



Title:

Retinol 4500 IU and Colecalciferol 450 IU Capsules

Ref:

RETCOL/TG/V1

Client:

Tor Generics / Sabine De Swaaf

Date:

18/04/16 Amended 10/02/17

Item code:

TBA

Size:

38mm x 150mm (Label Leaflet)

Colours (label/leaflet)

Process

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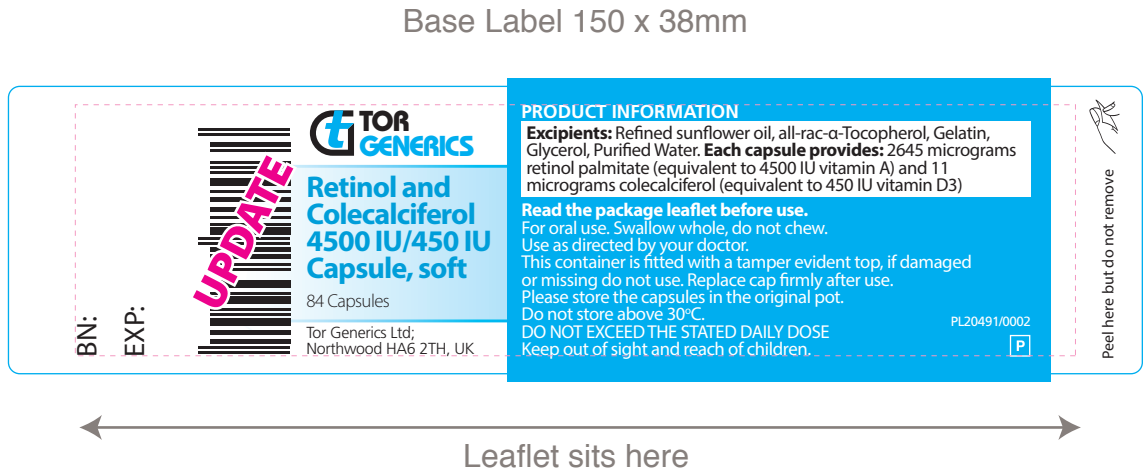
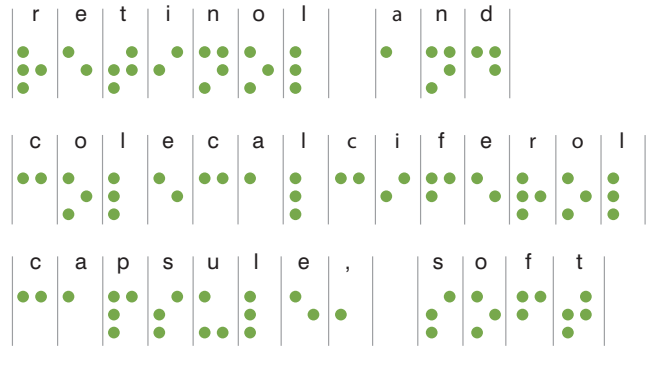
GUIDE

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<p><b>Package leaflet: Information for the user</b></p> <p><b>Retinol and Colecalciferol 4500 IU/450 IU Capsule, Soft</b></p> <p>Retinol (Vitamin A) and Colecalciferol (Vitamin D3)</p> <p><b>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</b></p>	<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, ask your doctor or 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>	<p><b>What is in this leaflet</b></p> <ol style="list-style-type: none"><li>1. What Retinol and Colecalciferol 4500 IU/450 IU Capsules are and what they are used for</li><li>2. What you need to know before you take Retinol and Colecalciferol 4500 IU/450 IU Capsules</li><li>3. How to take Retinol and Colecalciferol 4500 IU/450 IU Capsules</li><li>4. Possible side effects</li><li>5. How to store Retinol and Colecalciferol 4500 IU/450 IU Capsules</li></ol>	<ol style="list-style-type: none"><li>6. Contents of the pack and other information</li></ol> <p><b>1. What Retinol and Colecalciferol 4500 IU/450 IU Capsules are and what they are used for</b></p> <p>Retinol and Colecalciferol 4500 IU/450 IU Capsules contain the active ingredients Vitamin A or retinol palmitate (2645 micrograms of retinol palmitate are equivalent to 4500 IU Vitamin A) and Vitamin D3 or colecalciferol (11 micrograms of colecalciferol are equivalent to 450 IU of Vitamin D3).</p>	<p>Vitamin A is found in the diet. Vitamin A helps your immune system to work against infections, helps vision and helps to keep your skin and linings of some body parts, such as the nose, healthy.</p> <p>Vitamin D is found in the diet and is also produced in the skin after exposure to the sun. Often vitamin D is given in combination with calcium. Vitamin D helps to regulate the amount of calcium and phosphate in the body; these are needed to keep bones and teeth healthy.</p>	<p>Vitamins A and D may be prescribed by your doctor to prevent vitamin A and D deficiencies. Deficiency of vitamins A and D may occur when your diet or lifestyle does not provide you enough vitamins A and D.</p> <p><b>2. What you need to know before you take Retinol and Colecalciferol 4500 IU/450 IU Capsules</b></p> <p><b>Do not take Vitamins A and D if:</b></p> <ul style="list-style-type: none"><li>- You are allergic (hypersensitive) to vitamin A and/or D or any of the other ingredients in the capsules (these</li></ul>	<p>are listed in section 6, Further information)</p> <ul style="list-style-type: none"><li>- Have high levels of vitamin A and/or D in your blood (hypervitaminosis A and/or D)</li><li>- Have high blood levels of calcium (hypercalcaemia)</li><li>- Have urine levels of calcium (hypercalciuria)</li><li>- Have kidney stones or serious kidney problems</li></ul> <p><b>Warnings and precautions</b></p> <p>Talk to your doctor before taking Vitamins A and D if:</p> <ul style="list-style-type: none"><li>- You have kidney damage or disease. Your doctor will</li></ul>	<p>need to measure the levels of calcium in your blood or urine</p> <ul style="list-style-type: none"><li>- You suffer from liver disease</li><li>- You are being treated for heart disease</li><li>- You have sarcoidosis (an immune system disorder which may affect your liver, lungs, skin or lymph nodes)</li><li>- You are already taking additional doses of calcium or vitamin D. Whilst you are taking colecalciferol your doctor will monitor your blood levels of calcium to make sure they are not too high.</li></ul>	<p><b>Children and adolescents</b></p> <p>Retinol and Colecalciferol 4500 IU/450 IU Capsules are not suitable for children under 6 years.</p> <p><b>Other medicines and Retinol and Colecalciferol 4500 IU/450 IU Capsules</b></p> <p>Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular the following medicines may interact with Vitamin A and D3:</p>	<ul style="list-style-type: none"><li>- Contraceptive pills increase the level of vitamin A in your blood.</li><li>- Heart medicines (cardiac glycosides such as digoxin). Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the levels of calcium in your blood.</li><li>- Antiplatelet drugs, such as aspirin, and Vitamin E, the effects of antiplatelet drugs may be increased resulting in longer bleeding time.</li><li>- Medicines with an anticoagulant effect (such as</li></ul>	<p>abxiximab, clopidogrel, heparin, warfarin) may result in longer bleeding time.</p> <ul style="list-style-type: none"><li>- Medicines to treat epilepsy (such as phenytoin) or medicines to make you sleep (barbiturates such as phenobarbitone) as these medicines can decrease the effect of vitamin D.</li><li>- Thiazide diuretics ("water" pills) and vitamin D can increase the levels of calcium in your blood and may result in high blood levels of calcium (hypercalcaemia).</li></ul>	<ul style="list-style-type: none"><li>- Glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D.</li><li>- Laxatives (such as paraffin oil) or a cholesterol lowering drug called colestyramine may reduce the absorption of vitamins A and D.</li><li>- Actinomycin (a medicine used to treat some forms of cancer), drugs to treat HIV/AIDS (such as efavirenz and zidovudine) and imidazole antifungals (medicines such as clotrimazole and ketoconazole</li></ul>	<p>used to treat fungal diseases) as they may interfere with the metabolism of vitamin D.</p> <ul style="list-style-type: none"><li>- Medicines that can cause pseudotumor cerebri (a condition in which the pressure around the brain increases causing headaches and vision problems), including certain tetracycline antibiotics, as the pseudotumor cerebri symptoms may increase. Excessive alcohol consumption increases the risk of liver damage due to Vitamin A</li></ul>	<ul style="list-style-type: none"><li>- Retinoids, including bexarotene</li></ul> <p><b>Taking Retinol and Colecalciferol 4500 IU/450 IU Capsules with food and drink</b></p> <p>You can take Vitamins A and D3 with or without food and drink.</p> <p><b>Pregnancy, breast-feeding and fertility</b></p> <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 medicine.</p>
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<p>Do not use during pregnancy and lactation unless advised by your doctor.</p> <p><b>Driving and using machines</b></p> <p>These capsules should not affect your ability to drive or operate machinery.</p> <p><b>Retinol and Colecalciferol 4500 IU/450 IU Capsules contain refined sunflower oil, all-rac-<math>\alpha</math>-tocopherol. The capsule shell consists of gelatin, glycerol, purified water.</b></p>	<p><b>3. How to take Retinol and Colecalciferol 4500 IU/450 IU Capsules</b></p> <p>Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.</p> <p>The capsule should be swallowed whole with water, preferably with the main meal of the day.</p> <p>The recommended dose is one capsule per day.</p>	<p><b>Use in children and adolescents</b></p> <p>The recommended dose is one capsule per day.</p> <p><b>If you take more Retinol and Colecalciferol 4500IU/450 IU Capsules than you should</b></p> <p>If you accidentally take too many capsules tell your doctor or get other medical advice immediately. If possible, take the capsules, the box and this leaflet with you to show the doctor. If you take too many capsules you may experience drowsiness, feel</p>	<p>irritable, feel or be sick, become constipated or have stomach pains, weak muscles, tiredness, lack of appetite, kidney problems and in severe cases irregular heartbeats.</p> <p><b>If you forget to take Retinol and Colecalciferol 4500 IU/450 IU Capsules</b></p> <p>If you forget to take your capsules, take them as soon as you can. Do not take a double dose to make up for a forgotten dose. After that, take the next capsule in accordance with the instructions given to you by your doctor.</p>	<p>If you have any further questions on the use of this medicine, ask your doctor or pharmacist.</p> <p><b>4. Possible side effects</b></p> <p>Like all medicines, this medicine can cause side effects, although not everybody gets them.</p> <p>Side effects with Vitamin A at the prescribed dose are rare, however, the frequency could not be determined from the available data.</p>	<p>Vitamin A toxicity has been reported in children. Children may be irritable, be sick and lose appetite.</p> <p>Side effects with Vitamin D3 may include:</p> <p><b>Uncommon side effects</b> (affecting less than 1 in 100 people)</p> <ul style="list-style-type: none"><li>- too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion</li></ul>	<ul style="list-style-type: none"><li>- too much calcium in your urine (hypercalciuria).</li></ul> <p><b>Rare side effects</b> (affecting less than 1 in 1000 people)</p> <ul style="list-style-type: none"><li>- skin rash</li><li>- itching</li><li>- hives</li></ul> <p><b>Reporting of side effects</b></p> <p>If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects</p>	<p>directly via the Yellow Card Scheme at: <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a>.</p> <p>By reporting side effects you can help provide more information on the safety of this medicine.</p> <p><b>5. How to store Retinol and Colecalciferol 4500 IU/450 IU Capsules</b></p> <p>Keep this medicine out of the sight and reach of children.</p> <p>Please store the capsules in the original pot.</p>	<p>Do not store above 30°C.</p> <p>Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.</p> <p>Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.</p>	<p><b>6. Contents of the pack and other information</b></p> <p>What Retinol and Colecalciferol 4500 IU/450 IU Capsules contain</p> <ul style="list-style-type: none"><li>- The active substances are retinol palmitate or Vitamin A and colecalciferol or Vitamin D3</li><li>- The other ingredient in the capsule are refined sunflower oil, all-rac-<math>\alpha</math>-tocopherol; the capsule shell contains gelatin, glycerol, purified water.</li></ul>	<ul style="list-style-type: none"><li>- Free from: Gluten, nuts, starch, sugar, yeast and arachis oil</li></ul> <p><b>What Retinol and Colecalciferol 4500 IU/450 IU Capsules look like and contents of the pack</b></p> <p>Retinol and Colecalciferol 4500 IU/450 IU Capsules are available in PP pots containing 84 capsules.</p> <p><b>Marketing Authorisation Holder</b></p> <p>TOR Generics Ltd, Northwood, HA6 2TH, UK</p>	<p><b>Manufacturer</b></p> <p>Thorpe Laboratories Ltd, Golf Road Industrial Estate, Mablethorpe, Lincolnshire, LN12 1NB</p> <p><b>This leaflet was last revised in February 2017.</b></p>	
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