.**

**Tell your doctor if you become pregnant while taking TIBERAL.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

**Tell your doctor if you feel the tablets are not helping your condition.**

**Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

### ***Things you must not do***

**Do not stop taking TIBERAL or change the dose without first checking with your doctor.**

**Do not let yourself run out of medicine over the weekend or on holidays.**

**Do not give TIBERAL to anyone else even if they have the same condition as you.**

**Do not use TIBERAL to treat other complaints unless your doctor says to.**

**Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how TIBERAL affects you.**

As with many other medicines used to treat specific types of infection in the body, TIBERAL may cause dizziness, drowsiness or light-headedness in **some** people. Make sure you know how you react to TIBERAL before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy, drowsy or light-headed.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TIBERAL.**

TIBERAL helps most people but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- sleepiness/tiredness
- headache
- nausea and/or vomiting
- dizziness or vertigo (a spinning sensation)
- tremor
- taste disturbances
- skin reactions
- numbness or tingling in your fingers or toes

**Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:**

- rigidity
- poor co-ordination
- seizures
- loss of consciousness
- allergic reaction. Some of the symptoms of an allergic reaction may include severe skin rash, itching, hives, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles.

These may be serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## **After taking TIBERAL**

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### ***Storage***

**Keep your tablets in the blister pack until it is time to take them.**

If you take the tablets out of the packaging they may not keep well.

**Keep TIBERAL tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store it, or any other medicine, in a bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep TIBERAL where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### ***Disposal***

**If your doctor tells you to stop taking TIBERAL, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.**

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## **Product Description**

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### ***Availability***

TIBERAL comes in one tablet strength, 500mg.

TIBERAL comes in blister packs of 10's.

### ***What TIBERAL looks like***



TIBERAL 500mg film-coated tablets are white to slightly yellowish, cylindrical, biconvex tablets imprinted with 'ROCHE'.

### ***Ingredients***

#### **Active ingredient -**

- ornidazole

#### **Inactive ingredients -**

Maize starch, microcrystalline cellulose, methylhydroxyethylcellulose, methylhydroxypropylcellulose, magnesium stearate, talc and titanium dioxide.

### ***Distributor***

TIBERAL is distributed by:

Roche Products (New Zealand) Ltd  
P O Box 12-492  
Penrose  
AUCKLAND

Telephone: (09) 633 0700  
Toll Free: 0800 656 464

This leaflet was prepared on 7 July 2004.

**Reference: New Zealand Data Sheet dated 2 June 2004.**