

Package leaflet: Information for the user

Fasigyn® 500mg film-coated tablets
Tinidazole

Pfizer logo

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. Do not pass it on to others. It may harm them, even if their symptoms 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. See section 4.

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1. What Fasigyn 500mg film-coated tablets is and what it is used for

Fasigyn 500mg film-coated tablets contain 500mg of the active substance tinidazole. This medicine is an anti-infective agent. It is used to treat a variety of bacterial infections including:

- infections of the skin, blood, chest, lung, genitals or womb lining.
- an infection associated with stomach ulcers in combination with other drugs.
- infections caused by organisms called protozoa, such as amoebiasis and giardiasis (stomach infections) and trichomoniasis (a genital infection).
- vaginal infections (vaginitis) and gum infections (gingivitis).

It is also used before certain surgical operations to prevent bacterial infections developing.

You should ask your doctor if you are unsure why you have been given this medicine.

2. What you need to know before you take Fasigyn 500mg film-coated tablets

Do not take Fasigyn 500mg film-coated tablets if:

- you are allergic (hypersensitive) to tinidazole or any similar drugs or to any of the other ingredients listed in section 6. An allergic reaction could cause itching, a skin rash or wheezing.
- you have a blood disorder or a history of blood disorders
- you have central nervous system (CNS) disease, including epilepsy
- you are in the first 13 weeks of pregnancy or trying to become pregnant or you are breast-feeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse, if during therapy with Fasigyn 500mg film-coated tablets abnormal neurological signs develop (such as, dizziness, vertigo, difficulty in controlling movements) as you may be told to stop your treatment.

Other medicines and Fasigyn 500mg film-coated tablets

Tell your doctor if you are taking or have recently taken any other medicines including those obtained without a prescription.

You should tell your doctor if you are currently taking blood thinners such as warfarin to prevent blood clots as your doctor may wish to monitor you more closely.

Fasigyn 500mg film-coated tablets with food and drink

You should not drink wine, beer or spirits during treatment and for 3 days after stopping treatment with this medicine. The combination may cause flushing, stomach cramps, vomiting (being sick) and palpitations (pounding heart).

Pregnancy

You should not take this medicine if you are in the first 13 weeks of pregnancy or are trying to become pregnant. Always ask your doctor or pharmacist for advice before taking Fasigyn 500mg film-coated tablets or any other medicine.

Breast-feeding

You should not take this medicine if you are breast feeding as small amounts can pass into your milk. If you stop breast-feeding during treatment you should not start again until at least 3 days after stopping Fasigyn 500mg film-coated tablets.

Driving and using machines

Do not drive or use machinery if this medicine makes you feel drowsy or gives you problems with co-ordination or sensation (e.g. numbness or weakness).

3. How to take Fasigyn 500mg film-coated tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take Fasigyn 500mg film-coated tablets with a glass of water during or after a meal. Swallow the tablets whole. It is best to take the medicine at the same time each day.

Use in children under 12 years

For bacterial infections, this medicine is not recommended for use in children less than 12 years as it has not been tested in this age group.

For protozoal infections, Fasigyn 500mg film-coated tablets can be used in children and has not been shown to cause any different side effects or more problems than it does in adults.

The dose and length of treatment depends upon the infection being treated. If you are on dialysis, your doctor may prescribe a different dose.

The doses most commonly used for the different infections are shown in the table below:

For treating the infection associated with stomach ulcers

The usual dose is 1 tablet (500mg) taken twice a day. Your doctor will probably prescribe two other medicines to be taken with Fasigyn 500mg film-coated tablets. Treatment with the three medicines together will usually be for 1 week.

For treating most bacterial infections

The usual dose is 4 tablets (2g) on the first day then 2 tablets (1g) once a day or 1 tablet (500mg) twice a day.

The usual length of treatment is 5 to 6 days.

For treating bacterial vaginitis (a vaginal infection) and acute ulcerative gingivitis (a gum infection)

The usual dose is 4 tablets (2g) given as a single dose.

For vaginitis you may be given 4 tablets (2g) on two consecutive days.

For preventing bacterial infections after surgery

Usually 4 tablets (2g) are given as a single dose about 12 hours before surgery.

For treating protozoal infections

For treating intestinal amoebiasis (a stomach infection)

Adult The usual dose is 4 tablets (2g) once a day for 2 to 3 days.

Child The usual dose is 50 to 60mg/kg of body weight once a day for 3 days.

For treating amoebic involvement of the liver (a liver infection)

Adult The usual dose is 3 to 4 tablets (1.5 to 2g) once a day for 3 to 6 days.

Child The usual dose is 50 to 60mg/kg of body weight once a day for 5 days.

For treating giardiasis (an abdominal infection) and trichomoniasis (an infection of the sex organs in males and females)

Adult The usual dose is 4 tablets (2g) given as a single dose.

Child The usual dose is 50 to 75mg/kg of body weight given as a single dose.

Your doctor will calculate the dose required for a child and may repeat the dose once if the infection has not cleared up completely.

If you take more Fasigyn 500mg film-coated tablets than you should

If you take too much of this medicine tell your doctor or contact your nearest hospital casualty department immediately. Take any remaining tablets with you.

If you forget to take Fasigyn 500mg film-coated tablets

If you forget to take this medicine take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Fasigyn 500mg film-coated tablets

If you stop taking this medicine too soon, the infection may return. Take this medicine for the full time of treatment, even when you begin to feel better.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist for advice.

4. Possible side effects

Like all medicines, this medicine causes side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine.

Although they are very rare, the symptoms can be severe.

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips or tongue
- fits or seizures

The common side effects (that may affect up to 1 in 10 people) are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you.

- nausea (feeling sick) or vomiting, loss of appetite, diarrhoea, stomach pain or cramps
- headache
- vertigo (See section 2 'Warnings and precautions')
- skin rash or itching (especially affecting the whole body).

The frequency of the following side effects is not known (cannot be estimated from the available data). You should contact your doctor if you notice any of the following:

- numbness, tingling, pain or weakness in hands or feet
- clumsiness or unsteadiness
- fever or chills and painful ulcers in the mouth
- sore or swollen mouth/tongue
- redness of the face or neck
- dizziness
- tiredness
- dark urine
- tongue discolouration or unpleasant metallic taste.

Fasigyn 500mg film-coated tablets can sometimes cause a temporary reduction in white blood cells which does not usually give you any symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. How to store Fasigyn 500mg film-coated tablets

Keep all medicines out of the sight and reach of children.

Do not take this medicine after the expiry date stamped on the pack after EXP. The expiry date refers to the last day of that month.

Store below 25°C in a dry place. Store in the original package to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fasigyn 500mg film-coated tablets contains

The active substance is tinidazole. Each tablet contains 500mg of tinidazole.

The other ingredients are: alginic acid, hydroxypropyl methylcellulose, magnesium stearate, maize starch, microcrystalline cellulose, propylene glycol, sodium lauryl sulfate and titanium dioxide (E171).

What Fasigyn 500mg film-coated tablets look like and contents of the pack

Fasigyn 500mg film-coated tablets are white, round and biconvex with FAS 500 embossed on one side. The tablets come in blister packs of 16.

Marketing Authorisation Holder

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