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DIMENSIONS 150 + 150 x 304,5 mm
MATERIAL NUMBER 90001630/12
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PRODUCT CODE DP 86068917 ID-CP

Xenical®

Orlistat

86068917 ID-CP 90001630/12

1. DESCRIPTION

1.1 Therapeutic / Pharmacological Class of Drug
Peripherally acting anti-obesity agent

1.2 Type of Dosage Form
Capsule, hard, 120 mg.

1.3 Route of Administration
Oral

1.4 Sterile / Radioactive Statement
Not applicable.

1.5 Qualitative and Quantitative Composition
Active ingredient: orlistat.

2. CLINICAL PARTICULARS

2.1 Therapeutic Indication(s)

Xenical is indicated in conjunction with a mildly hypocaloric diet for treatment of obese patients with a body mass index (BMI) greater or equal to 30 kg/m², or overweight patients (BMI >28 kg/m² with associated risk factors).

Treatment with orlistat should only be started if diet alone has previously produced a weight loss at least 2.5 kg over a period of 4 consecutive weeks. Treatment with orlistat should be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of drug therapy.

2.2 Dosage and Administration

2.2.1 Standard Dosage

The recommended dose of Xenical is one 120 mg capsule with each main meal (during or up to one hour after the meal). If a meal is missed or contains no fat, the dose of Xenical may be omitted. There are no safety and efficacy data beyond 2 years, therefore the duration of treatment with orlistat should not be longer than 2 years.

The patient should be on a nutritionally balanced, mildly hypocaloric diet that contains approximately 30% of calories from fat. It is recommended that the diet should be rich in fruit and vegetables. The daily intake of fat, carbohydrate and protein should be distributed over three main meals.

Doses above 120 mg three times daily have not been shown to provide additional benefit.

2.2.2 Special Dosage Instructions

Hepatic and/or renal impairment & Elderly

The effect of orlistat in patient with hepatic and renal impairment and elderly has not been studied.

Children below the age of 18 years

The safety and efficacy of Xenical in children has not been established.

Orlistat is not intended to be used in children.

2.3 Contraindications

Xenical is contraindicated in patients with chronic malabsorption syndrome, cholestasis, breast-feeding and in patients with known hypersensitivity to orlistat or any of the components contained in the medicinal product.

2.4 Warnings and Precautions

2.4.1 General

A reduction in cyclosporine plasma levels has been observed when Xenical is co-administered. Therefore it is recommended to monitor more frequently than usual the cyclosporine plasma levels when Xenical is co-administered (see section 2.4.5, Interactions with other Medicinal Products and other Forms of Interaction).

The majority of patients in long term studies of up to four years of treatment had vitamin A, D, E and K and beta-carotene levels within normal range. In order to ensure adequate nutrition, the use of a multivitamin supplement should be considered.

Patients should be advised to adhere to dietary guidelines (see section 2.2, Dosage and Administration). The possibility of experiencing gastrointestinal events (see section 2.6, Undesirable Effects) may increase when Xenical is taken with a diet high in fat (e.g. in a 2000 kcal/day diet, >30% of calories from fat equates to >67 g of fat) [15]. The daily intake of fat should be distributed over three main meals. If Xenical is taken with any one meal very high in fat, the possibility of gastrointestinal effects may increase. Weight loss induced by Xenical is accompanied by improved metabolic control in type 2 diabetics which might allow or require reduction in the dose of hypoglycemic medication (e.g. sulfonylureas).

In clinical trials, the decrease in bodyweight with orlistat treatment was less in type II diabetic patients than in non-diabetic patients. Antidiabetic drug treatment may have to be closely monitored when taking orlistat. Treatment

with orlistat may potentially impair the absorption of fat-soluble vitamins (A,D,E,K).

In order to ensure adequate nutrition, patients on weight control diet should be advised to have a diet rich in fruit and vegetables and use of a multivitamin supplement could be considered. If a multivitamin supplement is recommended, it should be taken at least two hours after the administration of orlistat or at bedtime

2.4.2 Drug Abuse and Dependence

No text.

2.4.3 Ability to Drive and Use Machines

No information available.

2.4.4 Laboratory Tests

Coagulation parameters, such as international normalised ratio (INR) values, should be monitored in patients treated with concomitant oral anticoagulants.

2.4.5 Interactions with other Medicinal Products and other Forms of Interaction

Decreases in the absorption of vitamin D, E and β -carotene have been observed when co-administered with Xenical. If a multivitamin supplement is recommended, it should be taken at least two hours after the administration of Xenical or at bedtime.

A reduction in cyclosporine plasma levels has been observed when Xenical is co-administered (see section 2.4.1, Warnings and Precautions, General). Therefore it is recommended to monitor more frequently than usual the cyclosporine plasma levels when Xenical is co-administered (see section 2.4.1, Warnings and Precautions, General).

In a PK study, oral administration of amiodarone during orlistat treatment demonstrated a 25 - 30% reduction in the systemic exposure to amiodarone and desethylamiodarone. Due to the complex pharmacokinetics of amiodarone, the clinical effect of this is unclear. The effect of commencing orlistat treatment in patients on stable amiodarone therapy has not been studied. A reduced therapeutic effect of amiodarone is possible.

Convulsions have been reported in patients treated concomitantly with orlistat and antiepileptic drugs. A causal relationship has not been established however patients should be monitored for possible changes in the frequency and/or severity of convulsions.

The vast majority of patients in up to 2 years of treatment had vitamin levels that stayed well within normal range.

In the absence of pharmacokinetic interaction studies, the concomitant administration of orlistat with Acarbose or anorectic drug is not recommended.

No interactions based on specific drug-drug-interaction studies with amitriptyline, atorvastatin, biguanides, digoxin, metformin, fibrates, fluoxetine, losartan, phenytoin, oral contraceptives, phentermine, pravastatin, warfarin, nifedipine Gastrointestinal Therapeutic System (GITS), nifedipine slow release, sibutramine or alcohol have been observed. However, orlistat enhanced the bioavailability (plasma concentrations increases by approximately 30%) and lipid lowering effect of pravastatin.

However, When warfarin or other oral anticoagulants are given in combination with, international normalised ratio (INR) values should be monitored.

2.5 Use in Special Populations

2.5.1 Pregnancy

In animal reproductive studies, no embryotoxic or teratogenic effects were observed with orlistat. In absence of a teratogenic effect in animals, no malformative effect is expected in human beings. However, Xenical is not recommended for use during pregnancy in the absence of clinical data.

2.5.2 Labor and Delivery

No text.

2.5.3 Nursing Mothers

The secretion of orlistat in human breast milk has not been investigated. Xenical should not be taken during breast-feeding.

2.5.4 Pediatric Use

Clinical investigations in children under the age of 18 have not been undertaken.

2.5.5 Geriatric Use

No text.

2.5.6 Renal impairment

Clinical investigations in patients with renal and/or hepatic impairment have not been undertaken.

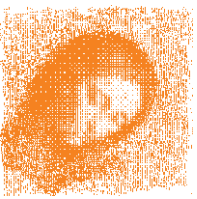
2.5.7 Hepatic impairment

Clinical investigations in patients with hepatic and/or renal impairment have not been undertaken.

2.6 Undesirable Effects

2.6.1 Clinical Trials

Adverse reactions to Xenical are largely gastrointestinal in nature and related to the pharmacologic effect of the drug on preventing the absorption of ingested fat. Commonly observed events are oily spotting, flatus with discharge, fecal



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urgency, fatty/oily stool, oily evacuation, increased defecation and fecal incontinence. The incidence of these increases the higher the fat content of the diet. Patients should be counseled as to the possibility of gastrointestinal effects occurring and how best to handle them such as reinforcing the diet, particularly the percentage of fat it contains. Consumption of a diet low in fat will decrease the likelihood of experiencing adverse gastrointestinal events and this may help patients to monitor and regulate their fat intake.

These adverse gastrointestinal reactions are generally mild and transient. They occurred early in treatment (within 3 months) and most patients experienced only one episode.

Treatment-emergent GI-adverse events that occurred commonly among patients treated with Xenical were: abdominal pain/discomfort, flatulence, liquid stools, soft stools, rectal pain/discomfort, tooth disorder, gingival disorder.

Other events observed were: upper respiratory infection, lower respiratory infection; influenza; headache; menstrual irregularity; anxiety; fatigue; urinary tract infection.

2.6.1.1 Laboratory Abnormalities

No text.

2.6.2 Post Marketing

Rare cases of hypersensitivity have been reported. Main clinical symptoms are pruritus, rash, urticaria, angioedema, bronchospasm, and anaphylaxis. Very rare cases of bullous eruption, increase in liver transaminases and in alkaline phosphatase, and exceptional cases of severe liver injury, some resulting in liver transplant or death, have been reported. No causal relationship or physiopathological mechanism between liver injury and orlistat therapy has been established.

Reports of decreased prothrombin, increased INR and unbalanced anticoagulant treatment resulting in change of hemostatic parameters have been reported in patients treated concomitantly with orlistat and anticoagulants during post-marketing (see section 2.4.5, Interactions with other Medicinal Products and other Forms of Interaction).

Convulsions have been reported in patients treated concomitantly with orlistat and antiepileptic drugs (see section 2.4.5, Interactions with other Medicinal Products and other Forms of Interaction).

Cases of hyperoxaluria and oxalate nephropathy have been reported. Some patients taking Xenical may develop an increased risk for the development of kidney stones. Promptly report any symptoms of back pain or blood in the urine.

2.6.2.1 Laboratory Abnormalities

No text.

2.7 Overdose

Single doses of 800 mg Xenical and multiple doses of up to 400 mg t.i.d. for 15 days have been studied in normal weight and obese subjects without significant adverse findings. In addition, doses of 240 mg t.i.d. have been administered to obese patients for 6 months without significant increase of adverse findings.

Orlistat overdose cases received during post-marketing reported either no adverse events or adverse events that are similar to those reported with recommended dose.

Should a significant overdose of Xenical occur, it is recommended that the patient be observed for 24 hours. Based on human and animal studies, any systemic effects attributable to the lipase-inhibiting properties of orlistat should be rapidly reversible.

3. PHARMACOLOGICAL PROPERTIES AND EFFECTS

3.1 Pharmacodynamic Properties

3.1.1 Mechanism of Action

Xenical is a potent, specific and reversible long-acting inhibitor of gastrointestinal lipases. It exerts its therapeutic activity in the lumen of the stomach and small intestine by forming a covalent bond with the serine residue of the active site of gastric and pancreatic lipases. The inactivated enzyme is thus unable to hydrolyse dietary fat, in the form of triglycerides, into absorbable free fatty acids and monoglycerides. As undigested triglycerides are not absorbed, the resulting caloric deficit has a positive effect on the weight control. Systemic absorption of the drug is therefore not needed for activity.

Based on fecal fat measurements, the effect of Xenical is seen as soon as 24 - 48 hours after dosing. Upon discontinuation of therapy, fecal fat content usually returns to pre-treatment levels, within 48-72 hours.

3.1.2 Efficacy / Clinical Studies

No text

3.2 Pharmacokinetic Properties

3.2.1 Absorption

In normal weight and obese volunteers, systemic exposure to orlistat was minimal. Plasma concentrations of intact orlistat were nearly non-measurable (< 5 ng/mL) following a single oral administration of 360 mg orlistat.

In general, after long-term treatment at therapeutic doses, detection of intact orlistat in plasma was sporadic

and concentrations were extremely low (<10 ng/mL or 0.02 µM), without evidence of accumulation showing consistency with negligible absorption.

3.2.2 Distribution

The volume of distribution cannot be determined because the drug is minimally absorbed. In vitro orlistat is > 99% bound to plasma proteins (lipoproteins and albumin were the major binding proteins). Orlistat minimally partitions into erythrocytes.

3.2.3 Metabolism

Based on animal data, it is likely that the metabolism of orlistat occurs mainly within the gastrointestinal wall. Based on a study in obese patients, of the minute fraction of the dose that was absorbed systemically, two major metabolites, M1 (4-member lactone ring hydrolysed) and M3 (M1 with N-formyl leucine moiety cleaved), accounted for approximately 42% of the total plasma concentration.

M1 and M3 have an open β-lactone ring and extremely weak lipase inhibitory activity (1000 and 2500 fold less than orlistat respectively). In view of this low inhibitory activity and the low plasma levels at therapeutic doses (average of 26 ng/ml and 108 ng/ml respectively), these metabolites are considered to be pharmacologically inconsequential.

3.2.4 Elimination

Studies in normal weight and obese subjects have shown that fecal excretion of the unabsorbed drug was the major route of elimination. Approximately 97% of the administered dose was excreted in feces and 83% of that as unchanged orlistat.

The cumulative renal excretion of total orlistat-related materials was <2% of the given dose. The time to reach complete excretion (fecal plus urinary) was 3-5 days. The disposition of orlistat appeared to be similar between normal weight and obese volunteers. Orlistat, M1 and M3 are all subject to biliary excretion.

3.2.5 Pharmacokinetics in Special Populations

No text

3.3 Preclinical Safety

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

3.3.1 Carcinogenicity

See section 3.3, Preclinical Safety.

3.3.2 Mutagenicity

See section 3.3, Preclinical Safety.

3.3.3 Impairment of Fertility

See section 3.3, Preclinical Safety.

3.3.4 Teratogenicity

In animal reproductive studies, no teratogenic effect was observed. In the absence of a teratogenic effect in animals, no malformative effect is expected in man.

3.3.5 Other

No text.

4. PHARMACEUTICAL PARTICULARS

4.1 Storage

This medicine should not be used after the expiry date (EXP) shown on the pack.

Do not store above 25°C. Store in original package and keep the blister in the outer carton, in order to protect from light and moisture.

Shelf life: 36 months

4.2 Special Instructions for Use, Handling and Disposal

No special requirements.

4.3 Incompatibilities

No known incompatibilities.

Packs

Capsules 120mg

Box of 4 blisters of 21 capsules

Box of 1 blister of 21 capsules

Reg. No.: DK11972200401A1

Medicine: keep out of reach of children
On medical prescription only
Harus dengan resep dokter

Made for:

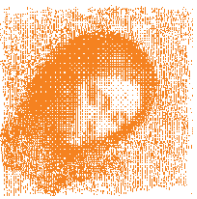
CHEPLAPHARM Arzneimittel GmbH, Ziegelhof 24,
17489 Greifswald, Germany

Manufactured by:

Delpharm Milano S.r.l.,
Via Carnevale 1, 20054 Segrate (MI), Italy

Registered by:

PT. Pyridam Farma Tbk.
Cianjur, Indonesia



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Informasi Produk untuk Pasien

Xenical® 120 mg kapsul keras

Orlistat

Baca isi leaflet ini dengan seksama sebelum Anda mulai menggunakan obat ini karena leaflet ini mengandung informasi yang penting bagi Anda.

- Simpan leaflet ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Obat ini hanya diresepkan untuk Anda. Jangan diberikan kepada orang lain. Karena mungkin berbahaya bagi mereka, bahkan jika gejala atau sakit yang mereka alami sama dengan Anda.
- Jika Anda mengalami efek samping, bicarakan dengan dokter atau apoteker Anda. Termasuk efek samping yang mungkin tidak tercantum dalam leaflet ini. Lihat bagian 4.

Apa saja yang ada pada leaflet ini

1. Apakah Xenical itu dan apa kegunaannya
2. Apa yang perlu Anda ketahui sebelum Anda menggunakan Xenical
3. Bagaimana cara penggunaan Xenical
4. Kemungkinan efek samping
5. Bagaimana cara penyimpanan Xenical
6. Isi kemasan dan informasi lainnya

1. Apakah XENICAL itu dan apa kegunaannya

Xenical adalah obat yang digunakan untuk mengobati kegemukan. Bekerja dalam sistem pencernaan untuk menghambat sekitar 1/3 lemak dalam makanan yang Anda makan untuk dicerna.

Xenical menempel pada enzim di sistem pencernaan Anda (lipase) dan menghambat mereka untuk memecah sebagian lemak yang Anda makan. Lemak yang tidak dicerna tidak dapat diserap dan dikeluarkan oleh tubuh Anda

Xenical diindikasikan dalam

pengobatan kegemukan bersamaan dengan asupan diet rendah kalori.

2. Apa yang perlu Anda ketahui sebelum Anda menggunakan XENICAL

Jangan menggunakan XENICAL

- jika anda alergi terhadap orlistat atau bahan lain yang terkandung dalam Xenical
- jika Anda mengalami sindrom malabrorspi kronik (penyerapan nutrisi yang tidak cukup dari saluran pencernaan)
- jika Anda mengalami kolestasis (gangguan hati)
- jika Anda sedang menyusui

Peringatan dan perhatian

Penurunan berat badan juga dapat mempengaruhi dosis obat yang digunakan untuk kondisi lain (misalnya kolesterol tinggi atau diabetes). Pastikan untuk mendiskusikan hal ini dan obat-obatan lain yang mungkin Anda gunakan dengan dokter Anda. Kehilangan berat badan mungkin berarti Anda perlu penyesuaian dengan dosis obat-obatan ini.

Untuk mendapatkan manfaat maksimal dari Xenical, Anda harus mengikuti program nutrisi yang direkomendasikan kepada Anda oleh dokter Anda. Seperti halnya program pengendalian berat badan, konsumsi lemak dan kalori yang berlebihan dapat mengurangi efek penurunan berat badan.

Obat ini dapat menyebabkan perubahan yang tidak berbahaya pada kebiasaan buang air besar Anda, seperti tinja berlemak atau berminyak, karena pengeluaran lemak yang tidak dicerna dalam faeces Anda. Kemungkinan hal ini terjadi dapat meningkat jika Xenical dikonsumsi dengan diet tinggi lemak. Selain itu asupan harian lemak Anda harus dibagi secara merata dalam tiga makanan utama karena jika Xenical dikonsumsi dengan makanan yang sangat tinggi lemaknya, kemungkinan efek gastrointestinal dapat meningkat.

Anak-anak

Xenical tidak digunakan pada anak-anak

Obat – obatan lain dan Xenical

Beritahu dokter atau apoteker Anda jika Anda sedang mengkonsumsi, baru saja mengkonsumsi obat-obatan lainnya, termasuk obat tanpa resep.

Ini penting karena menggunakan lebih dari satu obat pada saat yang bersamaan dapat memperkuat atau memperlemah efek obat-obatan.

Xenical dapat mengubah aktivitas dari:

- Obat antikoagulan (misal: Warfarin). Dokter Anda mungkin perlu memonitor koagulasi darah Anda.
- Ciclosporin. Dokter Anda mungkin perlu memonitor kadar ciclosporin dalam darah Anda lebih sering daripada biasanya.
- Amiodaron. Anda dapat meminta saran dokter Anda.
- Obat-obatan untuk depresi, gangguan psikiatri atau kecemasan

Xenical mengurangi penyerapan suplemen dari beberapa nutrisi yang larut dalam lemak, terutama beta-karoten dan vitamin E. Oleh karena itu, Anda harus mengikuti saran dokter Anda dalam mengambil diet seimbang yang kaya buah dan sayuran. Dokter Anda mungkin menyarankan Anda mengkonsumsi suplemen multivitamin.

Orlistat mungkin mempengaruhi pengobatan antikonvulsan, dengan mengurangi penyerapan obat antiepilepsi, sehingga menyebabkan kejang. Hubungi dokter Anda jika Anda berpikir bahwa frekuensi dan / atau keparahan dari kejang telah berubah ketika mengkonsumsi Xenical bersama dengan obat antiepilepsi.

Xenical tidak dianjurkan untuk orang yang menggunakan acarbose (obat anti-diabetes yang digunakan untuk mengobati diabetes mellitus tipe 2).

Xenical dengan makanan dan minuman

Xenical dapat diminum saat makan atau hingga satu jam setelah makan. Kapsul harus ditelan dengan air.

Kehamilan dan menyusui

Tidak dianjurkan mengkonsumsi Xenical selama kehamilan.

Anda tidak boleh menyusui selama pengobatan dengan Xenical karena tidak diketahui apakah Xenical masuk ke dalam Air Susu Ibu.

3. Bagaimana cara penggunaan XENICAL

Selalu gunakan Xenical persis seperti yang dikatakan dokter Anda. Jika Anda tidak yakin, Anda harus menanyakannya kepada dokter atau apoteker. Dosis umum Xenical adalah satu kapsul 120 mg yang diminum dengan masing-masing dari tiga makanan utama per hari. Dapat diminum saat makan atau hingga satu jam setelah makan. Kapsul harus ditelan dengan air.

Xenical harus digunakan bersamaan dengan diet seimbang, diet kalori terkontrol yang kaya buah dan sayuran dan mengandung rata-rata 30% kalori dari lemak. Asupan lemak, karbohidrat dan protein harian Anda harus dibagi dalam tiga kali makan. Ini berarti Anda biasanya akan mengkonsumsi satu kapsul saat sarapan, satu kapsul saat makan siang dan satu kapsul saat makan malam. Untuk mendapatkan manfaat optimal, hindari asupan makanan yang mengandung lemak di antara waktu makan, seperti biskuit, coklat, dan camilan gurih.

Xenical hanya berfungsi jika terdapat lemak makanan. Oleh karena itu, jika Anda melewatkan makanan utama atau jika Anda memakan makanan yang tidak mengandung lemak, Xenical tidak perlu diminum.

Katakan kepada dokter Anda jika, karena alasan apa pun, Anda belum minum obat persis seperti yang ditentukan. Jika tidak, dokter Anda mungkin berpikir bahwa itu tidak efektif atau ditoleransi dengan baik dan dapat mengubah pengobatan Anda secara tidak perlu.

Dokter Anda akan menghentikan pengobatan dengan Xenical setelah 12 minggu jika Anda belum kehilangan setidaknya 5% dari berat badan Anda yang diukur pada awal pengobatan dengan Xenical.

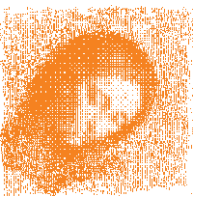
Jika Anda mengkonsumsi XENICAL lebih dari yang seharusnya

Jika Anda mengkonsumsi lebih banyak kapsul daripada yang seharusnya, atau jika orang lain secara tidak sengaja mengkonsumsi obat Anda, hubungi dokter, apoteker atau rumah sakit karena Anda mungkin memerlukan perawatan medis.

Jika Anda lupa mengkonsumsi XENICAL

Jika Anda lupa minum obat Anda kapan saja, minumlah segera setelah Anda ingat dalam waktu satu jam dari makanan terakhir Anda, kemudian lanjutkan untuk mengkonsumsi seperti biasanya. Jangan mengkonsumsi dosis ganda. Jika Anda melewatkan beberapa dosis, harap beri tahu dokter Anda dan ikuti saran yang diberikan kepada Anda. Jangan mengubah dosis yang ditentukan sendiri kecuali atas arahan dokter Anda.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.



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4. Kemungkinan efek samping

Seperti semua obat-obatan, Xenical dapat menimbulkan efek samping, meskipun tidak semua orang mengalaminya.

Segera beri tahu dokter atau apoteker Anda jika Anda merasa tidak enak badan selama menggunakan Xenical.

Mayoritas efek yang tidak diinginkan terkait dengan penggunaan Xenical merupakan hasil dari efek lokalnya dalam sistem pencernaan Anda. Gejala-gejala ini umumnya ringan, terjadi pada awal pengobatan dan terutama dialami setelah makan yang mengandung kadar lemak tinggi. Biasanya, gejala-gejala ini hilang jika Anda melanjutkan perawatan dan tetap mengikuti diet yang disarankan.

Kejadian efek samping pencernaan yang muncul secara umum yang terjadi pada pasien yang diobati dengan Xenical adalah: nyeri / ketidaknyamanan pada perut, perut kembung, tinja cair, tinja lunak, nyeri / ketidaknyamanan pada dubur, gangguan gigi, gangguan gusi.

Kejadian lain yang diamati adalah: infeksi saluran pernafasan atas, infeksi saluran pernapasan bawah; influenza; sakit kepala; ketidakteraturan menstruasi; kegelisahan; kelelahan; Infeksi saluran kemih.

Laporan Paska Pemasaran

Kasus hipersensitivitas langka telah dilaporkan. Gejala klinis utama adalah gatal, ruam, urtikaria, angioedema, bronkospasme, dan anafilaksis. Kasus erupsi bullae yang sangat langka, peningkatan transaminase hati dan fosfatase alkalin, dan kasus luar biasa kerusakan hati berat, beberapa mengakibatkan transplantasi hati atau kematian, telah dilaporkan. Belum ada hubungan kausal atau mekanisme fisiopatologis antara kerusakan hati dan terapi orlistat.

Laporan dari penurunan prothrombin, peningkatan INR dan perawatan antikoagulan yang tidak seimbang menghasilkan perubahan parameter hemostatik telah dilaporkan pada pasien yang diobati secara bersamaan dengan orlistat dan antikoagulan selama paska-pemasaran.

Kejang telah dilaporkan pada pasien yang diobati secara bersamaan dengan obat orlistat dan antiepilepsi.

Kasus hiperoksaluria dan nefropati oksalat telah dilaporkan. Beberapa pasien yang memakai Xenical mungkin dapat mengalami peningkatan risiko untuk pengembangan batu ginjal. Segera laporkan gejala sakit punggung atau darah di urin

5. Bagaimana cara penyimpanan XENICAL

Jauhkan obat ini dari jangkauan dan penglihatan anak-anak.

Kemasan blister

Jangan gunakan Xenical setelah tanggal kadaluwarsa yang tertulis di dus.

Jangan simpan di atas 25°C.

Simpan dalam kemasan asli dan simpan blister di dus untuk melindungi dari cahaya dan kelembaban.

Jangan membuang obat-obatan melalui air limbah atau limbah rumah tangga. Tanyakan kepada apoteker bagaimana cara membuang obat-obatan yang sudah tidak digunakan. Langkah ini dapat membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Apakah kandungan XENICAL

- Zat aktifnya adalah orlistat.
Setiap kapsul mengandung orlistat 120 mg.
- Bahan-bahan lainnya adalah microcrystalline cellulose (E460), sodium starch glycolate (type A), povidone (E1201), sodium laurilsulfate dan talc.
Cangkang kapsul mengandung gelatine, indigo carmine (E132), titanium dioxide (E171) dan printing ink yang dapat dimakan

Seperti apa XENICAL dan isi kemasannya

Xenical capsules berwarna toska dengan tanda „XENICAL 120“ dan dikemas dalam kemasan blister berisi 21 dan 84 kapsul.
Tidak semua ukuran kemasan mungkin dipasarkan.

HARUS DENGAN RESEP DOKTER

Reg. No.: **DKI1972200401A1**

Kemasan

Dus isi 1 blister @ 21 kapsul
Dus isi 4 blister @ 21 kapsul

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