

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Fasign[®] 500 mg Film-coated Tablets



Each tablet contains Tinidazole 500 mg

A list of inactive and allergenic ingredients can be found in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

- For the treatment of genitourinary tract infections in both women and men caused by trichomonas vaginalis.
- For prevention of anaerobic infections following gynecological or abdominal surgery.

Therapeutic group:

A medicine from the azole group for the treatment of parasitic and bacterial infections.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:

- × Do not use the medicine if you are hypersensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine.
- × Do not use the medicine if you are in the first trimester of pregnancy or are breastfeeding.
- × Do not use the medicine if you are suffering from any neurological disease.
- × Do not use the medicine if you are suffering, or have suffered in the past, from abnormalities in the composition of the blood (blood dyscrasias).

Do not take the medicine without consulting the doctor before commencing treatment:

- If you are in the second or third trimester of pregnancy.
- If you are suffering, or have suffered in the past, from impaired function of the nervous system.
- If you are taking anticoagulants; the dosage of the anticoagulants should be monitored and adjusted if necessary.

Special warnings regarding use of the medicine

- If you are hypersensitive to any type of food or medicine, inform your doctor before taking the medicine.

⚠ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:

- Anticoagulants, since the dosage has to be monitored and adjusted if necessary, according to doctor's instructions.
- Disulfiram (for alcohol withdrawal) or within 14 days of cessation of treatment.

⚠ Use of Fasign[®] and food

Take the medicine with or after a meal. Swallow the medicine with a little water.

⚠ Use of the medicine and alcohol consumption

Do not drink any alcohol during the course of treatment with the medicine and for at least 72 hours after stopping treatment.

⚠ Pregnancy and breastfeeding

Do not use the medicine if you are in the first trimester of pregnancy or are breastfeeding.

If you are in the second or third trimester of pregnancy, consult the doctor before commencing treatment.

⚠ Driving and using machinery

Do not drive or operate dangerous machinery in the event that use of Fasign[®] causes you side effects such as: dizziness,

sleepiness and coordination and movement disturbances.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions! Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose!

Do not crush/half/chew since the tablets are film-coated.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose **each time** you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Fasign[®] may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer to the doctor immediately if:

you suffer from an allergic reaction such as: difficulty breathing, wheezing, swelling of the eyelids, face, lips or tongue, rash (urticaria), itching.

Side effects that require special attention:

Dizziness, vertigo, convulsions (rare), coordination and movement disturbances, lack of muscle control, decreased sensitivity to pain, tingling, peripheral neuropathy, sensory disturbances, loss of appetite, mouth inflammation, tongue inflammation and tongue discoloration.

Additional side effects:

Fever, fatigue, diarrhea, nausea/vomiting, abdominal pain, headache, taste disturbances, dark urine, leukopenia.

If one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store the medicine at a temperature below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose PH 102, Alginate, Maize starch (dried), Hydroxypropyl methylcellulose 2910, Vegetable Magnesium stearate, Titanium dioxide E171, Propylene glycol, Sodium lauryl sulfate.

What does the medicine look like and what are the contents of the package:

Fasign[®] 500 mg: A round white tablet with "FAS 500" imprinted on one side.

The medicine is supplied in blister packs of 4 tablets.

Manufacturer: Pfizer PGM, France.

License holder: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

This leaflet was checked and approved by the Ministry of Health in December 2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 111-99-21327-00