Dear Patient,
Please read this leaflet carefully. It gives you important information about your medicine. If you have any questions, ask your doctor or pharmacist.

Information for Patients

DECOSTRIOL® 0.25 µg

mibe GmbH
Arzneimittel

Active ingredient: calcitriol (1α,25-dihydroxycholecalciferol)

Composition

Each capsule contains:
- Pharmaceutically active ingredient:
  calcitriol (1α,25-dihydroxycholecalciferol) 0.25 µg
- Other ingredients:
  butylhydroxytoluene (Ph.Eur.) (E 321), butylhydroxyanisole (Ph.Eur.) (E 320), ethanol 100 %, arachis oil, gelatin, glycerol 85 %, sorbitol, liquid 70 % (non crystallising) (Ph.Eur.), iron(III)oxide (E 172), titanium dioxide (E 171)

Pharmaceutical form and content

Pink (rose) soft capsule, oval. Each capsule contains yellow, clear, oily solution.
Blister and bottle pack
Pack of 30 soft capsules
Pack of 50 soft capsules
Pack of 100 soft capsules

Product classification
Vitamin D_3 metabolite

Marketing authorisation holder and manufacturer

Manufactured by (package and releaser):
mibe GmbH Arzneimittel
Münchener Str. 15
D-06796 Brehna, Germany

Bulk manufacturer:
Catalent Germany Eberbach GmbH,
Eberbach, Germany

For Malaysia
Product Registration Holder:
IMEKS Pharma Sdn. Bhd.
No. 5 & 9 Jalan Udang Harimau 2,
Medan Niaga Kepong,
51200 Kuala Lumpur, Malaysia.

For Mongolia
Authorised importer and distributor:
IKH Shuudergene Import LLC 14253
Ulaanbaatar, Mongolia

Indications
- Established postmenopausal osteoporosis
- Renal osteodystrophy (bone changes) in patients with chronic renal failure undergoing dialysis (e.g. artificial kidney)
- Hypofunction of the parathyroid gland (postoperative or idiopathic hypoparathyroidism), hereditary disorder of phosphate excretion (pseudohypoparathyroidism)
- Hypophosphataemic rickets (so-called vitamin D-resistant rickets)

Contraindication
When should you not use **Decostriol® 0.25 µg**?
Decostriol® 0.25 µg must not be used in:
- all diseases associated with an increased blood calcium level (e.g. hyperactivity of the parathyroid gland).
- Hypersensitivity to calcitriol or any other compound in this class of substances or to any of the other ingredients in this medicinal product.

What do you have to consider during pregnancy or while breast-feeding?
Decostriol® 0.25 µg may only be administered during pregnancy after the possible benefits have been carefully weighed against the potential risks for the mother and the child. In case of overdose (increased blood calcium level, placental transfer of the active ingredient to the foetus) there is a risk of malformation: risk of impaired physical and mental development, hypofunction of the parathyroid gland (hypoparathyroidism), particular forms of arteriostenosis (aortic stenosis). No results of controlled studies in humans are available.
It should be assumed that calcitriol passes into breast milk. For this reason, breast-feeding should not be carried out during calcitriol treatment owing to the danger of possible damaging effects on the infant.

Precautions for use and warnings
What precautions must be taken?
Since **Decostriol® 0.25 µg** contains the most efficacious vitamin D metabolite, neither vitamin D nor any derivatives (e.g. dihydrotachysterol) may be administered simultaneously. If treatment is switched from ergocalciferol (vitamin D2) to calcitriol, it should be noted that it may take several months for the blood ergocalciferol levels to return to their baseline values.
Pre-requisite for the optimal effect of calcitriol is a sufficient but not excessive intake of calcium (for adults about 800–1000 mg daily including food calcium intake). If necessary, additional calcium must be taken. The uncontrolled intake of calcium preparations can lead to hypercalcaemia. Owing to an improved absorption of calcium from the gastrointestinal tract, calcium intake may be reduced in some patients on **Decostriol® 0.25 µg**.
There is a danger of hypercalcaemia occurring under treatment with calcitriol. During investigations of patients with uraemic osteodystrophy hypercalcaemia was observed in about 40% of patients treated with calcitriol. You must strictly adhere to the diet your doctor has prescribed. Your doctor will inform you about how to recognise the symptoms of hypercalcaemia.
In patients on thiazide treatment and in patients who have sarcoidosis or a history of kidney stones, a calciuria (> 300 mg/day or 7.5 mmol/day) must be avoided.
The danger of hypercalcaemia is increased in particular for immobilised patients.
Patients with normal kidney function who are taking Decostriol 0.25 µg, should be careful to have an adequate liquid intake to avoid loss of body fluid (dehydration), because such a loss would increase the risk of hypercalcaemia (risk of increased concentration of calcium in blood).
Patients with vitamin D-resistant rickets and simultaneously reduced phosphate concentrations in blood (familial hypophosphataemic rickets) should continue with their oral phosphate therapy.
However, since the intestinal absorption of phosphate is also stimulated by Decostriol 0.25 µg, the requirement for oral phosphate may be reduced. Regular checks of the laboratory values are necessary as follows: serum concentrations of calcium, phosphorus, magnesium and alkaline phosphatase and the determination of calcium and phosphate in 24-hour urine.
Calcitriol elevates the inorganic phosphate concentration in serum. Although this has a positive effect for patients with hypophosphataemia, care is needed on the other hand for patients with chronic renal failure since there is danger of ectopic calcification. In such a case, the phosphate concentration has to be kept within the normal range (2–5 mg/100ml or 0.65–1.62 mmol/l) by the oral administration of the necessary phosphate-binding agents and a low-phosphate diet. Allergic reactions may occur with sensitive patients. In particular owing to the content of butylhydroxyanisole and butylhydroxytoluene hypersensitivity reactions can occur in predisposed patients in the form of irritations of the skin, eyes and mucous membranes.

Interaction with other agents
What other medicinal products influence the effect of **Decostriol® 0.25 µg** and what should be considered when other medicinal products are taken at the same time?

Vitamin D and derivatives
An enhancement of the effect of calcitriol is expected by the simultaneous administration of vitamin D or its derivatives (e.g. dihydrotachysterol). That is why Decostriol® 0.25 µg may not be taken simultaneously with vitamin D or its derivatives (See "Precautions and Warnings").

Calcium
Instructions on diet, in particular instructions related to the calcium consumption, must be followed strictly. In particular uncontrolled consumption of extra calcium-containing products must be avoided (See "Precautions and Warning").

Phosphate-binding agents
Since **Decostriol® 0.25 µg** also influences phosphate transport in the intestine, kidney and bone, the administration of phosphate-binding agents (e.g. aluminium hydroxide or aluminium carbonate containing compounds) must be based on the serum phosphate concentration (normal values: 2–5 mg/100ml or 0.65–1.62 mmol/l).

Magnesium
Magnesium containing medications (e.g. gastric acid binding preparations) may not be administered to patients with impaired kidney function during therapy with **Decostriol® 0.25 µg**, because this may lead to elevated magnesium concentrations in blood.

Thiazides and digitalis preparations
A reduction in the elimination of calcium ions caused by thiazide diuretics (medicinal products increasing the amount of urine excreted) results in an increased risk of hypercalcaemia in case of concomitant use of **Decostriol® 0.25 µg** and thiazides. Dosing of Decostriol 0.25 µg must be cautious under the concomitant administration of digitalis preparations since in these patients, abnormal heart rhythm (arrhythmias) associated with an increased blood calcium concentration (hypercalcaemia) can occur.

Cholestyramine
A reduction in the effect of **Decostriol® 0.25 µg** is possible, if cholestyramine (medicinal product reducing the blood fat values) is taken at the same time. Cholestyramine can reduce the absorption of fat-soluble vitamins from the intestine and can also interfere with the absorption of calcitriol from the intestine.

Corticosteroids
The effect of **Decostriol® 0.25 µg** may be reduced by the concomitant administration of glucocorticoids. A functional antagonism exists between the promotion of calcium uptake by calcitriol and its inhibition by corticosteroids.

Anticonvulsants, barbiturates
Higher doses of calcitriol may be required during concomitant administration with liver enzyme inducing medicinal products, such as barbiturates or drugs used in the treatment of epilepsy (anticonvulsants). Please note that these data may also be applicable to drugs used a short time ago.

Dosage instruction, mode and duration of use
The following statements apply to **Decostriol® 0.25 µg** unless otherwise prescribed by your doctor. Please adhere to the dosage instructions, since otherwise **Decostriol® 0.25 µg** cannot act properly.

General recommendations:
The optimal daily dose of **Decostriol® 0.25 µg** must be carefully established for each patient based on the serum calcium level. Therapy should always start with the lowest possible dose and only be increased under careful monitoring of serum calcium. During this time, the concentration of serum calcium should be determined at least twice per week. In case of normal kidney function, an additional monitoring of urine calcium is recommended twice per week.
Once the optimal dose of **Decostriol® 0.25 µg** has been ascertained, serum calcium should be checked at monthly intervals.
Samples for the determination of the serum calcium level should be taken without the use of a tourniquet (instrument for the compression of a blood vessel).
As soon as the serum calcium level rises to 1 mg/100ml (0.25 mmol/l) above the normal range (9–11 mg/100ml corresponding to 2.25–2.75 mmol/l) or as soon as the serum creatinine level rises above 1.36 mg/100ml corresponding to 120 µmol/l, the dose must be reduced or the treatment discontinued completely until a normal level of calcium has been reached.
As long as a hypercalcaemia is present, both the calcium and phosphate levels in serum must be monitored daily. Owing to the short half-life of calcitriol, serum calcium returns to normal levels within a few days of reducing the dose or of discontinuing the treatment. Once normal values have been attained, the treatment can be continued using a dose of 0.25 µg less than the dose previously administered.
The daily intake of calcium with food and with drugs should be estimated and, if necessary, adjusted to meet the requirements.

How many capsules **Decostriol® 0.25 µg** *should you take and how often?*

Established postmenopausal osteoporosis:
The recommended dose is 1 capsule **Decostriol® 0.25 µg** twice daily (corresponding to 0.5 µg calcitriol). Serum calcium and creatinine levels should be determined at 1, 3 and 6 months and at 6 monthly intervals thereafter.

Renal osteodystrophy (dialysis patients):
The initial daily dose should be 1 capsule Decostriol 0.25 µg (corresponding to 0.25 µg calcitriol).
For patients with normal or only slightly reduced calcium levels in blood, one dose of 0.25 µg calcitriol every second day is sufficient. If the effects on the results of clinical and biochemical investigations are not satisfactory within 2–4 weeks, the dose can be increased at intervals of 2–4 weeks by 0.25 µg calcitriol per day in each case. Most patients react to a dose of between 0.5 µg and 1.0 µg calcitriol per day with a substantial increase in the serum calcium concentration.

Hypofunction of the parathyroid gland, pseudohypoparathyroidism, hypophosphataemic rickets (so-called vitamin D-resistant rickets):
The recommended initial dose is 1 capsule **Decostriol® 0.25 µg** (corresponding to 0.25 µg calcitriol). If no improvement in the clinical picture or biochemical laboratory values are observed, then the dose may be increased at intervals of 2–4 weeks by 0.25 µg calcitriol in each case. In patients with severe hypocalcaemia the efficient dose is about 1 µg calcitriol per day. For patients with hypoparathyroidism, poor absorption is occasionally observed; in such cases, higher doses of Decostriol 0.25 µg may be necessary.

Dosing in elderly patients
No special dose for elderly patients is required. The recommendations concerning monitoring of the serum calcium and serum creatinine levels should be followed.

Dosing in children
As for adults, the optimal daily dosing will be determined on the basis of the serum calcium. Since insufficient experience with children under 3 years of age or on dialysis is currently available, the possible benefits must be weighed against the potential risk on an individual basis.

How and when should you continue to take **Decostriol® 0.25 µg**?
Capsules should be taken at breakfast with a little liquid. They should be swallowed whole. Capsule should not be dissolved before swallowing. Increased daily doses should be taken 2–3 times daily with meals (i.e. the total daily dose should be distributed over 2–3 portions).

How long should you continue to take **Decostriol® 0.25 µg**?
The duration of treatment is individualised by the doctor. It depends on the status of the illness and the laboratory findings.

Overdose and other errors of use
What to do if **Decostriol® 0.25 µg** *has been used in too large a dose (intended or erroneous overdose)?*
Since calcitriol is a derivative of vitamin D, the symptoms of overdose are the same as those for vitamin D. Intake of higher doses of calcium and phosphate together with calcitriol can lead to similar symptoms. An elevated calcium concentration in dialysate can contribute to the development of hypercalcaemia.

Symptoms of overdose:
Acute intoxication: anorexia (loss of appetite), headache, metallic taste, vomiting, obstipation, abnormal heart rhythm (arrhythmia) and psychic symptoms.
Chronic intoxication: dystrophy (weakness, weight loss), sensory disturbance, possible fever, polyuria (excessive excretion of urine), dehydration (deprivation of body fluid), apathy, growth inhibition and urinary tract infections. Hypercalcaemia with metastatic calcification of the renal cortex (cortex of the kidney), the myocardium (heart muscle), the lungs and the pancreas is the consequence.

Therapeutic measures in case of overdose:
In case of suspected overdose of **Decostriol® 0.25 µg** inform your doctor. Depending on the symptoms (s)he will decide on possibly required measures (discontinuation of the administration of calcitriol, strict low-calcium diet, frequent control of the serum calcium concentration until attainment of normal values).
Should an elevated serum calcium concentration persist, corticosteroids may be administered and measures for achieving an appropriate forced diuresis may be initiated.
Haemodialysis may be necessary in case of severe kidney damage.
In case of intoxication medical/emergency care should be sought immediately. The severity of an intoxication depends on the amount of the active substance calcitriol the body is supplied or takes up (absorbs). Measures for preventing further absorption such as immediate gastric lavage, induction of vomiting or the administration of paraffin oil to encourage faecal excretion of calcitriol are only indicated in cases of acute intake of very high doses.

What to do if you have taken too little a dose of **Decostriol® 0.25 µg** *or if you miss a dose?*
Do not take double the dose the next time, but continue with the capsule-taking as described in the dosage instruction.

Undesirable effects
What undesirable effects may occur on **Decostriol® 0.25 µg***?*
The undesirable effects correspond to those observed after a vitamin D overdose, i.e. hypercalcaemia syndrome. Dependent on the dose and duration of treatment, a severe and long-lasting hypercalcaemia can occur associated with its acute (abnormal heart rhythm [arrhythmia], nausea, vomiting, headache, obstipation, psychic symptoms, impaired consciousness) and its chronic (increased excretion of urine [polyuria], morbid thirst [polydipsia], loss of appetite [anorexia], weight loss, formation of kidney stones, calcium salt deposits in the kidney [nephrocalcinosis], calcification of the soft tissue) consequences.
Hypersensitivity reactions (pruritus, rash, urticaria and very rarely severe erythemayous skin disorder) may occur in susceptible individuals.
Simultaneously hypercalcaemia and hyperphosphataemia of > 6 mg/100 ml or 1.9 mmol/l can lead to calcification of the soft tissue. This is visible by using x-rays.
If you experience other undesirable effects which are not listed in this leaflet, please inform your doctor or pharmacist.

What measures are to be taken if undesirable effects occur?
At the first signs of hypercalcaemia Decostriol 0.25 µg and possibly prescribed calcium preparations should not be continued. Neither should you ingest any milk or dairy products. Inform your doctor so that (s)he can decide on the severity and any further measures that may have to be taken.

Information and data on the shelf life of this medicinal product
The expiry date for these capsules is given on the folding box. Do not use this pack after this date.

How is **Decostriol® 0.25 µg** *to be stored?*
Keep the blisters and bottle tightly closed in folding box to protect contents against light.
Do not store above 30°C.
Always make sure that you keep this drug out of the reach of children.

Date of this information
March 2025