

TRICHOZOLE

Metronidazole

200mg & 400mg tablets

What is in this leaflet

This leaflet answers some common questions about TRICHOZOLE. It does not contain all the available information. It does not take place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TRICHOZOLE against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again later.

What TRICHOZOLE is used for

TRICHOZOLE is used in the treatment of various infections caused by bacteria or other organisms, in different parts of the body.

It can be used to:

- Treat infections of the blood, brain, lung, bones, genital tract, pelvic area, stomach and intestines.
- Treat gum ulcers and other dental infections.
- Treat infected leg ulcers and pressure sores.
- Prevent infections after surgery.

The active ingredient in TRICHOZOLE is metronidazole; it belongs to the class of medicines known as antiprotozoals and antibacterials.

Your doctor may have prescribed TRICHOZOLE for another reason. Ask your doctor if you have any questions about why TRICHOZOLE has been prescribed for you.

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

There is no evidence TRICHOZOLE is addictive.

Before you take TRICHOZOLE

When you must not take it

Do not take TRICHOZOLE if you have an allergy to metronidazole (the active ingredient in TRICHOZOLE) or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include, rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing.

Do not take TRICHOZOLE after the expiry date (EXP) printed on the pack has passed.

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

Do not take TRICHOZOLE if the packaging is torn or shows signs of tampering.

Do not take TRICHOZOLE if you are pregnant or you are breastfeeding.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if have, or have ever had:

- liver or kidney problems

Your doctor may want to take special precautions if you have any of the above conditions.

Tell your doctor if you have any other medical conditions not listed above.

Tell your doctor if you think you may be pregnant or plan to become pregnant.

Like most medicines, TRICHOZOLE is not recommended during pregnancy. Your doctor will discuss the risks and benefits of using this medicine if you are pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Breastfeeding is not recommended while you are taking TRICHOZOLE. The active ingredient metronidazole, passes into the breast-milk and could affect your baby.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and TRICHOZOLE interfere with each other. These include:

- Anticoagulant medication (used to help prevent blood clots) e.g. warfarin.
- Lithium, a medicine used to treat depression and manic depressive illnesses.
- Convulsion or sedative medication e.g. phenobarbitone.
- Cyclosporin, a medicine used to prevent organ transplant rejection or to treat immune system disorders.
- Disulphiram, a medicines used to treat chronic alcohol dependence.
- Some anticancer drugs e.g. 5-fluorouracil.
- Busulphan, a medicine used to treat leukaemia (cancer of the blood).

These medicines may be affected by TRICHOZOLE, or may affect how well TRICHOZOLE works. You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking any of the above medicines.

If you are not sure whether you are taking any of the above medicines, check with your doctor or pharmacist.

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

How to take TRICHOZOLE properly

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

They may differ from the information contained in this leaflet.

If you do not understand the instruction printed on the label, ask your doctor or pharmacist for help.

Avoid alcohol while taking TRICHOZOLE and for at least two days (48 hours) after stopping it.

If you drink alcohol while taking TRICHOZOLE, it is likely you will experience some unpleasant effects. These may include nausea, vomiting, stomach cramps, fast heart beats, headache and flushing.

How much to take

The usual dose is between 200 and 800mg, taken 2 to 3 times a day. Your doctor may increase or decrease the dose depending on your condition and how well you respond to this medicine.

The usual dose in children is less than this. The dose will be calculated by your doctor depending on the age and weight of the child.

How to take it

Swallow TRICHOZOLE tablets whole with a glass of water, preferably with or after a meal.

Do not chew the tablets. Chewing the tablets may upset your stomach and may cause the TRICHOZOLE to not work as well.

How long to take it

Continue to take TRICHOZOLE until you finish the pack or until your doctor recommends that you stop taking it.

Do not stop taking the tablets because you feel better.

If you do not complete the full course prescribed by your doctor, all of the bacteria/organisms causing your infection may not have been killed. The bacteria/organisms remaining may continue to grow and multiply so that your infection may not clear completely or it may return.

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.

Do not take a double dose to make up for the dose you missed.

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

If you have trouble remembering when to take your medicine, ask your doctor for some hints.

If you take too much (overdose)

You should only take the number of tablets that you have been told to take.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any TRICHOZOLE by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of TRICHOZOLE with you if you can.

Keep telephone numbers for these places handy.

While you are taking TRICHOZOLE

Things you must do

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

If you become pregnant while taking TRICHOZOLE, stop taking it and tell your doctor immediately.

Tell your doctor or pharmacist that you are taking TRICHOZOLE before you start any new medicine.

If you plan to have surgery, tell the surgeon or dentist that you are taking TRICHOZOLE.

If you need to have a blood test while you are taking TRICHOZOLE, tell your doctor. TRICHOZOLE may affect the results of some laboratory tests.

Things you must not do

Do not drink alcoholic drinks while taking TRICHOZOLE or for at least two days (48 hours) after finishing treatment. Drinking alcohol may cause some unpleasant effects such as nausea, vomiting, stomach cramps, fast heartbeat, headaches or flushing.

Do not give this medicine to anyone else, even if they have the same condition or their symptoms seem similar to yours.

Do not use TRICHOZOLE to treat any other complaints unless your doctor tells you to do so.

Do not stop taking your tablets, or lower the dose because you are feeling better unless advised by your doctor. If you do complete the full course prescribed by your doctor, not all of the bacteria/organisms causing your infection may have been killed. These bacteria/organisms may continue to grow and multiply so that your infection may not completely clear or may return.

Thing to be careful of

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

TRICHOZOLE may cause dizziness, confusion, convulsions or light-headedness in some people. Make sure you know how you react to TRICHOZOLE before you drive a car, operate machinery, or do anything else that could be dangerous.

Side effects

Tell your doctor as soon as possible if you do not feel well while taking TRICHOZOLE.

All medicines can have unwanted side effects. Sometimes they are serious, most of the time they are not. If they occur, they are usually minor and temporary.

Sometimes however, side effects can be serious and may need medical treatment.

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:

- Fits (convulsions).
- Mental problems such as feeling confused and seeing or hearing things that are not there (hallucinations).
- Problems with your eyesight such as blurred or double vision.
- Skin rash.
- Headache.
- Darkening of the urine.
- Feeling sleepy or dizzy.
- Pains in the muscles or joints.
- Numbness, tingling, pain or a feeling of weakness in the arms or legs.
- Unpleasant taste in the mouth.
- Furred tongue.
- Feeling sick (nausea) being sick (vomiting) upset stomach, or diarrhoea.
- Loss of appetite.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- Yellowing of the skin and eyes, also called jaundice. This could be due to a liver problem.
- Changes in mood including depression, confusion or hallucination.
- Tremor, in-coordination or uncoordinated movements.
- Disease of the blood cells. Symptoms may include: tiredness; headaches; dizziness; being short of breath when exercising and looking pale; frequent infections such as fever, severe chills, sore throat or mouth ulcers; bleeding or bruising more easily than normal; and nosebleeds.
- Severe stomach pain which may reach through to your back (pancreatitis).

These may be serious side effects of TRICHOZOLE. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking TRICHOZOLE, and tell your doctor immediately, or go Accident and Emergency at your nearest hospital:

- You get swelling of the hands, feet, ankles, face, lips, tongue or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria).
This may mean you have a serious allergic reaction to TRICHOZOLE.
- A serious but very rare side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache, see or hear things that aren't there. You might also have problems using your arms and legs, problems with speaking or feel confused.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Other side effects not listed above may also occur in some patients. Tell you doctor if you notice any thing else that is making you feel unwell.

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

After using it

Storage

Keep the tablets in the bottle or pack until it is time to take them.

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

Keep in a cool dry place that is protected from light and where the temperature stays below 25°C.

Do not store TRICHOZOLE, or any other medicine in the bathroom or near a sink. Do not leave it in the car or on the windowsills.

Heat and dampness can destroy some medicines.

Keep TRICHOZOLE out of reach from children.

A locked cardboard 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 the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do.

Product description

What it looks like

TRICHOZOLE comes in two strengths:

- TRICHOZOLE 200mg: are white, round tablets imprinted "M" breakline "200" on one side and plain on the other.
- TRICHOZOLE 400mg: are yellow, round tablets imprinted "M" over "400" on one side and plain on the other.

Each tablet contains either 200mg or 400mg of metronidazole.

The 200mg tablet also contains:

- maize starch
- microcrystalline cellulose
- magnesium stearate
- povidone
- lactose

The 400mg tablet also contains:

- maize starch
- microcrystalline cellulose
- sodium starch glycollate
- magnesium stearate
- povidone
- lactose
- quinoline yellow

Both 200mg and 400mg TRICHOZOLE tablets are gluten free.

If you want to know more

Should you have any more questions about this medicine, ask your doctor or pharmacist for advice.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone (09) 579 2792

Date of information

8 January 2010

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