

**1. NAME OF THE MEDICINAL PRODUCT**

CALCIUM LACTATE TABLETS BP 300mg

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains 300mg Calcium Lactate BP equivalent to 0.96mmol calcium (Ca<sup>2+</sup>).

**3. PHARMACEUTICAL FORM**

White uncoated tablets.

**Clinical Particulars**

**4.1. Therapeutic Indications**

1) Indicated for the treatment of calcium deficiency states as a therapeutic supplement in pregnancy, lactation, osteoporosis, post-gastrectomy malabsorption, osteomalacia and rickets.

**4.2. Posology and Method of Administration**

Calcium Lactate Tablets BP should not be taken for long periods without medical advice.

*Adults including elderly:* 1-2 tablets (300-600mg) daily.

*Pregnant women:* (During the third trimester and also during lactation) 3-4 tablets (0.9-1.2g) daily.

*Children over 3 years:* One tablet (300mg) daily.

For oral administration.

**4.3. Contra-indications**

Severe hypercalcaemia and hypercalciuria (*eg* hypervitaminosis D, hyperparathyroidism, severe renal failure, osteoporosis due to immobility and decalcifying tumours such as plasmocytoma and skeletal metastases). Patients receiving therapy with cardiac glycosides such as digoxin must not be given calcium supplements.

**4.4. Special Warnings and Precautions For Use**

Careful monitoring of blood levels and urinary calcium excretion is necessary, particularly when high dose calcium therapy has been used, especially in children.

Treatment should be suspended if calcium blood levels exceed 2.625-2.75mmol/litre (105-110mg/litre) or if urinary calcium excretion exceeds 5mg/kg.

Calcium salts should be administered with care to infants with hypokalaemia, as elevation of serum calcium levels may further reduce serum potassium levels.

Calcium salts should be administered with caution to patients with impaired renal function, cardiac disease, or sarcoidosis.

#### **4.5. Interaction with other Medications and other forms of Interaction**

Calcium Lactate Tablets BP must be used with care in patients receiving alternative compound vitamin or mineral preparations, which often contain additional sources of calcium.

Calcium enhances the effects of digitalis on the heart and may precipitate digitalis intoxication.

Calcium salts reduce the absorption of tetracyclines.

No Data Held

#### **4.6. Pregnancy and Lactation**

There is epidemiological evidence of the safety of calcium in pregnancy.

No problems are anticipated with the administration of Calcium Lactate Tablets during lactation.

#### **4.7. Effects on Ability to Drive and Use Machines**

None known.

#### **4.8 Undesirable Effects**

Calcium salts may cause constipation.

##### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9 Overdose**

The symptoms of overdosage with calcium include anorexia, lassitude, nausea, vomiting, headache, extreme thirst, vertigo, and raised blood urea; calcium may be deposited in many

tissues including the kidney and arteries and the plasma cholesterol level may become elevated. Cardiac arrhythmias and bradycardia may also occur.

Calcium intake should be reduced to a minimum and any dehydration and electrolyte imbalance corrected immediately. Severe hypercalcaemia should be treated with an *iv* infusion of sodium chloride 0.9%; a loop diuretic may be given to increase urinary calcium excretion. If this fails, calcitonin may be administered by injection, or alternative, biphosphonates, plicamycin or corticosteroids may be used. Phosphate infusion must not be given due to the danger of metastatic calcification. In severe cases, significant amounts of calcium may be removed by peritoneal dialysis.

Patients with symptoms of overdosage should avoid exposure to direct sunlight.

Special care must be exercised when treating overdosage in patients with impaired renal or hepatic function.

## **Pharmacological Properties**

### **5.1. Pharmacodynamic Properties**

Calcium lactate is used in calcium deficiency.

### **5.2. Pharmacokinetic Properties**

Calcium is absorbed from the small intestine; about one third of ingested calcium is absorbed. Absorption decreases with age and may be more efficient when the body is deficient in calcium or from diets deficient in calcium. It is excreted in sweat, bile, pancreatic juice, saliva, urine, faeces and milk.

### **5.3. Preclinical Safety Data**

Not applicable.

## **6. Pharmaceutical Particulars**

### **6.1. List of Excipients**

Also contains lactose, magnesium stearate, maize starch and stearic acid.

### **6.2. Incompatibilities**

None known.

### **6.3. Shelf Life**

*Shelf-life*

Three years from the date of manufacture.

*Shelf-life after dilution/reconstitution*

Not applicable.

*Shelf-life after first opening*

Not applicable.

### **6.4. Special Precautions for Storage**

Store in a cool dry place.

### **6.5. Nature and Contents of Container**

The product containers are rigid injection moulded polypropylene or injection blow-moulded polyethylene containers with polyfoam wad or polyethylene ullage filler and snap-on polyethylene lids; in case any supply difficulties should arise the alternative is amber glass containers with screw caps and polyfoam wad or cotton wool. An alternative closure for polyethylene containers is a polypropylene, twist on, push down and twist off child-resistant, tamper-evident lid.

Pack sizes: 14s, 28s, 30s, 56s, 60s, 84s, 100s, 250s, 500s, 1000s.

Product may also be supplied in bulk packs, for reassembly purposes only, in polybags contained in tins, skillets or polybuckets filled with suitable cushioning material. Bulk packs are included for *temporary* storage of the finished product before final packaging into the proposed marketing containers.

Maximum size of bulk packs: 25,000.

### **6.6. Instructions for Use, Handling and Disposal**

Not applicable.

**7    MARKETING AUTHORISATION HOLDER**

Accord-UK Ltd  
(Trading style: Accord)  
Whiddon Valley  
Barnstaple  
Devon  
EX32 8NS  
United Kingdom

**8.    MARKETING AUTHORISATION NUMBERS**

PL 0142/6140 R

**9.    DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION**

11.7.86 / 14.11.96

**10    DATE OF REVISION OF THE TEXT**

22/11/2019