FUDANTIN

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using FUDANTIN?

FUDANTIN contains the active ingredient Nitrofurantoin.

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

For more information, see Section 1. Why am I using FUDANTIN? in the full CMI.

2. What should I know before I use FUDANTIN?

Do not use if you have ever had an allergic reaction to FUDANTIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use FUDANTIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FUDANTIN and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use FUDANTIN?

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

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

The directions given to you by your doctor on how to take

FUDANTIN may differ from the information contained in this leaflet.

More instructions can be found in Section 4. How do I use FUDANTIN? in the full CMI.

5. What should I know while using FUDANTIN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using FUDANTIN. • 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 FUDANTIN, tell your doctor.
Things you should not do	• If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. • Do not take antacid preparations at the same time as FUDANTIN. These preparations may affect how well FUDANTIN works.
Driving or using machines	• Be careful driving or operating machinery until you know how FUDANTIN affects you.
Looking after your medicine	• FUDANTIN must be stored where it stays below 30°C • Do not store your FUDANTIN, or any other medicine in a bathroom or near the sink. Do not leave the medicine in the car or on window sills. Heat and dampness can destroy some medicines.

For more information, see Section 5. What should I know while using FUDANTIN? in the full CMI.

6. Are there any side effects?

common side effects: nausea and vomiting, diarrhoea, headache and dizziness.

Serious side effects: swelling of the face, lips, mouth, throat or neck which may cause difficulty with swallowing or breathing; numbness or tingling in any area of the body; chest pain, difficulty with breathing and cough; asthma attack. Refer to the CMI for the full list.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

FUDANTIN

Active ingredient(s): *Nitrofurantoin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FUDANTIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FUDANTIN.**

Where to find information in this leaflet:

1. Why am I using FUDANTIN?
2. What should I know before I use FUDANTIN?
3. What if I am taking other medicines?
4. How do I use FUDANTIN?
5. What should I know while using FUDANTIN?
6. Are there any side effects?
7. Product details

1. Why am I using FUDANTIN?

FUDANTIN contains the active ingredient either 50mg or 100mg of nitrofurantoin as active ingredient.

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

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

2. WHAT SHOULD I KNOW BEFORE I USE FUDANTIN?

Warnings

Do not use FUDANTIN if:

- you have an allergy to FUDANTIN 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.
- Always check the ingredients to make sure you can use this medicine.
- you have severe kidney problems
- you are pregnant and close to giving birth.

Check with your doctor if you:

- have any other medical conditions
- 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 FUDANTIN your urine may turn brown. This is temporary and not associated with any serious effects.
- FUDANTIN may interfere with the normal production of sperm cells. This is reversible. If this causes you any concerns, please speak to your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Use in adults and children

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 50 mg or 100 mg strength) taken at night.

Infant and Children

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

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

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

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.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Do not take FUDANTIN if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Do not take FUDANTIN if you are breastfeeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with FUDANTIN and affect how it works.

Tell your doctor if you are taking or plan to take any of the following:

- 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 FUDANTIN or may affect how well they work. You may need different amounts of your medicine or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FUDANTIN.

4. How do I use FUDANTIN?

How much to take

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 FUDANTIN 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

FUDANTIN 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 FUDANTIN 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 FUDANTIN. 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.

5. What should I know while using FUDANTIN?

Things you should 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 FUDANTIN, tell your doctor

- If you are about to start taking any new medicines, tell pharmacist that your doctor and you are taking FUDANTIN.
- If you have to have any urine or blood tests, tell your doctor you are taking FUDANTIN. This medicine may affect the results of some laboratory tests.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking FUDANTIN.

Remind any doctor, dentist or pharmacist you vist that you are usingFUDANTIN.

Things you should not do:

Do not stop taking your medicine before you finish the blister pack 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 FUDANTIN. These preparations may affect how well FUDANTIN works.

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

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FUDANTIN affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep the medicine in the blister pack until it is time to take it.
- If you take the capsules out of the blister pack, the medicine may not keep well.
- Keep the medicine in a cool dry place.

Follow the instructions in the carton on how to take care of your medicine properly.

- FUDANTIN must be stored where it stays below 30°C. Do not store your FUDANTIN, 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 FUDANTIN 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• nausea and vomiting • diarrhoea • headache and dizziness • drowsiness and altered mood • feeling weak.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
• 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 What to do 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.	**These serious are side effects.** **You may need urgent medical attention or hospitalization. These side effects are very rare.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What FUDANTIN contains

Active ingredient (main ingredient)	FUDANTIN capsule contain either 50mg or 100mg of nitrofurantoin as the active ingrediant
(inactive ingredients)	maize starch Purified Talc Lactose monohydrate Capsule shell: Gelatin Purified water Sodium lauryl sulfate Iron oxide yellow Titanium dioxide Tekprint SW-9008 Black Ink
Potential Allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What FUDANTIN looks like

FUDANTIN 50mg is Hard gelatin capsule size '3' with "A9" imprint on opaque yellow cap and plain opaque white body (Aust R 486469).

FUDANTIN 100MG is Hard gelatin capsule size '2' with "A8" imprint on opaque yellow cap and plain opaque yellow body (Aust R 486465).

Who distributes FUDANTIN

Nova Pharmaceuticals Australia Pty Ltd
Suite 305, 10 Norbrik Drive
Bella Vista,
NSW 2153 Australia
Toll free: 1800 002 171
www.novapharm.com.au

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