Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to take Sandocal+D 600 Effervescent Tablets carefully to get the best results from it.

• Keep this leaflet. You may need to read it again.

• Ask your pharmacist if you need more information or advice.

• If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Sandocal+D 600 Effervescent Tablets are and what they are used for

Sandocal+D 600 Effervescent Tablets contain calcium and vitamin D3.

Sandocal+D 600 Effervescent Tablets are used in the prevention and treatment of calcium and vitamin D deficiency, and may be used, with other medicines, to prevent and treat a condition called
osteoporosis (weakening of the bones) for patients who are at risk of calcium and vitamin D deficiency.

Calcium and vitamin \( \text{D}_3 \) are absorbed from the intestine and distributed throughout the body in the blood.

99% of the calcium in the human body is located in bone as crystallized hydroxyapatite and amorphous calcium phosphate. These compounds are important for the maintenance of strong bones and teeth. Calcium plays an important role in several body functions. It is essential for nerve, muscle and heart function as well as for the clotting of blood. In addition, it helps many hormones to work properly in the body. To carry out these various roles, calcium must be available in the appropriate concentration.

Vitamin \( \text{D}_3 \) helps the absorption of calcium and phosphorus from the intestine and their uptake by the bone.

Vitamin D can be found in certain foods or food supplements such as cod liver oil, oily fish, eggs, and is also produced by the skin in the presence of sunlight. Nevertheless, vitamin D deficiency can still occur depending on where you live in the world (latitude), the time you spend outdoors, and your diet. For instance, vitamin D deficiency (hypovitaminosis) is especially common during winter and early spring in many countries in Europe due to less periods of sunlight. Also people who spend a lot of time indoors and so not exposed to sufficient sunlight can be more prone to vitamin D deficiency (hypovitaminosis).

2. Before you take Sandocal+D 600 Effervescent Tablets

Do not take Sandocal+D 600 Effervescent Tablets if you:

- are allergic (hypersensitive) to calcium, vitamin D or any of the other ingredients in Sandocal+D 600 Effervescent Tablets (see the list of ingredients in section 6 at the end of the leaflet).
- have an elevated blood calcium level (hypercalkaemia).
- have increased calcium excretion in the urine (hypercalkiuria).
- have kidney stones (nephrolithiasis) and calcium deposits in your kidney tissue (nephrocalcinosis).
- have too much vitamin D in your body (hypervitaminosis).

Take special care with Sandocal+D 600 Effervescent Tablets:

- During long-term use with Sandocal+D 600 Effervescent Tablets, your blood and urine calcium levels, as well as your kidney function, should be monitored regularly by your doctor. This is especially important if you have a tendency to develop kidney stones.
Please consult your doctor before taking Sandocal+D 600 Effervescent Tablets and follow your doctor’s instruction carefully if:

- You are taking other calcium and vitamin D products.
- You suffer from a kidney disorder, especially if also taking aluminium supplements.
- You suffer from certain lung diseases such as sarcoidosis/Besnier-Boeck disease

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription, because calcium and vitamin D can interact with certain other medicines if taken at the same time. For example, if you are taking or have recently taken:

- cardiac glycosides, thiazide diuretics, or corticosteroids, you must follow your doctor’s instructions carefully.
- oral bisphosphonates or sodium fluoride, take Sandocal+D 600 Effervescent Tablets at least 3 hours after taking these medicines as calcium reduces the absorption of these compounds.
- a group of antibiotics called tetracyclines, take Sandocal+D 600 Effervescent Tablets at least 2 hours after or 4 to 6 hours before the tetracycline as calcium reduces the absorption of these compounds.
- cholestyramine or laxatives preparations, take Sandocal+D 600 Effervescent Tablets at least 4 to 6 hours after or 1 hour before taking these medicines.

**Taking Sandocal+D 600 Effervescent Tablets with food and drink**

Sandocal+D 600 Effervescent Tablets should not be taken within 2 hours of eating foods rich in oxalic acid or phytic acid such as spinach, rhubarb and whole cereals

**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. Pregnant and breast-feeding women require more calcium and vitamin D than normal.

- If you start using Sandocal+D 600 Effervescent Tablets during the third trimester of pregnancy, the daily intake should not exceed 1500 mg calcium and 1000 I.U. (International Units) vitamin D3, therefore do not take more than the recommended daily dose.

- Calcium passes into breast-milk, without having a negative effect on the baby. Vitamin D also passes into breast-milk, and this should be considered when giving additional vitamin D to the baby.

**Driving and using machines**
There is no known effect on ability to drive or operate machines caused by taking Sandocal+D 600 Effervescent Tablets.

**Important information about some of the ingredients of Sandocal+D 600 Effervescent Tablets:**

- **Diabetics** can take Sandocal+D 600 Effervescent Tablets (1 effervescent tablet of 600 mg / 400 I.U. contains 0.003 Carbohydrate Units).

- Sandocal+D 600 Effervescent Tablets contain 82.14 mg of sodium per tablet. Patients on a controlled **sodium diet** should seek advice from health professionals prior to taking Sandocal+D 600 Effervescent Tablets.

- If you think you have an **intolerance to some sugars**, contact your doctor before taking this medicinal product.

- Sandocal+D 600 Effervescent Tablets contain **aspartame**, a source of phenylalanine, and may be harmful for people with phenylketonuria.

### 3. How to take Sandocal+D 600 Effervescent Tablets

Always take Sandocal+D 600 Effervescent Tablets exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is:

- **Children**: take one effervescent tablet (one single dose) once a day.

- **Adolescents and adults**: take one effervescent tablet (one single dose) once or twice a day, equivalent to 600 or 1200 mg of calcium and 400 or 800 I.U. (International Units) of vitamin D3.

Dissolve Sandocal+D 600 Effervescent Tablets in a glass of water (approximately 200 ml) and drink immediately. Do not swallow or chew the tablet.

Sandocal+D 600 Effervescent Tablets can be taken at anytime, except if you are taking certain medicines (see the section 2 “Taking other medicines”), and can be taken with or without food (see the section 2 “Taking Sandocal+D 600 Effervescent Tablets with food and drink” for further advice).

**How long should you take Sandocal+D 600 Effervescent Tablets?**

Take the recommended daily dose of Sandocal+D 600 Effervescent Tablets for as long as you are advised to by your doctor. Given the intended use of Sandocal+D 600 Effervescent Tablets, it is likely this will be a long term treatment.
During long-term use of Sandocal+D 600 Effervescent Tablets, your blood and urine calcium levels, as well as kidney function, should be monitored regularly by your doctor. This is especially important if you have a tendency to develop kidney stones.

If you take more Sandocal+D 600 Effervescent Tablets than you should

Overdose of Sandocal+D 600 Effervescent Tablets may lead to symptoms such as nausea, vomiting, extreme thirst or constipation. If overdose is suspected, contact your doctor or pharmacist immediately.

If you forget to take Sandocal+D 600 Effervescent Tablets

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

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

4. Possible side effects

Like all medicines, Sandocal+D 600 Effervescent Tablets can cause side effects, although not everybody gets them.

Some rare and very rare side effects might be serious.

If you experience any of the following, STOP taking Sandocal+D 600 Effervescent Tablets and tell your doctor immediately:

• **Very rare side effects** *(occur in less than 1 in 10 000 people)* include: serious allergic (hypersensitivity) reactions such as swelling of the face, lips, tongue or throat.

• **Rare side effects** *(occur in less than 1 person out of 1000)* include: increased calcium levels in the blood (hypercalcaemia) and excessive excretion of calcium in the urine (hypercalciuria).

Less serious side effects

Other side effects which may occur are usually mild, passing and harmless. Tell your doctor or pharmacist, as soon as you can, if you notice any of the following:

• **Uncommon side effects** *(occur in less than 1 person out of 100)* may include: nausea, diarrhoea, abdominal pain, constipation, flatulence, bloating, itching, redness and/or burning of the skin.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
5. How to store Sandocal+D 600 Effervescent Tablets

• Keep out of the reach and sight of children.

• Do not use Sandocal+D 600 Effervescent Tablets after the expiry date which is stated on the box and on the tube after “EXP”. The expiry date refers to the last day of that month.

• Do not store above 30 °C.

• Store in the original package and keep the tube tightly closed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Sandocal+D 600 Effervescent Tablets contain

The active substances are: calcium lactate gluconate, calcium carbonate and colecalciferol (vitamin D3). Each effervescent tablet of 600 mg / 400 I.U. contains 1358 mg of calcium lactate gluconate and 1050 mg of calcium carbonate (equivalent to 600 mg of calcium), 10 µg colecalciferol (equivalent to 400 I.U. of vitamin D3) as active substances.

The other ingredients are: citric acid, sodium hydrogen carbonate, macrogol 6000, aspartame, orange flavouring (contains: orange essential oils, maltodextrin, arabic gum, sorbitol (E 420), dextrose), sucrose, gelatin, maize starch, partially hydrogenated soya oil and alpha-tocopherol. (see also end of section 2 “Important information about some of the ingredients of Sandocal+D 600 Effervescent Tablets” for further information on sugars, sodium and aspartame).

What Sandocal+D 600 Effervescent Tablets look like and contents of the pack

The effervescent tablet is white, circular and has an orange odour.

Sandocal+D 600 Effervescent Tablets are available in packs of 10, 20, 40 (2 tubes of 20), 60 (3 tubes of 20), 80 (4 tubes of 20), 100 (5 tubes of 20) effervescent tablets. Not all pack sizes may be marketed.

Marketing authorisation holder: GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

Manufactured by: Novartis Consumer Health, Horsham, RH12 5AB, UK.

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