

MACRODANTIN(R)

Nitrofurantoin

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking MACRODANTIN. This leaflet answers some common questions about MACRODANTIN. It does not contain all the available information and 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 this medicine against the expected benefits it will have for you.

Take MACRODANTIN as instructed and follow the advice given in this leaflet.

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.

What MACRODANTIN is used for

MACRODANTIN is used to treat infections of the urinary system caused by bacteria, for example, bladder infections.

MACRODANTIN is an antibiotic which belongs to a group of medicines called nitrofurans. It works by killing or stopping the growth of the bacteria and other organisms causing these infections.

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

prescribed for you.

These medicines are only available with a doctor's prescription.

Before you take MACRODANTIN

When you must not take it

Do not take MACRODANTIN if:

1. you have an allergy to MACRODANTIN or any other nitrofuran, or to any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction include skin rash, itching, difficulty with breathing, fever and chills.
2. you have severe kidney problems.
3. you are pregnant and close to giving birth.

Infants under one month of age should not be given MACRODANTIN.

Do not use MACRODANTIN if the packaging is torn or shows signs of tampering.

Do not use it after the expiry date (EXP) printed on the pack.

Before you start taking it

You must tell your doctor if:

1. you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking MACRODANTIN during pregnancy.
2. you are breastfeeding or intend to

breastfeed. Your doctor will discuss the risks and benefits of taking MACRODANTIN while breastfeeding.

3. you have or have had any other health problems including :
 - kidney problems
 - if you lack an enzyme in red blood cells (G-6-PD deficiency) which occurs in a very small number of people of African descent , people of Mediterranean and near Eastern origin.
 - anaemia (a blood disorder), diabetes, or vitamin B deficiency

When taking MACRODANTIN your urine may turn brown. This is temporary and not associated with any serious effects.

MACRODANTIN may interfere with the normal production of sperm cells. This is reversible. If this causes you any concerns, please speak to your doctor.

If you have not told your doctor or pharmacist about any of the above, tell them before you start to take MACRODANTIN.

Taking other medicines

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

There may be interference between MACRODANTIN and some other medicines including:

- * phenobarbitone, a medicine used to treat epilepsy
- * medicines used to treat gout, such as probenecid and sulfinpyrazone

- * antacids, medicines used to treat heartburn, indigestion or reflux
- * agents used to make the urine more acidic, such as ammonium chloride tablets
- * agents used to make the urine more alkaline, such as sodium bicarbonate

These medicines may be affected by MACRODANTIN or may affect how well they work. You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking MACRODANTIN.

How to take MACRODANTIN

Your doctor or pharmacist will tell you how to take your medicine.

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

The directions given to you by your doctor or pharmacist on how to take MACRODANTIN may differ from the information contained in this leaflet. You may be given a different dosage depending on your condition or how you react to the medicine.

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

How much to take

Adults

If you already have an infection:

The usual dose is 1 capsule (either the 50 mg or 100 mg strength) four times daily.

To prevent an infection:

The usual dose is 1 capsule (either the 50 mg or 100 mg strength) taken at night.

Children

The dose for children will depend on

their body weight. The usual dose is 1.25 to 1.75 mg/kg of body weight given four times a day. Your doctor will calculate the proper dose taking into account the age and weight of the child and how severe the infection is.

When to take it

MACRODANTIN should be swallowed with or immediately after food or with a glass of milk.

If taken on an empty stomach it may cause stomach upset.

How long to take it

Continue taking MACRODANTIN until you finish the bottle or until your doctor recommends.

Do not stop taking your medicine earlier than this, even if you are feeling better.

Check with your doctor if you are not sure how long you should be taking the medicine.

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, then go back to taking your medicine as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to the Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much MACRODANTIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep telephone numbers for these services handy. Have the

medicine or this leaflet available to give details if needed.

While you are using MACRODANTIN

Things you must do

- * If the symptoms of your infection do not improve, or if they become worse, tell your doctor
- * If you become pregnant while you are taking MACRODANTIN, tell your doctor
- * If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking MACRODANTIN
- * If you have to have any urine or blood tests, tell your doctor you are taking MACRODANTIN. This medicine may affect the results of some laboratory tests
- * Tell all doctors, dentists and pharmacists who are treating you that you are taking MACRODANTIN

Things you must not do

Do not stop taking your medicine before you finish the bottle or as advised by your doctor, even if you are feeling better.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or may return.

Do not take antacid preparations at the same time as MACRODANTIN. These preparations may affect how well MACRODANTIN works.

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

Do not use MACRODANTIN to treat any other medical complaints unless your doctor tells you to.

Side effects

Check with your doctor as soon as possible if you have any problems while taking MACRODANTIN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like many medicines, MACRODANTIN may cause side effects. If they occur, they are likely to be minor and temporary. However, some may be serious and need medical attention.

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:

- * nausea and vomiting
- * diarrhoea
- * headache and dizziness
- * drowsiness and altered mood
- * feeling weak

Tell your doctor immediately if you notice any of the following:

- * swelling of the face, lips, mouth, throat or neck which may cause difficulty with swallowing or breathing
- * diarrhoea (which may occur up to several weeks after finishing the course)
- * numbness or tingling in any area of the body
- * confusion, having hallucinations or illusions
- * hepatitis, an inflammation of the liver which can result in yellowing of the skin and eyes, lower back pain, dark urine, tiredness and a general feeling of being unwell
- * fever and chills
- * chest pain, difficulty with breathing and cough
- * skin rash and itchiness
- * asthma attack
- * sore throat or gums and a continual feeling of tiredness

Other side effects not listed above may also occur in some patients.

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

After using MACRODANTIN

Storage

Keep the medicine in the bottle until it is time to take it.

If you take the capsules out of the bottle, the medicine may not keep well.

Keep the medicine in a cool dry place.

MACRODANTIN must be stored where it stays below 30 degrees C. Do not store your MACRODANTIN, or any other medicine in a bathroom or near a sink. Do not leave the medicine in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your MACRODANTIN where 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 MACRODANTIN, or the medicine has passed its expiry date, ask your pharmacist what to do with any left over.

Product Description

What it looks like

MACRODANTIN is available in a bottle containing 30 capsules. There are two strengths of capsules available, 50 mg and 100 mg.

The 50 mg capsules are yellow and white and have the word "EATON

008" marked on them. They are identified by the Australian Registration number AUST R 60064.

The 100 mg capsules are yellow and have the word "EATON 009" marked on them. They are identified by the number AUST R 60065.

Ingredients

MACRODANTIN capsules contain either 50 mg or 100 mg of nitrofurantoin as the active ingredient. The other ingredients in the two strengths of MACRODANTIN are maize starch, talc and lactose.

Supplier

MACRODANTIN is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll Free number: 1800 675 229

This leaflet was revised on 06 August 2008

(C) Pfizer Australia Pty Ltd
(R) Registered Trademark