

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

The medicine is dispensed with a doctor's prescription only

# Xenical® 120 mg, Capsules

Composition: Each capsule contains: **Orlistat 120 mg**  
\* For information on the inactive ingredients, see section 6 "Further Information".

Read this leaflet carefully in its entirety before using this 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 the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children under 12 years of age.

**Important information for your review:**

- **Xenical** is used to treat obesity.
- It is important to follow the nutritional program (diet) recommended for you. Adhering to the doctor's guidelines (dosage, directions for use and duration of treatment) increases the chance of treatment success. Please review sections 2 and 4 for detailed safety information.

**1. WHAT IS THE MEDICINE INTENDED FOR?**

For treatment of obesity, in conjunction with a mild diet, when the body mass index (BMI) is equal to or greater than 30 kg/m<sup>2</sup> (or with other risk factors, when the BMI is equal to or greater than 28 kg/m<sup>2</sup>).

This preparation blocks certain enzymes in the digestive system and consequently prevents the absorption of approximately 30% of the fats in the meal, which are eliminated undigested from the body.

**Xenical** attaches to enzymes in the digestive system (lipases) and blocks them from breaking down fats you have eaten during your meal. The undigested fats cannot be absorbed and are eliminated by your body.

**Therapeutic group:**

**Xenical** is a medicine for the treatment of obesity which does not act on the central nervous system.

**2. BEFORE USING THE MEDICINE**

- ☒ Do not use the medicine if:
- you have a known sensitivity to the active ingredient orlistat or to any of the ingredients of the medicine mentioned in section 6 "Further Information".
  - you suffer from chronic absorption problems in the digestive system.
  - you suffer from impaired function of the liver (cholestasis).
  - you are breastfeeding.

**Special warnings regarding use of the medicine**

Do not use the medicine without consulting a doctor before commencing treatment:

- If you are taking medicines for other ailments. Weight loss may affect the dosage of other medicines that you are taking to treat other conditions (e.g., high cholesterol or diabetes). Consult a doctor; a dosage adjustment of the other medicines may be necessary due to weight loss.
- In order to achieve the maximal benefit from **Xenical** treatment, follow the nutrition program recommended to you by the doctor. As with any weight loss program, over-consumption of fats and calories may reduce weight loss effect.
- This medicine may cause harmless changes in bowel habits, such as oily stools, due to the elimination of undigested fats from your body. The possibility of this happening increases when the medicine is taken with a meal high in fats. It is therefore important to distribute the daily fat intake evenly over the three main meals.
- In cases of severe diarrhea, the use of an additional contraceptive method is recommended in order to prevent possible failure of oral contraception.
- If you suffer from impaired kidney function. Use of the medicine may be associated with renal stones in patients suffering from a chronic kidney disease.

**Xenical and other medicines**

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

- Anticoagulants (e.g., warfarin). The doctor may monitor blood coagulation.
- Cyclosporine. Co-administration with cyclosporine is not recommended. The doctor may monitor cyclosporine blood levels more frequently than usual.
- Iodine salts and/or levothyroxine. Cases of hypothyroidism and/or reduced balance of existing hypothyroidism may occur.
- Amiodarone.
- Medicines to treat AIDS.
- Medicines to treat depression, psychiatric disorders and anxieties.

**Xenical** reduces the absorption of some oil-soluble vitamins, particularly beta carotene and vitamin E. It is important to follow the doctor's instructions and to keep a well-balanced diet, rich in fruits and vegetables. The doctor may recommend that you take multivitamins.

**Xenical** may reduce absorption of antiepileptic medicines, and thus unbalance treatment, and lead to an epileptic attack. Contact the doctor if you notice a change in the frequency and/or severity of the attacks during the course of treatment with **Xenical** given in combination with antiepileptic medicines.

**Xenical** is not recommended for patients taking acarbose (an anti-diabetic drug given to treat type 2 diabetes mellitus).

**Use of the medicine and food**

The medicine can be taken immediately before the meal, during the meal or up to one hour after the meal. Swallow the medicine with water.

**Pregnancy and breastfeeding**

If you are pregnant, consult a doctor. **Xenical** is not recommended during pregnancy.

Do not breastfeed your baby during the course of treatment with **Xenical**, as it is not known if the medicine passes into the breastmilk.

**Driving and use of machines**

The preparation has no known effect on the ability to drive or operate machinery.

**3. HOW SHOULD YOU USE THE MEDICINE?**

Always use according to the doctor's instructions. The dosage and the treatment regimen will be determined by the doctor only. Check with the doctor or pharmacist if you are uncertain.

The usual dosage is generally one 120 mg capsule taken with each of the three main meals per day.

Do not exceed the recommended dose.

The medicine can be taken immediately before the meal, during the meal or up to one hour after the meal. Swallow the capsules with water.

**Xenical** should be taken with a balanced, low-calorie and well-controlled diet, rich in fruits and vegetables, where 30% of the calories are from fat sources.

It is important to equally distribute the fat, carbohydrate and protein intake amongst the three main meals. Therefore, one capsule should usually be taken with breakfast, one with lunch and one with dinner.

In order to reach optimal results with the **Xenical** treatment, it is important to adhere to the nutritional program (diet) recommended for you. As with any weight loss program, overeating fats and high-calorie food products may reduce the weight loss. It is recommended to avoid eating food containing fat between meals, such as cookies, chocolate and the like.

If the medicine is taken with a meal very rich in fats, there may be an increase in side effects in the digestive system.

**Xenical** is effective only in the presence of dietary fats. Therefore, if you miss a main meal or if you have a meal containing no fat, then the dose of **Xenical** should be omitted.

Inform the doctor if, for any reason, you did not take the medicine exactly as per the guidelines that you were given, as if you don't, the doctor may think that the medicine is not effective and may unnecessarily change the treatment.

The doctor may discontinue the **Xenical** treatment after 12 weeks if there was no decrease of at least 5% of the body weight.

**Xenical** reduces the absorption of oil-soluble vitamins, and therefore, there may be a need to take multivitamins. If you are taking multivitamins containing vitamins A, D, E, K or beta carotene, be sure to take them at an interval of at least two hours from taking **Xenical** or before bedtime – see above "Xenical and other medicines".

To date, there are clinical data for the **Xenical** preparation from long-term clinical studies of up to four years duration.

If you accidentally took a higher dosage or if a child 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; you may need medical attention.

If you forgot to take the medicine at the scheduled time, take it as soon as you remember, on the condition that no more than one hour from the last meal has passed. After that, continue taking the preparation at the designated times. Do not take two doses together. If you forgot to take the medicine a few times, consult with the doctor and follow his guidelines. Do not change the dosage of the medicine unless instructed to do so by the doctor.

Adhere to the treatment regimen as recommended by the doctor. **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 **Xenical** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Most of the side effects associated with use of **Xenical** arise from its activity on your digestive system. These symptoms are generally mild, occur at the beginning of treatment and are manifested after meals rich in fats. These symptoms usually pass, if the treatment is continued and adhered to and the recommended diet is followed.

**Very common side effects (affect more than one patient in 10 patients):**

Headache, abdominal pain/discomfort, urgent or increased need to move the bowels, flatulence with discharge, oily discharge, oily or liquid stools, low blood sugar levels (experienced by some people with type 2 diabetes), upper respiratory tract infections.

**Common side effects (affect 1-10 patients in 100 patients):**

Rectal pain/discomfort, soft stools, difficulty controlling bowel movements, sensation of abdominal bloating (experienced by some people with type 2 diabetes), tooth/gum problems, irregularity of menstrual cycle, tiredness, lower respiratory tract infections, anxiety, urinary tract infections.

Additional side effects reported at unknown frequency:

Allergic reactions. The main symptoms are: itching, rash, wheals (slightly elevated, itchy skin areas that are paler or redder than the surrounding skin), severe difficulty in breathing, nausea, vomiting and feeling unwell, skin blisters including blisters that burst. Diverticulitis. Bleeding from the rectum, elevation of certain liver enzyme levels in blood tests. Hepatitis symptoms which can include: yellow skin and eyes, itching, dark-colored urine, stomach pain and liver tenderness (experienced as a pain under the ribs on the right-hand side), sometimes accompanied by loss of appetite. Stop taking **Xenical** and inform the doctor if these symptoms occur. Gallstones. Pancreatitis, kidney disease (build-up of calcium oxalate which may lead to kidney stones). See section 2 - "Before using the medicine". When taking anticoagulants - coagulation may be affected.

If any of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the online side effects reporting form that can be found on the homepage of the Ministry of Health [www.health.gov.il](http://www.health.gov.il) or through the following link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdverseEffectMedic@mo.gov.il>

**5. HOW SHOULD THE MEDICINE BE STORED?**

**Avoid poisoning!** This medicine and any other medicine must be kept in a closed 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. **Storage conditions:** Do not store above 25°C. Store in the original package to protect the medicine from moisture and light.

Do not dispose the medicine in the sink or household wastebin. Consult a pharmacist as to how to dispose of medicines no longer required. These measures will help protect the environment.

**6. FURTHER INFORMATION**

In addition to the active ingredient, the medicine also contains: Microcrystalline cellulose, sodium starch glycolate, polyvidone K30, sodium lauryl sulphate and talc.

Indigo carmin (E132 Cl 73015), Titanium dioxide (E171, Cl 77891), Printing ink, Gelatin.

What does the medicine look like and what are the contents of the pack?

**Xenical** capsules are turquoise, with imprint "XENICAL 120". The capsules are provided in trays (blisters) that contain 7, 21, 42, 84 capsules. Not all package sizes may be marketed. License holder and address: Tzamal Bio-Pharma Ltd., 20 Hamagshimim St., Petach-Tikva, Israel Manufacturer and address: CHEPLAPHARM Arzneimittel GmbH, Greifswald, Germany.

This leaflet was checked and approved by the Ministry of Health in November 2015. Registration number of the medicine in the National Drug Registry of the Ministry of Health: 114.32.29627