Brand Name : AGOCAL TABLETS **Generic Name :** Calcium Lactate Tablets BP 300 mg	2021
Module 1 Administrative Information and Product Information **1.5** Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

AGOCAL TABLETS (Calcium Lactate Tablets BP 300 mg)

2. Qualitative and Quantitative Composition:

Each uncoated tablets contains: Equivalent of 300 mg of Calcium Lactate Pentahydrate BP

3. Pharmaceutical form:

White, circular, flat, uncoated tablet having a break line on one side & other side plain.

4. 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.

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

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 Contraindications

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 medicinal products 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.

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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 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.

5. Pharmacological properties:

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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:

Sodium Starch Glycolate	BP
Micro Crystalline Cellulose Powder	BP
Purified talc	BP
Magnesium stearate	BP

6.2 Incompatibilities:

None Reported

6.3 Shelf-Life:

36 months from the date of manufacture.

6.4 Special Precautions for Storage:

Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:

1000 tablets packed in one jar. Such jar packed in export worthy shipper.

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6.5 Special precautions for disposal:

None reported.

7. Registrant:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

8. Manufacturer:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane,
India.

9. Date of revision of the text: