

## **Package Leaflet: Information for the patient**

### **Ergocalciferol 300,000 IU solution for injection**

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet, Ergocalciferol 300,000 IU solution for injection will be called Ergocalciferol.

#### **What is in this leaflet**

1. What Ergocalciferol is and what it is used for
2. What you need to know before you are given Ergocalciferol
3. How you will be given Ergocalciferol
4. Possible side effects
5. How to store Ergocalciferol
6. Contents of the pack and other information.

#### **1. What Ergocalciferol is and what it is used for**

This medicine contains the active ingredient ergocalciferol which is a form of vitamin D. It belongs to a group of medicines called vitamin D and analogues.

Ergocalciferol increases levels of calcium and phosphate in the blood by increasing their absorption from the gut and reducing the amount removed by the kidneys.

Ergocalciferol is used to treat:

- Low levels of phosphate in the blood
- Weak bones and teeth (called 'Rickets')
- Other problems with how bones are formed.

These disorders are due to poor absorption of vitamin D within the body usually caused by diseases of the gut, liver or gall bladder.

It is important that you have this medicine so that your bones and teeth form properly.

#### **2. What you need to know before you are given Ergocalciferol**

##### **You must not be given Ergocalciferol:**

- if you are allergic to ergocalciferol (vitamin D) or any of the other ingredients of this medicine (listed in section 6)
- if you have high levels of calcium in your blood
- if you already have high levels of vitamin D in your blood, or if you are especially sensitive to vitamin D
- if you have kidney problems
- if you have an accumulation of calcium salts in the body's tissue.

If any of the above applies to you talk to your doctor or nurse.

#### **Warnings and precautions**

Talk to your doctor or nurse before being given Ergocalciferol:

- if you have heart disease, problems with your kidneys or with your circulation

- if you have kidney stones
- if you have low levels of parathyroid hormone (PTH)
- if you already have high levels of vitamin D in your blood or if you are especially sensitive to vitamin D.

It is important that you are **taking enough calcium** in your diet so that your body can respond properly to your medicine

### **Other medicines and Ergocalciferol**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

- Medicines for heart disease such as digoxin or verapamil as these can cause high levels of calcium in the blood leading to an irregular or fast heart beat.
- Antacids containing magnesium for indigestion. If you are on kidney dialysis this can lead to high levels of magnesium in the blood which causes muscle weakness, low blood pressure, depression and coma.
- Thiazide diuretics ('water tablets') to relieve water retention such as bendroflumethiazide as these can lead to high levels of calcium if your body does not produce enough parathyroid hormone (PTH).
- Phenytoin, carbamazepine, primidone or phenobarbital used for the treatment of epilepsy as these may cause ergocalciferol to be lost from the body too quickly.
- Any other medicine, including medicines obtained without a prescription.

If any of the above applies to you talk to your doctor or nurse before being given Ergocalciferol.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine.

Your doctor will tell you if you need to have Ergocalciferol when you are pregnant.

You should not be given Ergocalciferol if you are breast-feeding.

This medicine will be given to you in pregnancy only if your doctor decides it is necessary.

### **Driving and using machines**

Ergocalciferol may cause drowsiness or your eyes to become very sensitive to light. If this happens to you, do not drive or use machinery.

## **3. How you will be given Ergocalciferol**

Ergocalciferol will be given to you by your doctor or nurse.

**Important: Your doctor will choose the dose that is right for you.**

You will be given Ergocalciferol by your doctor or nurse as an injection into a muscle. You may be given it just once or it may be repeated daily depending on how much your body needs.

Your doctor may also prescribe for you other medicines containing calcium and phosphorus.

### **Use in adults and elderly**

The recommended dose is typically a single dose of 300,000 IU every 3-6 months.

### **Use in children**

The recommended dose in children of 1-12 years is a single dose of 300,000 IU generally given in 2 divided doses.

### **Medical check-ups**

While you are receiving this medicine, your doctor will test your blood and urine regularly. This is to make sure that your medicine is working properly and that the dose you are taking is right for you. If the level of sugar in your blood becomes higher than normal your doctor will stop your treatment with Ergocalciferol.

#### **If you are given more Ergocalciferol than you should**

If you think you have been given too much Ergocalciferol you should tell your doctor.

If you have too much Ergocalciferol you may get increased calcium levels in your blood which may lead to the following: feeling sick, feeling weak, weight loss, stiffness, constipation, diarrhoea, hallucinations, fainting, increased levels of urination or feeling thirsty.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects include:

##### **Very common: may affect more than 1 in 10 people**

- Too much calcium in blood (hypercalcaemia)
- Decrease activity of parathyroid gland (hypoparathyroidism)
- Disturbed parathyroid hormone metabolism (pseudohypoparathyroidism)
- Increased levels of creatinine in the blood which may indicate kidney problems.

##### **Rare: may affect up to 1 in 1,000 people**

- Psychosis – changes in abilities and personality.

##### **Not known: frequency cannot be estimated from the available data**

##### **Effects on the heart and blood**

- Hardening of the blood vessels
- Irregular heart beat
- High blood pressure
- High cholesterol
- Imbalanced salt levels.

##### **Effects on liver or kidneys**

- Kidney problems including kidney stones
- Increase in liver enzymes
- Protein in the urine.

##### **Effects on the stomach and bowel**

- Inflammation of the pancreas, which causes severe pain in the abdomen and back
- Feeling sick or being sick
- Constipation
- Diarrhoea
- Loss of appetite
- Weight loss.

##### **Effects on thirst and urinating**

- Dry mouth
- A metallic taste
- Drinking a lot
- Passing a lot of urine especially at night.

#### **Effects on the eyes and skin**

- Conjunctivitis
- Sensitivity to light
- Itchy skin.

#### **Effects on mood**

- Being irritable
- Loss of sex drive.

#### **Effects on the nervous system**

- Weakness
- Headache
- Dizziness
- Sleepiness.

#### **Other effects**

- Calcium deposits in parts of the body other than bone
- Muscle pain
- Bone pain
- Tiredness
- Feeling too hot
- Runny nose.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via Yellow Card Scheme Website:

[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. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Ergocalciferol**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store below 25°C. Keep the ampoules in the outer carton in order to protect it from light.

Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Ergocalciferol contains**

The active substance is ergocalciferol. Each 1 ml ampoule contains 300,000 IU of ergocalciferol. The only other ingredient is ethyl oleate.

#### **What Ergocalciferol looks like and contents of the pack**

Ergocalciferol is a colourless to pale yellow solution for injection.  
The product is available in clear glass (Type I) ampoules in packs containing 5 or 10 ampoules. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

##### **Marketing Authorisation Holder**

RPH Pharmaceuticals AB  
Box 603  
101 32 Stockholm  
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##### **Manufacturer**

Biologici Italia Laboratories S.r.l.  
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If this leaflet is difficult to see or read or you would like it in a different format, please contact:

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