



## Plot in A0 Paper size

	<div data-bbox="272 258 637 277" data-label="Page-Header">PACKAGE LEAFLET: INFORMATION FOR THE USER</div> <div data-bbox="885 258 936 277" data-label="Page-Header">P2693T</div> <div data-bbox="272 284 584 325" data-label="Section-Header"> <h1>Orlistat <i>120mg</i> hard capsules</h1> </div> <div data-bbox="272 331 325 354" data-label="Text">Orlistat</div> <div data-bbox="272 367 885 402" data-label="Text"> <p>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</p> </div> <div data-bbox="272 402 936 510" data-label="List-Group"> <ul style="list-style-type: none"> <li>• Keep this leaflet. You may need to read it again.</li> <li>• If you have any further questions, please ask your doctor or your pharmacist.</li> <li>• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.</li> <li>• If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.</li> </ul> </div> <div data-bbox="272 526 386 542" data-label="Section-Header"> <h2>In this leaflet:</h2> </div> <div data-bbox="272 545 601 660" data-label="List-Group"> <ol style="list-style-type: none"> <li>1. What Orlistat is and what it is used for</li> <li>2. What you need to know before you take Orlistat</li> <li>3. How to take Orlistat</li> <li>4. Possible side effects</li> <li>5. How to store Orlistat</li> <li>6. Contents of the pack and other information</li> </ol> </div> <div data-bbox="272 679 680 702" data-label="Section-Header"> <h2>1. What Orlistat is and what it is used for</h2> </div> <div data-bbox="272 708 936 740" data-label="Text"> <p>Orlistat is a medicine used to treat obesity. It works in your digestive system to block about one-third of the fat in the food you eat from being digested.</p> </div> <div data-bbox="272 740 936 791" data-label="Text"> <p>Orlistat attaches to the enzymes in your digestive system (lipases) and blocks them from breaking down some of the fat you have eaten during your meal. The undigested fat cannot be absorbed and is eliminated by your body.</p> </div> <div data-bbox="272 794 864 813" data-label="Text"> <p>Orlistat is indicated in the treatment of obesity in conjunction with a low calorie intake diet.</p> </div> <div data-bbox="272 829 782 852" data-label="Section-Header"> <h2>2. What you need to know before you take Orlistat</h2> </div> <div data-bbox="272 858 431 877" data-label="Section-Header"> <h3>Do not take Orlistat</h3> </div> <div data-bbox="272 877 936 979" data-label="List-Group"> <ul style="list-style-type: none"> <li>• If you are allergic (hypersensitive) to Orlistat or any of the other ingredients of Orlistat (see section 6 for further information)</li> <li>• If you have a chronic malabsorption syndrome (insufficient absorption of nutrients from alimentary tract)</li> <li>• If you have cholestasis (liver disorder)</li> <li>• If you are breast-feeding.</li> </ul> </div> <div data-bbox="272 986 482 1005" data-label="Section-Header"> <h3>Warnings and precautions</h3> </div> <div data-bbox="272 1005 936 1056" data-label="Text"> <p>Weight loss may also affect the dose of medicines taken for other conditions (e.g. high cholesterol or diabetes). Be sure to discuss these and other medicines you may be taking with your doctor. Losing weight may mean you need adjustments to the dose of these medicines.</p> </div> <div data-bbox="272 1053 936 1104" data-label="Text"> <p>To gain the maximum benefit from Orlistat you should follow the nutrition program recommended to you by your doctor. As with any weight-control program, over consumption of fat and calories may reduce any weight loss effect.</p> </div> <div data-bbox="272 1104 936 1187" data-label="Text"> <p>This medicine can cause harmless changes in your bowel habits, such as fatty or oily stools, due to the elimination of undigested fat in your faeces. The possibility of this happening may increase if Orlistat is taken with a diet high in fat. In addition your daily intake of fat should be distributed evenly over three main meals because if Orlistat is taken with a meal very high in fat, the possibility of gastrointestinal effects may increase.</p> </div> <div data-bbox="272 1187 936 1222" data-label="Text"> <p>The use of an additional contraceptive method is recommended to prevent possible failure of oral contraception that could occur in case of severe diarrhoea.</p> </div> <div data-bbox="272 1222 936 1254" data-label="Text"> <p>The use of orlistat may be associated with renal stones in patients suffering from chronic kidney disease. Inform your doctor whether you suffer from problems with your kidney.</p> </div> <div data-bbox="272 1260 478 1279" data-label="Section-Header"> <h3>Children and adolescents</h3> </div> <div data-bbox="272 1279 672 1295" data-label="Text"> <p>Orlistat is not intended to be used in children or adolescents.</p> </div> <div data-bbox="272 1302 505 1321" data-label="Section-Header"> <h3>Other medicines and Orlistat</h3> </div> <div data-bbox="272 1321 936 1372" data-label="Text"> <p>Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed. This is important as using more than one medicine at the same time can strengthen or weaken the effects of the medicines.</p> </div> <div data-bbox="272 1372 497 1388" data-label="Text"> <p>Orlistat may modify the activity of:</p> </div> <div data-bbox="272 1391 936 1528" data-label="List-Group"> <ul style="list-style-type: none"> <li>• Anticoagulant drugs (e.g. warfarin). Your doctor may need to monitor your blood coagulation.</li> <li>• Ciclosporin. Co-administration with ciclosporin is not recommended. Your doctor may need to monitor your ciclosporin blood levels more frequently than usual.</li> <li>• Iodine salts and/or levothyroxine. Cases of hypothyroidism and/or reduced control of hypothyroidism may occur.</li> <li>• Amiodarone. You may ask your doctor for advice.</li> <li>• Medicines for depression, psychiatric disorders or anxiousness.</li> <li>• Medicines to treat HIV.</li> </ul> </div> <div data-bbox="272 1532 936 1596" data-label="Text"> <p>Orlistat reduces the absorption of supplements of some fat soluble nutrients, particularly beta-carotene and vitamin E. You should therefore follow your doctor's advice in taking a well-balanced diet rich in fruit and vegetables. Your doctor may suggest you take a multivitamin supplement.</p> </div> <div data-bbox="272 1599 936 1650" data-label="Text"> <p>Orlistat may unbalance anticonvulsant treatment, by decreasing the absorption of antiepileptic drugs, thus leading to convulsions. Please contact your doctor if you think that the frequency and/or severity of the convulsions have changed when taking Orlistat together with antiepileptic drugs.</p> </div> <div data-bbox="272 1650 936 1682" data-label="Text"> <p>Orlistat is not recommended for people taking acarbose (an anti-diabetic drug used to treat type 2 diabetes mellitus).</p> </div> <div data-bbox="272 1688 493 1707" data-label="Section-Header"> <h3>Orlistat with food and drink</h3> </div> <div data-bbox="272 1707 936 1739" data-label="Text"> <p>Orlistat can be taken immediately before, during a meal or up to one hour after a meal. The capsule should be swallowed with water.</p> </div> <div data-bbox="272 1746 580 1765" data-label="Section-Header"> <h3>Pregnancy, breast-feeding and fertility</h3> </div> <div data-bbox="272 1765 936 1813" data-label="Text"> <p>If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicines. Taking Orlistat during pregnancy is not recommended.</p> </div> <div data-bbox="272 1816 936 1848" data-label="Text"> <p>You must not breast-feed your infant during treatment with Orlistat as it is not known whether Orlistat passes into human milk. Studies do not indicate harmful effects with respect to fertility.</p> </div> <div data-bbox="272 1854 495 1873" data-label="Section-Header"> <h3>Driving and using machines</h3> </div> <div data-bbox="272 1873 787 1889" data-label="Text"> <p>Orlistat has no known effect on your ability to drive a car or operate machinery.</p> </div> <div data-bbox="272 1896 936 1927" data-label="Text"> <p>This medicine contains less than 1mmol sodium (23mg) per hard capsule, that is to say essentially 'sodium free'.</p> </div> <div data-bbox="272 1947 503 1969" data-label="Section-Header"> <h2>3. How to take Orlistat</h2> </div> <div data-bbox="272 1975 936 2010" data-label="Text"> <p>Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.</p> </div> <div data-bbox="272 2010 936 2055" data-label="Text"> <p>The usual dose of Orlistat is one 120 mg capsule taken with each of the three main meals per day. It can be taken immediately before, during a meal or up to one hour after a meal. The capsule should be swallowed with water.</p> </div> <div data-bbox="272 2058 936 2157" data-label="Text"> <p>Orlistat should be taken with a well-balanced, calories controlled diet that is rich in fruit and vegetables and contains an average of 30% of the calories from fat. Your daily intake of fat, carbohydrate and protein should be distributed over three meals. This means you will usually take one capsule at breakfast time, one capsule at lunch time and one capsule at dinner time. To gain optimal benefit, avoid the intake of food containing fat between meals, such as biscuits, chocolate and savoury snacks.</p> </div> <div data-bbox="272 2160 936 2196" data-label="Text"> <p>Orlistat only works in the presence of dietary fat. Therefore, if you miss a main meal or if you have a meal containing no fat, Orlistat need not be taken.</p> </div> <div data-bbox="272 2196 936 2243" data-label="Text"> <p>Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective or well tolerated and may change your treatment unnecessarily.</p> </div> <div data-bbox="272 2247 936 2282" data-label="Text"> <p>Your doctor will discontinue the treatment with orlistat after 12 weeks if you have not lost at least 5% of your body weight as measured at the start of treatment with Orlistat.</p> </div> <div data-bbox="272 2282 787 2301" data-label="Text"> <p>Orlistat has been studied in long-term clinical studies of up to 4 years duration.</p> </div> <div data-bbox="272 2304 601 2323" data-label="Section-Header"> <h3>If you take more Orlistat than you should</h3> </div> <div data-bbox="272 2323 936 2358" data-label="Text"> <p>If you take more capsules than you have been told to take, or if someone else accidentally takes your medicine, contact a doctor, pharmacist or hospital as you may need medical attention.</p> </div> <div data-bbox="272 2362 499 2381" data-label="Section-Header"> <h3>If you forget to take Orlistat</h3> </div> <div data-bbox="272 2381 936 2416" data-label="Text"> <p>If you forget to take your medicine at any time, take it as soon as you remember provided this is within one hour of your last meal, then continue to take it at the usual times.</p> </div>	<div data-bbox="1030 258 1697 309" data-label="Text"> <p>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.</p> </div> <div data-bbox="1030 312 1609 331" data-label="Text"> <p>If you have further questions on the use of this medicine, ask your doctor or pharmacist.</p> </div> <div data-bbox="1030 347 1266 370" data-label="Section-Header"> <h2>4. Possible side effects</h2> </div> <div data-bbox="1030 376 1630 395" data-label="Text"> <p>Like all medicines, this medicine can cause side effects, although not everybody gets them.</p> </div> <div data-bbox="1030 395 1697 481" data-label="Text"> <p>Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Orlistat. The majority of unwanted effects related to the use of Orlistat result from its local action in your digestive system. These symptoms are generally 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 treatment and keep to your recommended diet.</p> </div> <div data-bbox="1030 485 1546 504" data-label="Section-Header"> <h3>Very common side effects (may affect more than 1 in 10 people)</h3> </div>
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Weight specification: 50 g/m<sup>2</sup>

Product:	Orlistat 120mg Capsules (Rontis)
Item Code:	P2693T
Size:	165 x 500mm
Min. Point size:	9pt
O. Artwork	09/04/24
Proof No.	1
Amendment Date	

Colours Used	
	Process Black
	Keyline - does not print