PACKAGE LEAFLET: INFORMATION FOR THE USER

Cadelius 600 mg / 2,000 IU
orodispersible tablets
calcium/cholecalciferol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- 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.
- 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.

What is in this leaflet:

1. What Cadelius is and what it is used for

Cadelius is used to treat calcium and vitamin D deficiency in adults.
Cadelius contains calcium and vitamin D_3 which both are important components for the formation of bone. Vitamin D_3 regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Ask your doctor or pharmacist if you have further questions and always follow their instructions.

You must talk to a doctor if you do not feel better or if you feel worse after some days.

2. What you need to know before you take Cadelius

Do not take Cadelius
- if you are allergic to the calcium, vitamin D or any of the other ingredients of this medicine. (listed in section 6)
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels in the urine).
- if you have hypervitaminosis D (increased levels of vitamin D in the blood).
- if you have kidney stones
- if you have kidney failure
- if you are pregnant
- if you are allergic to soya or peanuts.

Warnings and precautions
Talk to your doctor or pharmacist before taking Cadelius
- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- if you are taking other drugs containing vitamin D or calcium.
- if you have poor kidney function or high tendency of renal stone formation.
- if you are immobilized with osteoporosis.

Children and adolescents
Cadelius orodispersible tablets is not intended for use in children and adolescents.

Other medicines and Cadelius
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.
The effect of the treatment can be affected if this drug is taken simultaneously with certain other drugs against:
- high blood pressure (thiazide diuretic)
- heart problems (cardiac glycosides such as digoxin)
- high cholesterol (cholestyramine)
- constipation (laxatives such as liquid paraffin)
- epilepsy (phenytoin or barbiturates)
- inflammatory conditions/suppression of immunity (corticosteroids)
- obesity (orlistat)

Please make sure your doctor knows if you are taking any of the medicines listed above. Your dosage may need to be adjusted.

If you simultaneously use a certain drug for;
- osteoporosis (bisphosphonates)

you should take this at least three hours before you take Cadelius

If you simultaneously use certain drugs for;
- infection (quinolones)

you should take these two hours before or six hours after taking Cadelius.

If you simultaneously use certain drugs for;
- infection (tetracyclines)

you should take these two hours before or four to six hours after taking Cadelius.

If you simultaneously take certain drugs for;
- dental caries (sodium fluoride)
- anaemia (iron)

you should take these drugs at least three hours before taking Cadelius.

If you simultaneously use a certain drug for;
- hypothyroidism (levothyroxine)

you should separate the intake with Cadelius by at least four hours.

Cadelius with food and drink and alcohol

The calcium absorption may be inhibited by food containing oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals). You should wait at least two hours before you take Cadelius if you have eaten food with high content of oxalic acid or phytic acid.

Pregnancy and breast-feeding and fertility
Cadelius should not be used during pregnancy.

Cadelius can be used during breast-feeding. Calcium and vitamin D_3 pass over into breast milk. This should be considered when giving additional vitamin D to the child. Such supplementation does not replace the administration of vitamin D in newborns.

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.

Driving and using machines
Cadelius has no known effects on ability to drive or use machines.

Cadelius contains aspartame.
This medicine contains 8.67 mg aspartame in each orodispersible tablet.
Aspartame is a source of phenylalanine. Phenylalanine may be harmful for people with phenylketonuria, a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
Cadelius contains lactose and sucrose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine;
Cadelius contains soya oil.
If you are allergic to peanut or soya**,** do not use this medicinal product.

3. How to take Cadelius
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The dosage is individually decided for you by your doctor.
The recommended dose is 1 tablet daily.
The tablets may be sucked, they should not be swallowed whole.
The tablets should be taken preferably after meals

The amount of calcium in Cadelius is lower than the usually recommended daily intake. Cadelius is therefore meant for patients with need for additional vitamin D, but with a dietary intake of 500-1000 mg of calcium per day. Your dietary intake of calcium should be estimated by your doctor.

Use in children and adolescent
Cadelius are not intended for use in children and adolescents.

If you take more Cadelius than you should
If you may have taken more Cadelius than you should, talk to your doctor or pharmacist immediately.

Some symptoms of overdose of Cadelius are loss of appetite, thirst, abnormal increased urine secretion, nausea, vomiting and constipation.

If you forget to take Cadelius

Take it as soon as you remember. Then take your next dose at the usual time. However, if it is almost time for your next dose, skip the missed dose and continue as usual. Never take two doses at the same time.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should stop taking Cadelius and see your doctor immediately if you experience symptoms of serious allergic reactions, such as

- swollen face, lips, tongue or throat
- difficult to swallow
- hives and difficulty breathing

Uncommon (may affect up to 1 in 100 people): hypercalcaemia (increased levels of serum calcium) and/or hypercalciuria (increased levels of urine calcium).

Rare (may affect up to 1 in 1,000 people): constipation, flatulence, nausea, abdominal pain, diarrhoea, abdominal distension, pruritus, rash and urticaria.

Not known (frequency cannot be estimated from the available data): serious allergic reactions:

Other special population
Patients with renal impairment could have a potential risk of hyperphosphatemia, nephrolithiasis and nephrocalcinosis.

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: HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Cadelius

- Keep this medicine out of the sight and reach of children.
- Keep container tightly closed. Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from light. Keep the container tightly closed in order to protect from moisture.
- After first opening, the shelf life is 30 days.
- Do not use this medicine if you notice any signs of deterioration.
- 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 to protect the environment.

6. Contents of the pack and other information

What Cadelius contains

- The active substances are calcium carbonate 1500 mg corresponding to calcium 600 mg and cholecalciferol (Vitamin D_3) 2,000 IU corresponding to 0,050 mg.
- The other ingredients are maltodextrin, aspartame (E 951), low-substituted hydroxypropyl cellulose (E 463), lactose monohydrate, anhydrous citric acid (E 330), orange flavouring agent (containing flavouring preparations, natural flavouring substances, maltodextrin and dextrin), stearic acid, DL-α-tocopherol (E 307), partially hydrogenated soybean oil, gelatin, sucrose, maize starch.

What Cadelius **looks like and contents of the pack**

Cadelius is an orodispersible tablet, white to almost white, with round, bevelled edge shape, 30 tablets in the bottle.
Multipacks contain 60 (2 packs of 30) orodispersible tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Italfarmaco S.A.
C/ San Rafael, 3
28108 Alcobendas (Madrid) España

This medicinal product is authorised in the Member States of EEA under the following names:

Italy:	Dincrel 600 mg / 2000 U.I. Orodispersible Tablet
France:	Demilos 600 mg / 2000 IU comprimés orodispersibles
Spain:	Demilos 600 mg / 2000 IU comprimidos bucodispersables
Portugal:	Demilos Plus 600 mg / 2000 IU comprimidos orodispersíveis
Ireland:	Cadelius 600 mg /2000 IU orodispersible tablets

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