



medicinal products and FASIGYN™

Package leaflet: Information for the patient

FASIGYN®

Tinidazole

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any questions or if you are in any doubt, talk to 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.

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FASIGYN 500 mg film-coated tablet

(tinidazole)

- The active substance of FASIGYN is tinidazole
- The other ingredients are
 - Tablet core: microcrystalline cellulose, alginate acid, maize starch, magnesium stearate, sodium lauryl sulphate
 - Coating: hydroxypropyl methylcellulose 2910, propylene glycol, titanium dioxide (E171)

Marketing Authorisation Holder: PFIZER S.A., Boulevard de la Plaine 17, 1050 Brussels.

Manufacturer: Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France.

Marketing Authorisation Number: 241 IS 193 F3

1. What FASIGYN 500 mg film-coated tablet is and what it is used for

FASIGYN is made available in the form of 500 mg film-coated tablets in packs of 4 tablets. The tablets are film-coated, white, round, convex, and marked "FAS 500" on one side.

FASIGYN is an antiparasitic and antibacterial agent.

FASIGYN is indicated for oral-route treatment of:

- 1) certain types of vaginitis, including those caused by *Trichomonas vaginalis* or *Gardnerella vaginalis*;
- 2) certain urinary tract infections in men and in women, caused by *Trichomonas vaginalis*;
- 3) some digestive parasitic infections caused by *Entamoeba histolytica* (an amoeba that can cause infections of the intestine and liver); *Giardia lamblia* (intestinal infection);
- 4) some bacterial infections caused by anaerobic microbes, mainly *Bacteroides fragilis*, other *Bacteroides* species and *Fusobacteria*; as well as species of *Peptococcus*, *Peptostreptococcus*, *Clostridium*, *Eubacteria* and *Veillonella*.

2. What you need to know before taking FASIGYN 500 mg film-coated tablet

Do not take FASIGYN

- If you have or have had a disease of the blood
- If you have an organic neurological disorder
- If you are hypersensitive (allergic) to tinidazole, to one of the other ingredients of FASIGYN or any medicine with a similar chemical structure (5-nitroimidazole)
- During pregnancy and when breastfeeding (read section "Pregnancy and breastfeeding")

Important note:

- alcohol should be avoided during treatment and for at least 3 days after stopping treatment with tinidazole because of the risk of side effects (read "FASIGYN with food and drink")
- If you are already taking other medicines, read "Other

Always follow your doctor's instructions strictly, especially regarding the duration of your treatment.

Talk to your doctor if any of the circumstances above applies to you, or has applied to you in the past.

FASIGYN with food and drink

The intake of alcoholic beverages should be avoided during treatment and for at least 3 days after stopping treatment because of an effect called the "disulfiram-alcohol reaction" which can cause abdominal cramps, vomiting, hot flashes and a rapid heart rhythm.

Pregnancy

This medicine is contraindicated during the first three months of pregnancy. During the second and third three months, it will only be prescribed on the advice of a doctor, and in case of absolute necessity. Talk to your doctor or pharmacist before taking any medicine.

Breastfeeding

Breastfeeding is contraindicated during treatment and at for least three days after treatment with FASIGYN has stopped. Talk to your doctor or pharmacist before taking this medicine.

Driving and using machines

The effect of tinidazole on the ability to drive and use machines has not been studied. But there is no reason to believe that tinidazole may affect these abilities.

Important information about some of the ingredients of FASIGYN

Not applicable

Using FASIGYN in combination with other medicinal products

FASIGYN, like other medicines with a similar chemical structure, can increase the activity of coumarin anticoagulants (medicines used prevent blood clots). Your doctor will adjust the dose of anticoagulant if necessary. Tell your doctor or pharmacist if you are taking any other medicines or if you have recently taken any other medicines, even if they were obtained without a prescription.

3. How to take FASIGYN 500 mg film-coated tablet

You should follow these instructions carefully unless your doctor has given you different instructions. If you are unsure, talk to your doctor or pharmacist.

FASIGYN tablets (500 mg tablets) should be taken with half a glass of water, preferably during or after a meal.

1) Urinary and vaginal *Trichomonas vaginalis* infections:

(trichomoniasis): take 4 tablets (2 g) in a single dose. The same treatment is recommended for your sexual partner.
In children: 50 to 75 mg per kg in a single dose.
In some cases the treatment should be repeated once.

2) Vaginal *Gardnerella vaginalis* infections (non-specific vaginitis):

take 4 tablets of 500 mg (2 g) as a single dose or 4 tablets over two consecutive days (4 g in total).

3) *Entamoeba histolytica* infections (amebiasis):

- a) intestinal infections (acute dysentery)
 - take 4 tablets (2 g) as a single dose for 2 to 3 days and up to 6 days if necessary
 - in children, 50 to 60 mg per kg, in one dose, for 3 days.
- b) liver infections (amoebic liver abscess)
 - take 3 to 4 tablets as a single dose for 3 days and up to 6 days if necessary
 - in children: 50 to 60 mg per kg, in a single dose for 5 days

4) *Giardia lamblia* intestinal infections (giardiasis):

- take 4 tablets (2 g) in one dose
- In children 50 to 75 mg per kg in a single dose
In some cases the treatment should be repeated once. The stools of a patient must be screened for giardiasis 7 to 10 days after treatment in order to detect any possible remaining presence of *Giardia lamblia*.

5) Infections caused by anaerobic microbes:

- take 4 tablets, as a single dose on the first day, then 2 tablets in one dose, for 4 to 5 days
Use in children under 12 years of age is not recommended.

Dosage table

Indications	Number of tablets or mg/kg per day (in a single dose, with a meal)	Duration of treatment
Urogenital trichomoniasis in adult men and women In children ≥ 12 years old	4 tablets of 500 mg 50 to 75 mg/kg	1 day 1 day (repeat once if necessary)
Non-specific vaginitis, Gardnerella	4 tablets of 500 mg	1 to 2 days
Acute amoebic dysentery in adults In children ≥ 12 years old	4 tablets of 500 mg 50 to 60 mg/kg	2 to 3 days (up to 6 days if necessary) 3 days
Amoebic liver abscesses in adults In children ≥ 12 years old	3 to 4 tablets of 500 mg 50 to 60 mg/kg	3 to 6 days 5 days
Giardiasis in adults In children ≥ 12 years old	3 to 4 tablets of 500 mg 50 to 75 mg/kg	1 day 1 day (repeat once if necessary)
Anaerobic infections	4 tablets of 500 mg on the first day followed by 2 tablets of 500 mg for the following 4 to 5 days	} 5 to 6 days

The maximum adult dose should not be exceeded in children.

Use in children under 12

Use in children under 12 years of age is not recommended.

Use in patients with severe kidney impairment

It is usually not necessary to adjust the dosage in patients with impaired renal function. However, because tinidazole is easily eliminated by haemodialysis, patients may need additional doses of tinidazole to compensate.

Your doctor will tell you for how long you should take FASIGYN. Do not stop your treatment prematurely, as your infection may not be cured. If no improvement is seen, talk to your doctor again.

If you forget to take FASIGYN

If one you miss one or more doses, you should talk to your doctor.

Effects which may occur when treatment with FASIGYN is stopped

Do not stop your treatment prematurely, as the symptoms may recur if all the bacteria and parasites are not killed.

If you have taken more FASIGYN you should

If you have taken more FASIGYN than you should, contact your doctor, pharmacist or the Poison Centre immediately. If you take too much FASIGYN (called an overdose), symptomatic treatment and support will be implemented. Gastric lavage may be helpful. Tinidazole is easily dialysable.

4. Possible side effects

Like all medicines, FASIGYN may have side effects, although not everybody gets them.

Mild gastrointestinal side effects, such as loss of appetite, a metallic taste in the mouth, diarrhoea, nausea, abdominal pain and vomiting may occur. Other side effects which have been reported occasionally are headache, fatigue, fever, lingua villosa (black hairy tongue), inflammatory lesions of the tongue, flushing, tingling, sensory disorders, lack of sensation and dark-coloured urine. Allergic reactions may occur, sometimes severe, although they are rare. These reactions show as a rash, itching, hives, angioedema and anaphylactic shock. Severe skin reactions and inflammation of the lining of the mouth have been reported rarely.

Neurological disorders such as dizziness, vertigo, seizures (rarely) and uncoordinated movements, may occur. If any suspicious neurological symptoms appear, treatment should be stopped immediately.

Also reported are a transient decrease in white blood cells and changes in some clinical laboratory tests, which may be signs of an allergy to the medicine.

At the time of treatment, an additional vaginal infection in due to *Candida albicans* may also occur.

If you notice any side effects not listed in this leaflet, and which you consider to be serious, talk to your doctor or pharmacist.

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

5. How to store FASIGYN 500 mg film-coated tablet

Do not store above 25 ° C, or expose to light

Expiry date

Stop using FASIGYN after the expiry date (written as: month-year) on the packaging after "EXP."

6. Contents of the pack and other information

Contact your doctor or pharmacist for information on this medicine.

General classification for supply: by medical prescription.

7. FURTHER INFORMATION

Marketing Authorisation Holder:

Pfizer S.A. Boulevard de la Plaine, 17, 1050 Brussels, Belgium

Finished Product Manufacturing:

FAREVA AMBOISE
Zone Industrielle, 29 route des Industries, 37530 Pocé Sur Cisse, France

This Label was last revised in October 2014

To report any side effect(s):	
United Arab Emirates (UAE): Website : www.moh.gov.ae P.O. Box 848 Abu Dhabi Tel: (+971 2) 6117 329/6117389 Fax: (+971 2) 3613 742 Email: pv@moh.gov.ae	Iraq: Website: www.moh.gov.iq
Jordan: Website : www.jfda.jo Tel: 0096265632000 - 0096264602550 Fax: 0096265105916 - 0096265105893 E-mail : info@jfda.jo	Kuwait: Website: www.moh.gov.kw/kd/c/ P.O. BOX: 22575, SAFAT 13086 KUWAIT
Lebanon : Website : www.moph.gov.lb	Oman: Web site: www.moh.gov.om Tel: 0096824601044 Fax: 0096824602287 E-mail: mohphar@omantel.net.om
Qatar: Website: www.sch.gov.qa E-mail: info@sch.gov.qa	

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach and sight of children

**Council of Arab Health Ministers
Union of Arabic Pharmacists**