

## **Package leaflet: Information for the user**

### **Calciflex-D<sub>3</sub> Citron 500 mg/400 IU film-coated tablets** calcium / cholecalciferol (vitamin D<sub>3</sub>)

[For medicinal products available only on prescription:]

**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.

[For medicinal products available without prescription:]

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.

[To be completed nationally]

#### **What is in this leaflet**

1. What Calciflex-D<sub>3</sub> Citron is and what it is used for
2. What you need to know before you take Calciflex-D<sub>3</sub> Citron
3. How to take Calciflex-D<sub>3</sub> Citron
4. Possible side effects
5. How to store Calciflex-D<sub>3</sub> Citron
6. Contents of the pack and other information

#### **1. What Calciflex-D<sub>3</sub> Citron is and what it is used for**

Calciflex-D<sub>3</sub> Citron are film-coated tablets containing calcium and vitamin D<sub>3</sub>, which both are important substances in bone formation. Calciflex-D<sub>3</sub> Citron is used in the prevention and treatment of calcium and vitamin D deficiency in adults with an identified risk of calcium and vitamin D deficiency, and as a supplement to specific treatment of osteoporosis.

#### **2. What you need to know before you take Calciflex-D<sub>3</sub> Citron**

##### **Do not take Calciflex-D<sub>3</sub> Citron:**

- if you are allergic to calcium, vitamin D, or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney problems
- if you have excessive amounts of calcium in the blood or in the urine.
- if you have kidney stones.
- if you have excessive amounts of vitamin D in the blood.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Calciflex-D<sub>3</sub> Citron

- if you are on long-term treatment, especially if you also take diuretics (used in treatment of high blood pressure or oedema) or cardiac glycosides (used to treat heart disorders).
- if you have signs of impaired renal function or high tendency of renal stone formation.
- if you have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body).
- if you have osteoporosis and at the same time are unable to move around.
- if you take other products containing vitamin D. Additional doses of calcium and vitamin D should be taken under close medical supervision.

### **Children**

Calciflex-D<sub>3</sub> Citron is not intended for use in children

### **Other medicines and Calciflex-D<sub>3</sub> Citron**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you also take tetracyclines (a type of antibiotics), you should take these at least 2 hours before or 4-6 hours after intake of Calciflex-D<sub>3</sub> Citron. Calcium carbonate may interfere with the absorption of tetracycline preparations if taken at the same time.

Medicines containing bisphosphonates (used to treat osteoporosis) should be taken at least one hour before intake of Calciflex-D<sub>3</sub> Citron.

Calcium can reduce the effect of levothyroxine (used to treat thyroid deficiency). For this reason, levothyroxine should be taken at least four hours before or four hours after Calciflex-D<sub>3</sub> Citron.

The effect of quinolone antibiotics may be reduced if taken at the same time as calcium. Take quinolone antibiotics two hours before or six hours after taking Calciflex-D<sub>3</sub> Citron.

Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Consequently iron, zinc or strontium ranelate preparations should be taken at least two hours before or after Calciflex-D<sub>3</sub> Citron.

Other medicines that may influence or be influenced by Calciflex-D<sub>3</sub> Citron are:

- thiazide diuretics (used in treatment of high blood pressure and oedema)
- cardiac glycosides (used to treat heart disorders).

Orlistat (used to treat obesity) may disturb the absorption of fat-soluble vitamins, e.g. vitamin D<sub>3</sub>.

If you are taking any of the above-mentioned medicines, your doctor will give you further instructions.

### **Calciflex-D<sub>3</sub> Citron with food and drink**

Calciflex-D<sub>3</sub> Citron can be taken with or without food and drink.

### **Pregnancy, breast-feeding and fertility**

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.

#### *Pregnancy*

Calciflex-D<sub>3</sub> Citron can be used during pregnancy, in case of calcium and vitamin D deficiency. During pregnancy you should not take more than 2500 mg calcium and 4000 IU vitamin D per day, as overdoses may harm the unborn child.

#### *Breast-feeding*

Calciflex-D<sub>3</sub> Citron can be used during breastfeeding. Calcium and vitamin D<sub>3</sub> pass into breast milk. This should be considered when giving additional vitamin D to the child.

### **Driving and using machines**

Calciflex-D<sub>3</sub> Citron has no known influence on the ability to drive and use machines.

**Calciflex-D<sub>3</sub> Citron contains sorbitol and sucrose**

Calciflex-D<sub>3</sub> Citron contains sucrose (0.8 mg) , which if the tablets are chewed, may be harmful to the teeth. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product..

Calciflex-D<sub>3</sub> Citron contains 154 mg sorbitol in each tablet. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

**Calciflex-D<sub>3</sub> Citron is essentially sodium-free**

This medicine contains less than 23 mg sodium per tablet, that is to say essentially 'sodium-free'.

**3. How to take Calciflex-D<sub>3</sub> Citron**

[For medicines available on prescription only:]

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

[For medicines available without prescription:]

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage:

The recommended dose is one tablet twice daily. The tablet may be swallowed or chewed.

**Use in children**

Calciflex-D<sub>3</sub> Citron is not intended for use in children.

**If you take more Calciflex-D<sub>3</sub> Citron than you should**

If you may have taken more Calciflex-D<sub>3</sub> Citron than you should, talk to your doctor or pharmacist immediately.

**If you forget to take Calciflex-D<sub>3</sub> Citron**

Do not take a double dose to make up for a forgotten tablet.

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.

Hypersensitivity reactions have occurred with unknown frequency (cannot be estimated from the available data). If you experience the following symptoms, you should immediately contact a doctor. Swelling of the face, tongue, lips (angioedema) or swelling of the throat (laryngeal oedema).

**Uncommon side effects (may affect up to 1 in 100 people):** Excessive amounts of calcium in the blood (hypercalcaemia) or in the urine (hypercalciuria) may occur with large doses.

**Rare side effects (may affect up to 1 in 1 000 people):** constipation, dyspepsia, flatulence, nausea, gastric pain, diarrhoea.

**Very rare side effects (may affect up to 1 in 10 000 people):** itching, rash and hives. Milk-alkali syndrome (also called Burnett's syndrome and usually only seen when excessive amounts of calcium have been

ingested), symptoms are frequent urge to urinate, headache, loss of appetite, nausea or vomiting, unusual tiredness or weakness, along with elevated levels of calcium in the blood and kidney impairment.

If you have impaired renal function, you may be at risk of increased amounts of phosphate in the blood, kidney stone formation and increased amounts of calcium in the kidneys.

### **Reporting of side effects**

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 directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Calciflex-D<sub>3</sub> Citron**

Do not store above 25°C. Keep the container tightly closed in order to protect from moisture.

Keep this medicine out of the sight and reach of children.

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.

Do not throw 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.

## **6. Contents of the pack and other information**

### **What Calciflex-D<sub>3</sub> Citron contains**

- The active substances are 500 mg calcium (as calcium carbonate) and 400 IU vitamin D<sub>3</sub> (equivalent to 10 micrograms cholecalciferol).
- The other ingredients are
- tablet core: sorbitol E420, mannitol, acesulfame potassium, flavouring (lemon), croscarmellose sodium, microcrystalline cellulose, magnesium stearate, maltodextrin, tocopherol-rich extract, all-rac-alpha-tocopherol, sucrose and modified maize starch, medium chain triglycerides, sodium ascorbate and anhydrous colloidal silica.
- film-coating: talc, hypromellose, propylene glycol.

### **What Calciflex-D<sub>3</sub> Citron looks like and contents of the pack**

Calciflex-D<sub>3</sub> Citron are white/off white, oval film-coated tablets, which may have hardly visible grey spots. The tablets are embossed on one side with 500/400.

Pack sizes:

Plastic bottle with HDPE screw cap: 20, 30, 50, 60, 90, 100, 120, 180 and 250 tablets

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

[To be completed nationally]

Manufacturer:

Takeda Pharma AS

Jaama 55B

63308 Põlva

Estonia

or

Takeda GmbH  
Lehnitzstr. 70-98  
DE-16515 Oranienburg  
Germany

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

Austria: Cal-D-or 500 mg/400 I.E. - Filmtabletten  
Belgium: Steovit D<sub>3</sub> 500 mg/400 I.E., filmomhulde tabletten  
Finland: Calcichew D<sub>3</sub> Forte sitruuna 500 mg/10 mikrog – kalvopäällysteinen tabletti  
Latvia: Calcigran Forte Flex 500 mg / 400 SV apvalkotās tabletes  
Luxembourg: Steovit D<sub>3</sub> 500 mg/400 U.I., comprimés pelliculés  
Netherlands: Calci-Chew D<sub>3</sub> FLEX 500 mg/400 I.E.  
Norway: Calcigran Forte 500 mg/400 IE tabletter, filmdrasjerte  
Sweden: Calciflex-D<sub>3</sub> Citron 500 mg/400 IE filmdragerad tablett  
UK: Calcichew D<sub>3</sub> Forte 500 mg/400 IU Film-coated Tablets

**This leaflet was last revised in 2019-01-17.**

#### **Other sources of information**

Detailed information on this medicine is available on the web site of {name of MS Agency (link)}