

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### MEDAZOL

400mg Tablets

METRONIDAZOLE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What MEDAZOL is and what it is used for
2. Before you take MEDAZOL
3. How to take MEDAZOL
4. Possible side effects
5. How to store MEDAZOL

#### 1. WHAT MEDAZOL IS AND WHAT IS IT USED FOR

The name of this medicine is Medazol 400mg Tablets (called Medazol in this leaflet). Medazol contains a medicine called metronidazole. This belongs to a group of medicines called antibiotics.

It works by killing bacteria and parasites that cause infections in your 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

If you need any further information on your illness, speak to your doctor.

#### 2. BEFORE YOU TAKE MEDAZOL

##### **Do not take Medazol and tell your doctor if:**

- You are allergic (hypersensitive) to metronidazole, nitroimidazoles (e.g. tinidazole) or any of the other ingredients in your medicine.

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Do not take Medazol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Medazol.

***Take special care with Medazol if:***

- You have or have ever had a liver problem.
- You are having kidney dialysis (see section 3: ‘People having kidney dialysis’)
- You have a disease of the nervous system

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking your medicine. Do this even if they have applied in the past.

***Taking other medicines***

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Medazol can affect the way some other medicines work. Also, some other medicines can affect the way Medazol works.

In particular tell your doctor if you are taking any of the following medicines:

- Medicines used to thin the blood such as warfarin
- Lithium for mental illness
- Phenobarbital or phenytoin for epilepsy
- 5 fluorouracil for cancer
- Busulfan for leukaemia (cancer of the blood cells)
- Ciclosporin – to prevent the rejection of organs after transplant
- Disulfiram for alcoholism

If you are not sure, talk to your doctor or pharmacist before taking Medazol.

***Taking Medazol with food and drink***

Do not drink any alcohol while you are taking Medazol and for 48 hours after finishing your course. Drinking alcohol while using Medazol might cause unpleasant side effects, such as feeling sick (nausea), being sick (vomiting), stomach pain, hot flushes, very fast or uneven heartbeat (palpitations) and headache.

***Pregnancy and breast-feeding***

Tell your doctor before using Medazol if:

- You are pregnant, might become pregnant or think you may be pregnant. Medazol should not be taken during pregnancy unless considered absolutely necessary.
- You are breast-feeding. It is better not to use Medazol if you are breast-feeding. This is because small amounts may pass into the mother’s milk.

***Driving and using machines***

While taking Medazol you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

***Tests***

Your doctor may wish to carry out some tests if you have been using this medicine for more than 10 days.

***3. HOW TO TAKE MEDAZOL***

### ***Taking your medicine***

Always take Medazol exactly as your doctor has told you. It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated.

Check with your doctor or pharmacist if you are not sure.

- Swallow the tablets whole with a drink of water
- Do not crush or chew the tablets
- Take these tablets during or just after a meal
- The dose of Medazol will depend on your needs and the illness being treated
- The length of your treatment will depend on the type of illness you have and how bad it is

The usual dose for adults and children is given below:

#### **To treat bacterial infection**

##### **Adults**

- The initial dose is 800mg
- After 8 hours take another dose of 400mg and repeat this dose every 8 hours

##### **Children**

- Your doctor will work out how much your child should take depending on their weight
- Repeat the dose every 8 hours
- If your child is a baby under 8 weeks of age, your doctor will give them one daily dose or two separate doses 12 hourly

#### **To prevent infections from happening after surgery**

##### **Adults**

- Start Taking Medazol Tablets 24 hours before your operation
- Take 400 mg of Medazol every 8 hours
- After the operation you may be given Medazol either through a drip into a vein or rectally as a suppository until you are able to take tablets again

##### **Children**

- Give your child Medazol Tablets 1-2 hours before their operation
- Your doctor will work out how much your child should take depending on their weight
- After the operation your child may be given Medazol either through a drip into a vein or rectally as a suppository until they are able to take tablets again

#### **Other types of infections**

For treatment of other infections caused by parasites and some bacteria your doctor will decide how much Medazol you need to take and how often. This will depend on your illness and how bad it is. The pharmacist's label on the packaging will tell you how many tablets to take and how often to take them.

#### **People having kidney dialysis**

Kidney dialysis removes Medazol from your blood. If you are having kidney dialysis you must take this medicine after your dialysis treatment.

#### **People with liver problems**

Your doctor may tell you to use a lower dose or to use the medicine less often.

#### **If you take more Medazol than you should**

If you take more Medazol than you should, tell your doctor or go to your nearest hospital casualty department straight away. Take the pack and any tablets left with you. This is so the doctor knows what you have taken.

#### ***If you forget to take Medazol***

If you forget to take Medazol, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Medazol can cause side effects, although not everybody gets them.

**Stop taking Medazol and see a doctor or go to a hospital straight away if:**

- You get swelling of the hands, feet, ankles, face, lips 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 are having an allergic reaction to Medazol.

- 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.

**Talk to your doctor straight away if you notice the following side effects.**

- Yellowing of the skin and eyes. This could be due to a liver problem (jaundice).
- Unexpected infections, mouth ulcers, bruising, bleeding gums, or severe tiredness. This could be caused by a blood problem.
- Severe stomach pain which may reach through to your back (pancreatitis)

**Tell your doctor or pharmacist if you notice any of the following side effects:**

**Very rare (affects less than 1 in 10 000 people)**

- 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 or flushing
- Headache
- Darkening of the urine
- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Liver problems including life-threatening liver failure (hepatocellular liver injury)

**Not known (frequency cannot be estimated from the available data)**

- 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, stomach pain or diarrhoea
- Loss of appetite
- Fever
- Feeling depressed
- Pain in your eyes (optic neuritis)
- A group of symptoms together including: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis)

If any of the side effects gets serious, lasts longer than a few days or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### 5. HOW TO STORE MEDAZOL

- Keep your medicine in a safe place and out of the reach and sight of children.
- Store below 30° C in the original packaging (protect from light)

- Do not use this medicine after the expiry date shown on the pack.
- Ask your pharmacist how to dispose of medicines no longer required. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help protect the environment.