프로젝트 완료 A방서

작성자 / 작성완료일	김미영 / 2025.11.17
지재명/지재코드/개정번호/배율	본카연질캡슐 설명서 / LT0933 / 04 / 100%
규격(장폭고/두께(mm)	160 (가로) x 290(세로)
인쇄도수	1 도
용지/코팅/후가공	모조지 70 g/m²
수정내역	1. 성비변경에 따른 사이즈 변경 2. 03 -> 04
도안담당(디자인부)	김미영 매니저 (02-6972-9032 / 내선번호 : 332)
도안확인(국제부)	엄영훈 팀장 (02-6972-9175 / 내선번호 : 175)
도안확인(마케팅부)	ETC
도안확인(QA)	이주연 (043-653-9612 / 내선번호 : 953)

Yuyu (주)유유제약

For Osteoporosis

BONKY 0.25 μg Soft Cap.

Calcitriol is the most active known form of vitamin D_3 in stimulating intestinal calcium transport. In acutely uremic rats, calcitriol has been shown to stimulate intestinal calcium absorption. The kidneys of uremic patients cannot adequately synthesize calcitriol, the active hormone formed from vitamin D precursor. Resultant hypocalcemia and secondary hyperparathyroidism are major causes of the metabolic bone disease of renal failure. However, other bone toxic substances which accumulate in uremia (e.g, aluminum) may also contribute. The beneficial effect of Bonky in renal osteodystrophy appears to result from correction of hypocalcemia and secondary hyperparathyroidism. It is uncertain whether Bonky produces other independent beneficial effects.

Description An oval ivory white soft gel capsule containing colorless oily liquid. (print : BKC)

Composition Each capsule contains,
Active Ingredient : Calcitriol ····· 0.25 μg
Inactive Ingredients :
Medium-Chain Triglycerides ····· 160mg
Butylated Hydroxyanisole ····· 16.0μg
Butylated Hydroxytoluene ····· 16.0μg
Gelatin (BSE free bovine source) ····· 75mg
Concentrated Glycerin ····· 23.3 mg
D-Sorbitol Solution ····· 10 mg
Ethyl Parahydroxybenzoate ····· 0.18 mg
Propy Parahydroxybenzoate ····· 0.01 mg
Titanium oxide ····· q.s

Indications and usage
• Osteoporosis
• Rickets, osteomalacia (vitamin D dependent rickets, hypophosphatemic vitamin D resistant rickets)
• Hypoparathyroidism (postoperative, idiopathic hypoparathyroidism, pseudohypoparathyroidism)
• Patients with chronic renal failure. particularly renal osteodystrophy in patients undergoing hemodialysis.

Dosage and Administration
The optimal daily dosage of Bonky must be catefully determined for each patient.
• **Osteoporosis:** The recommended dosage of Bonky is one capsule(0.25mcg), twice a day. If a satisfactory response in clinical manifestation is not observed, dosage may be increased to two capsules(0.5mcg), twice a day at four week intervals. During this titration period, serum calcium levels should be measured at least twice weekly, and if hypercalcemia is noted, the drug should be immediately discontinued until normocalcemia ensues. The usual dosage is more convenient to be decided on the basis of the patients receiving an adequate daily intake of calcium. Calcium supplement in postmenopausal osteoporosis patients is rarely necessary, because calcium absorption is increased due to Bonky.
• **Hypoparathyroidism, rickets or osteomalacia** : The recommended initial dosage of Bonky is one capsule(0.25mcg)/-day given in the morning. If a satisfactory response on the biochemical parameters and clinical manifestations is not observed, the dosage may be increased at 2-4 week intervals. During this titration period, serum calcium levels should be measured at least twice weekly. Higher doses in patients with hypoparathyroidism may be necessary as malabsorption is observed occasionally.
• **Renal osteodystrophy (dialysis patients)**: The recommended initial dosage of Bonky is one capsule(0.25mcg)/ day. Patients with normal or only slightly reduced serum calcium levels may respond to doses of 0.25mcg every other day. If a satisfactory response in the biochemical parameters and clinical manifestations is not observed, dosage may be increased by one capsule(0.25mcg)/day at 2-4 week intervals. During this titration period, serum calcium levels should be measured at least twice weekly. Most patients respond to doses between two capsules(0.5mcg)/day and four capsules(1.0mcg)/day.
Higher doses may be necessary if barbiturates or anticonvulsants are administered simultaneously. The effectiveness of Bonky therapy is predicated on the assumption that each patient is receiving an adequate daily intake of calcium. The U.S. RDA for calcium in adults is 800 to 1,000mg. A low-calcium diet may be sufficient in some patients taking calcitriol, because calcium gastrointestinal absorption is improved. In patients with a history of hypercalce- mia, a low-calcium diet may be sufficient or no calcium supplement may be required.
• **General:** Once the dose is stabilized, serum calcium levels should be measured every month. If serum calcium level is increased by 1mg/100ml more than normal range(mean value of 9-11mg/100ml), the dosage should be immediately reduced sufficiently or discontinued until normocalcemia ensues.
Stopping additional intake of calcium may be effective for rapid normalization of serum calcium levels. Careful consideration should also be given to lowering the dietary calcium intake. When the hypercalcemia reactions are observed, serum calcium and alkaline phosphatase levels should be measured everyday.
If those serum levels are normalized, Bonky can be restarted at a lower dose of 0.25mcg/day than previously.

Precautions
1. Contraindications
1) Patients with hypercalcemia relevant diseases
2) Patients with a known hypersensitivity to calcitriol or any of its ingredients
3) Patients with evidence of vitamin D toxicity

2. Careful administration
1) Pregnancy : Safety of this drug in pregnant or possible pregnant women are not determined yet. Thus, this drug should be used only if the potential benefits justify the potential risks to the mother and fetus.
2) Infants under 3 years of age or undergoing hemodialysis : Clinical experience is limited. This drug should be used only if the potential benefits justify the potential risks to the each patients

3. Adverse reactions
1) Bonky has not been reported adverse reactions in usual dosage.
2) Bonky is believed to be the active hormone which exert vitamin D activity in the body, adverse effects are,
in general, similar to those encountered with excessive vitamin D intake. Acute reactions include anorexia, headache, vomiting or constipation.
The relatively short biological half-life of Bonky permits rapid elimination of the compound when treatment is stopped or when dosage is reduced, and normalization of serum calcium levels may be observed within a few days. This rate of reversal of biological effects is more rapid than when other vitamin D derivatives are used. Chronic reactions include weakness, weight loss, dysesthesia, polyuria, pyrexia with polydipsia, dehydration, or apathia.
3) In 15 year clinical studies on all the indications for this drug, there were few adverse reaction reports. Hypercalcemia and hyperphosphatemia together may lead to soft tissue calcification. Radiographic evaluation may be useful in detection of this condition
4) In patients with normal renal function, chronic hypercalcemia may occur associated with an elevation of serum creatinine.
5) This drug may cause hypersensitivity to sensitive patients.

4.General precautions
1) Excessive dosage of Bonky induces hypercalcemia. Excessive calcium intake such as increased intake of dairy products can lead to hypercalcemia. The patients and his or her parents or spouse should be carefully informed about the adherence to instructed diet and symptoms of hypercalcemia. If serum calcium level is greater than 1mg/dL above the upper limit of the normal range, 9-11mg/dL or serum creatinine is greater than 120 μ mol/l the drug should be immediately discontinued until normocalcemia ensues.
2) Immobile patients after surgery are particularly prone to hypercalcemia.
3) Calcitriol induces an increase in serum phosphate level, which is good for hypophos- phatemia. But calcitriol may lead to ectopic calcification in patients with impaired renal function. Both appropriate oral phosphate-binders and a low phosphate diet should be used to control serum phosphate levels(2-5mg/100ml or 0.65-1.62mmol/l) in patients undergoing dialysis. The patients with vitamin D resistant rickets (familial hypophos- phatemia) should be administered phosphate orally. But, Bonky should be used with caution, because calcitriol may lead to stimulate intestinal phosphorus absorption. Serum calcium, phosphorus, magnesium, alkaline phosphatase, and 24-hour urinary calcium and phosphate should be determined periodically. Therefore, early in treatment during dosage adjustment, serum calcium levels should be determined at least twice weekly.
4) Since calcitriol is the most potent metabolite of vitamin D, vitamin D and its derivatives should be withheld during treatment.
5) When switching from ergocalciferol to calcitiol, it may take several months to recover baseline level of serum ergocalciferol.
6) Patients with normal renal function taking Bonky should be given adequate fluid to avoid dehydration.

5. Drugs interactions
1) Since calcitriol is the most potent metabolite of vitamin D available, pharmacologic doses of vitamin D and its derivatives should be withheld during Bonky treatment to avoid possible additive effects or hypercalcemia.
2) Patients should be informed about adherence to diet and calcium supplementation and avoidance of the use of excessive calcium intake.
3) The concomitant of thiazide diuretics and calcitriol can increase hypercalcemia.
4) The optimal dose of Bonky must be carefully given to patients on digitalis, because hypercalcemia in such patients may precipitate cardiac arrhythmias.
5) Vitamin D metabolites which enhance calcium absorption are the antagonists of corticosteroids which inhibit calcium absorption.
6) Magnesium-containing antacid and Bonky should not be used concomitantly to patients undergoing chronic renal dialysis, because such use may lead to hypermagne- smia.
7) The known site of action of calcitriol are intestine, bone and kidney. Bonky has been shown to stimulate phosphorus transport. A phosphate-binding compound should be used to control serum phosphate level(normal:2-5mg/100ml or 0.65-1.62mmol/l)
8) Patients with vitamin D resistant rickets (familial hypophos- phatemia) should be administered phosphate orally. But Bonky should be used with caution, because calcitriol may lead to stimulate intestinal phosphorus absorption.
9) Concurrent administration of enzyme inducing drugs such as phenytoin and phenobarbital may increase the clearance of Bonky. Thus, an increase in Bonky dosage may be necessary.
10) Cholestyramine has been reported to reduce intestinal absorption of fat soluble vitamins; as such it may impair intestinal absorption of Bonky.

6. Pregnancy • Nursing Mothers
1) Calcitriol given orally at lethal dose has been reported to induce aortic stenosis in rabbits. No teratogenic evidence with high intake of vitamin D was observed in human. However, calcitriol should be used during pregnancy only if the potential benefit justifies the potential risk to fetus.
2) Calcitriol is believed to be excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother and potential for hypercalcemia in nursing infants. Thus, serum calcium level of nursing mother and infant should be determined when Bonky is administered to a nursing woman.

7. Treatment of overdosage.
1) General treatment of hypercalcemia.
2) Adverse effects of calcitriol are, in general, similar to those encountered with excessive vitamin D intake. High intake of calcium and phosphate concomitant with Bonky may lead to similar abnormalities. High levels of calcium in the dialysate bath may contribute to hypercalcemia.
3) The acute symptoms of vitamin D intoxication include anorexia, headache, vomiting, or constipation. The chronic symptoms include weakness. weight loss, dysesthesia, polyuria, pyrexia with polydipsia, dehydration, apathism, and hypercalcemia. Widespread calcification of soft tissues, including heart, kidneys, and lungs, can occur.
4) The treatment of accidental overdosage of Bonky should consist of general supportive measures. Induction of emesis, gastric lavage, or administration of liquid paraffin may be of benefit in preventing further absorption. Serum calcium level should be obtained. Should, however, persistent and markedly elevated serum calcium levels occur, use drugs such as phosphates and corticosteroids to induce and appropriate forced diuresis.

8. Effect on ability of operating machinery or motor vehicle.
Bonky appears to be safe considering its characteristics of adverse reaction with no such activities.

Storage Store in airtight container at 30℃ and below. Protect from sunlight and moisture.
Keep out of reach of children.

Package Units 60 Capsules (10Cap/Blister X 6)

Product Registration Holder Bio-Pharmaceuticals Sdn Bhd, 48-2 Jalan Sungai Burung AA32/AA, Section 32, Bukit Rimau, 40460 Shah Alam, Selangor Malaysia

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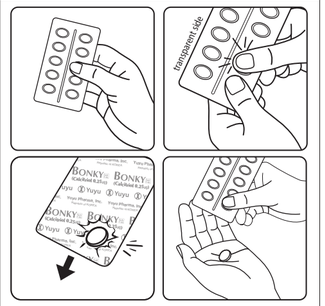
How to remove capsules from the blister



Place your thumb on the transparent side of the blister as shown in the illustration. Press firmly on the transparent side of the blister until the capsule pops out.
Do not try to do the opposite side.

Manufactured by
Yuyu Pharma, Inc.
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