Orlistat 120 mg Capsules, hard

4. Possible side effects

- Oily spotting from the rectum and faeces
- Lower respiratory tract infection
- Incontinence (stools)
- Tooth/gum disorder
- Rectal pain/discomfort
- Upper respiratory tract infection
- Skin and eye symptoms
- Itching, redness, or rash
- Severe difficulty in urination
- Enlarged tongue
- Severe difficulty in breathing
- Changes in the colour of your testicles

5. How to store Orlistat 120 mg

- Protect from light and moisture.
- Do not store above 25°C.
- Store in the original container.
- Do not refrigerate.
- Do not freeze.
- Do not use after the expiry date.

6. Disposal of the unused product

- Do not flush pharmaceutical products down the toilet or pour them on the ground. Place any unused product out of the reach of children.

For more information, contact the local waste authority, the national disposal service, or your doctor.

7. Further information

- Always ask your doctor or pharmacist if you are not sure about anything.
- The active substance is orlistat. Each capsule contains 120 mg of orlistat.
- The inactive ingredients are: cellulose microcrystalline, sodium laurylsulfate, silica colloidal anhydrous, sorbitol, magnesium stearate, ammonium carbonate, hydroxypropyl methylcellulose, polyethylene glycol 6000, titanium dioxide (type A), croscarmellose sodium.
- The capsule filling: microcrystalline cellulose, lactose monohydrate, silica anhydrous, magnesium stearate.
- The hard capsule contains 120 mg of orlistat.
Orlistat Capsules is not intended to be taken with renal stones in patients suffering from them. It could occur in cases of severe diarrhoea. A diet is recommended to prevent this happening. The use of an additional contraceptive method is recommended to prevent pregnancy. The possibility of this happening may occur in women who are using a method which could fail. To gain the maximum benefit from Orlistat Capsules, it may be taking with your doctor. Losing weight may also affect the dose of other medicines you are taking with your doctor. Losing weight may also affect the dose of other medicines you are taking.

Weight loss may also affect the dose of some other medicines you are taking with your doctor. Losing weight may also affect the dose of some other medicines you are taking.

To the dose of these medicines. Your doctor will discontinue the treatment with Orlistat Capsules after 12 weeks if you have lost at least 5% of your body weight as measured at the start of treatment with Orlistat Capsules and have continued to lose weight. Orlistat Capsules has been studied in long-term clinical studies of up to 4 years duration.

If you take more Orlistat Capsules than you should
If you take more than you have been told to take, or if someone else accidentally takes your medicine, contact a doctor, pharmacist or hospital immediately as you may need medical attention.

If you forget to take Orlistat Capsules
If you forget to take your medicine at any time, take it as soon as possible. Do not take a double dose to make up for a forgotten dose. If you have missed several doses, please inform your doctor and follow the advice given to you.

Do not change the prescribed dose yourself unless your doctor tells you to.

If you have further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Orlistat Capsules. The majority of unwanted effects related to the use of Orlistat Capsules result from its local action in your digestive system. The symptoms are usually mild, occur at the beginning of treatment and are particularly experienced after meals containing high levels of fat. Normally, these symptoms disappear if you continue to take the medicine and keep to your recommended diet.

Very common side effects (these may affect more than 1 in 10 patients)
• headache
• upper respiratory tract infection
• abdominal pain/discomfort
• oily spotting from the rectum
• urgent or increased need to open the bowels
• flatulence (wind) with or without discharge
• oily or fatty stools
• liquid stools
• low blood sugar levels (experienced by some people with type 2 diabetes)
• flu infection

Common side effects (these may affect up to 1 in 10 patients)
• lower respiratory tract infection
• rectal pain/discomfort
• soft stools
• incontinence (stools)
• bloating (experienced by some people with type 2 diabetes)
• breathlessness (dyspnoea)
• urinary tract infection
• irregularity of menstrual cycle
• tiredness
• anxiety

The following side effects have also been reported but their frequency cannot be estimated from the available data:
• allergic reactions. The main symptoms are itching, rash, wheals (slightly elevated, itchy skin patches that are paler or redder than surrounding skin), severe difficulty in breathing, nausea, vomiting and feeling unwell. Contact your doctor immediately if you experience any of these.
• bleeding from the back passage (rectum).
• increases in the levels of some liver enzymes may be found in blood tests.
• diarrhoea. The most common symptom is abdominal pain. Champing, nausea, vomiting, loss of appetite or a change in bowel habits may also appear.
• gallstones
• haematuria (inflammation of the liver). Symptoms can include yellowing of skin and eyes, itching, dark coloured urine, stomach pain and liver tenderness (induced by pain under the front of the rib cage on your right hand side), sometimes with loss of appetite.
• skin blistering (including blisters that burst).
• effects on clotting with antiepileptic drugs.
• pancreatitis (inflammation of the pancreas)
• oxalate nephropathy (build up of calcium oxalate which may lead to kidney stones). See section 2, Warnings and precautions.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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.

How to store Orlistat 120 mg Capsules
Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after “EXP” the expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original packaging in order to protect from light and moisture.

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

Contents of the pack and other information
What Orlistat 120 mg Capsules contains
• The active ingredient is: orlistat 120 mg (per hard capsule).
• The other ingredients are: cellulose, sodium starch glycolate (E460), magnesium stearate (E460), croscarmellose sodium (E301), sodium lauryl sulphate (E491), red iron oxide (E172), yellow iron oxide (E172), hydrogenated vegetable oil (E467), kaolin (E551), titanium dioxide (E171), magnesium stearate (E172). See section 6, What other ingredients are in this medicine?

What Orlistat 120 mg Capsules looks like and contents of the pack
Orlistat 120 mg Capsules are blue and are supplied in blister packs, containing 21, 42, 60, 90 and 120 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Teva UK Limited, Eastbourne, BN22 9AG, United Kingdom
Manufacturer: Pharmaceutical Works Polpharma SA, 18, Piotrkowska Street, 83-200 Starogard Gdański, Poland

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