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

The medicine is dispensed with a doctor's prescription only

PROTOCIDE

Film-coated Tablets

Active ingredient:

Each tablet contains:

Tinidazole 500 mg

For the list of inactive and allergenic ingredients in the preparation, see section 6: "Further information" and section 2: "Before using the medicine".

Read the 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 to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of infections in the genitals and in the urinary tracts in both women and men, caused by trichomonas vaginalis.

For prevention of infections by anaerobic bacteria after gynecological and abdominal surgeries.

Therapeutic group: Azole antibiotics.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to tinidazole, to similar medicines, or to any of the additional ingredients contained in the medicine (see section 6: "Further information"). An allergic reaction can cause itching, skin rash or breathing difficulties with wheezing.
- You are in the first trimester of pregnancy (the first 13 weeks of pregnancy), are trying to become pregnant or are breastfeeding.
- You suffer from a central nervous system disease, including epilepsy.
- You suffer, or have suffered in the past, from an impairment in the blood system (blood dyscrasia).

Special warnings regarding use of the medicine:

Inform the doctor or pharmacist if you develop abnormal neurological signs (such as: dizziness, vertigo, difficulty in controlling movements) during treatment with **Protocide**, as you may be asked to stop treatment with the medicine.

If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In particular, inform the doctor if you are taking:

Blood thinners to prevent blood clots, such as Warfarin; your doctor may need to monitor your condition more carefully.

Use of the medicine and consumption of food and beverages

Do not drink wine, beer or alcoholic beverages during the course of treatment with the medicine, and for 3 days after completing treatment with **Protocide**. The combination of alcohol with this medicine may cause flushing, abdominal cramps, vomiting and a pounding heart (palpitations).

Pregnancy, breastfeeding and fertility

Pregnancy

Do not use this medicine during the first trimester of pregnancy (the first 13 weeks of pregnancy) or if you are trying to become pregnant. **Consult the doctor or pharmacist about taking this medicine during the second and third trimesters of pregnancy.**

Breastfeeding

Do not use this medicine if you are breastfeeding, as small amounts of the medicine may pass into breast milk. If you stop breastfeeding during the course of treatment with the medicine, do not start breastfeeding again before at least 3 days have passed after stopping treatment with the medicine.

Fertility

Fertility of both sexes can be affected by taking this medicine. Therefore, consult the doctor if you plan to become pregnant.

Driving and operating machinery

Do not drive a vehicle or operate machinery if using this medicine causes you to feel drowsy or to have problems with coordination or sensation (for example, numbness or weakness).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

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

Adhere to the treatment regimen as recommended by the doctor.

Swallow the medicine with a glass of water, with or after a meal.

Do not halve the tablet. There is no information regarding crushing or chewing the tablet.

It is recommended to take the medicine at the same time each day.

Do not exceed the recommended dose.

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

If you forgot to take this medicine at the required time, take the forgotten dose as soon as you remember. However, if it is almost time for the next dose, skip the forgotten dose and take the next dose at the right time. Do not take a double dose to compensate for the forgotten dose.

If you stop taking the medicine too soon, the infection may return. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a 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 **Protocide** 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.

Refer to a doctor immediately if you experience the following symptoms during the course of treatment with the medicine:

Although the following side effects are very rare, the symptoms can be severe.

- Difficulty in breathing accompanied by sudden wheeziness, swelling of the eyelids, face, lips or tongue.
- Fits or seizures.

Common side effects (occur in 1-10 in 100 users):

These effects may go away during treatment when the body adjusts to the medicine. Refer to the doctor if these side effects bother you.

- Nausea or vomiting, loss of appetite, diarrhea, stomach pain or cramps.
- Headache.
- Vertigo (see section 2: "Special warnings regarding use of the medicine").
- Skin rash or itching (especially if occur over the whole body).

The frequency of the following side effects is not known (the frequency cannot be estimated based on the available data):

Refer to the doctor if you notice the following side effects:

- Numbness, tingling, pain or weakness in the hands and feet.
- Clumsiness or unsteadiness.
- Fever or chills and painful ulcers in the mouth.
- Pain or swelling in the mouth/tongue.
- Redness of the face or neck.
- Dizziness.
- Tiredness.
- Dark urine.
- Tongue discoloration or metallic taste in the mouth.

Protocide may sometimes cause a temporary reduction in white blood cells (leukopenia) which, in most cases, does not manifest itself by symptoms.

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

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects. Additionally, you can report to "Unipharm Ltd".

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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 below 25°C and in a place protected from light.

6. FURTHER INFORMATION

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

Maize starch; Calcium hydrogen phosphate; Microcrystalline cellulose; Povidone; Pregelatinized starch; Hydroxypropyl methylcellulose; Propylene glycol; FD&C yellow; Opadry orange OY-3569.

What the medicine looks like and the contents of the package:

Protocide are orange, film-coated, round, biconvex tablets. **Protocide** is packaged in trays (blisters) contained in a carton box. Each package of **Protocide** has 4, 14, 20 and 1000 tablets. Not all package sizes may be marketed.

Registration holder and address:
Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

Manufacturer and address:
Unipharm Ltd., "Mevo Carmel" Industrial Park.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Protocide: 107 87 21159 01

Revised in February 2022 according to MOH guidelines.

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