

# Decostriol<sup>®</sup> 0.25 µg Capsule

(Calcitriol)

## WHAT IS IN THIS LEAFLET?

1. What *Decostriol*<sup>®</sup> is used for
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3. Before you take *Decostriol*<sup>®</sup>
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8. Product description.
9. Marketing Authorization Holder & Manufacturer.

- Read this entire leaflet before you start taking the medication.
- Keep this leaflet. You may need to read again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 1. WHAT *Decostriol*<sup>®</sup> IS USED FOR

*Decostriol*<sup>®</sup> capsule contains the active ingredient *Calcitriol*.

It is used in treatment of:

- Osteoporosis (weaken bones) in women after menopause.
- Bone disease (osteodystrophy) in patients with kidney problems and undergoing dialysis.
- Hypoparathyroidism (decreased function of the parathyroid gland).
- Vitamin D- resistant rickets.

## 2. HOW *Decostriol*<sup>®</sup> WORKS

*Calcitriol* is the active form of Vitamin D. It works by helping the body to use more of the calcium found in foods or supplements. Low blood levels of calcium may cause bone disease.

## 3. BEFORE YOU TAKE *Decostriol*<sup>®</sup>

**When you must not take it**

Do not take *Decostriol*<sup>®</sup> capsule if you:

- Have any diseases associated with an increase blood calcium level.
- Have allergic reaction to the active ingredient *Calcitriol* or to any other ingredients in this product.

If you are not sure whether you should start taking this medicine, consult your doctor.

## Before you start to take it

Tell your doctor if you are:

- Taking any diuretic medicine from *thiazide* group (e.g. *hydrochlorothiazide*).
- Patient with sarcoidosis (inflammation of lymph node, lungs, livers, eyes, etc).
- Have history of kidney stone.
- Have kidney failure.
- Pregnant or plan to become pregnant.
- Breast feeding or plan to start breast feeding.
- Have allergies to any other medicines, foods, preservatives or dyes.

## Taking / using other medicines

Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicine and *Decostriol*<sup>®</sup> may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Any other type of Vitamin D supplements e.g. *dihydrotachsterol*, *ergocalciferol*.
- Extra calcium-containing product.
- Phosphate-binding agents e.g. aluminium hydroxide for treatment of heartburn and gastritis.
- Magnesium containing medication, such as medicines for gastric.
- *Thiazides* diuretics for treatment of high blood pressure (eg. *hydrochlorothiazide*)
- Digitalis preparation (eg. *digoxin*)
- Medicine to treat heart failure
- *Cholestyramine* to lower serum cholesterol level.
- *Corticosteroids* to treat asthma.
- Medicines for seizure or epilepsy, treatment from barbiturates group (eg. *Phenobarbital* and other anti-convulsant (eg. sodium valproate)

## Pregnancy and breast-feeding

Tell your doctor if you are pregnant; think you are pregnant or planning to become pregnant. Your doctor will be

able to advice you on the suitability of using *Decostriol*<sup>®</sup> during pregnancy.

Tell your doctor if you are breastfeeding or about to start breastfeeding. *Decostriol*<sup>®</sup> is not recommended for mothers who are breastfeeding. This is because small amounts of *Calcitriol* may pass into the mother's milk. Your doctor will discuss the risks and benefits of taking *Decostriol*<sup>®</sup> during pregnancy and breast-feeding.

## 4. HOW TO TAKE *Decostriol*<sup>®</sup>

Always take *Decostriol*<sup>®</sup> capsule exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

## How much to take

*Decostriol*<sup>®</sup> capsule comes in 0.25µg capsule.

Your doctor will take into account your medical conditions and calcium level in your blood before deciding on the appropriate dosage for you.

## When to take it

Capsules should be taken at breakfast with a little liquid. It should be swallowed whole and should not be dissolved before swallowing. If you are given higher daily doses, it should be divided evenly and taken 2 – 3 times daily with meals.

## How long to take it

The duration of treatment depends on medical condition being treated. Your doctor will be able to advise you on this.

## If you forget to take it

Take your dose as soon as you remember and continue to take it as you would normally. Do not take a double dose to make up for the dose you missed or taking more doses at a time. This may cause unwanted side effects.

## If you take too much (overdose)

If you or anyone else takes too many capsules, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort

or poisoning. Take the carton or any remaining medicine you have with you.

Symptoms observed after an overdose of this medicine includes;

*Acute intoxication*

Loss of appetite, headache, metallic taste, vomiting, constipation, abnormal heart rhythm and psychic symptoms

*Chronic intoxication*

Weakness, weight loss, sensory disturbance, fever, frequent urination, dehydration, apathy, growth inhibition, urinary tract infections and hypercalcaemia.

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

## 5. WHILE YOU ARE USING

### *Decostriol®*

#### Things you must do

- Always take *Decostriol®* exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
- If you are pregnant, while taking *Decostriol®*, tell your doctor immediately.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking *Decostriol®*.
- Ensure you have sufficient liquid intake to avoid loss of body fluid (dehydration).

#### Things you must not do

- Do not use *Decostriol®* after the expiry date which is stated on the carton, bottle and blister.
- Do not give this medication to anyone else, even if they have the same condition as you.
- Do not use *Decostriol®* to treat any other complaints unless your doctor tells you to.

## 6. POSSIBLE SIDE EFFECTS

All medicines can have side effects. *Decostriol®* may cause unwanted side effects although not everybody gets them.

The side effects are mostly due to high levels of calcium in your blood. Tell your doctor or pharmacist if you notice the following side effects:

- Abnormal heart beat
- Nausea or vomiting
- Constipation
- Headache
- Frequent urination
- Thirst
- Loss of appetite
- Weight loss
- Kidney stone

*Tell your doctor or pharmacist immediately if you notice the side effect continues or getting serious or anything else that make you feel unwell. Other side effects not listed above may also occur in some people.*

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## 7. AFTER USING *Decostriol®*

### Storage

Store in the original package. Do not store above 30°C. Store in a well-closed containers to protect from light, heat and moisture.

Keep out of the reach and sight of children.

### Disposal

The expiry date of *Decostriol®* is printed on the carton, bottle and blister. Do not use if after expiry date. If your doctor tells you to stop taking *Decostriol®* or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

## 8. PRODUCT DESCRIPTION

### What it looks like?

*Decostriol® capsule* is a soft pink color capsule.

Pack in blister and bottle pack of 30, 50 or 100 soft capsules.

### Ingredients

Active ingredient:

Each *Decostriol® 0.25µg* capsule contains 0.25µg of Calcitriol.

Other ingredients:

*Butylhydroxytoluene, butylhydroxyanisole, arachis oil, gelatin, glycerol, sorbitol iron oxide, titanium dioxide.*

### Registration Number

*Decostriol® 0.25µg:*

MAL05032527XCR

## 9. MARKETING

### AUTHORISATION HOLDER & MANUFACTURER

#### Marketing Authorisation Holder:

IMEKS Pharma Sdn Bhd.

5 & 9, Jalan Udang Harimau 2,

Medan Niaga Kepong,

51200 Kuala Lumpur, Malaysia.

#### Manufacturers:

Bulk manufacturer:

Catalent Germany Eberbach GmbH

Eberbach, Germany

Packager and releaser:

mibe GmbH Arzneimittel

Munchener Str.15

D-06796 Brehna, Germany

#### Date of Revision:

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