or lifestyle does not provide you with enough Deficiency of vitamin D may occur when your diet is found in the human body. Colecalciferol, is identical to the vitamin D3 that bone formation. The active ingredient, calcium levels must be monitored and renal tests to check the amount of calcium in your blood.

What is in this leaflet
1. What Aviticol Capsules are and what they are used for
Aviticol Capsules contain the active ingredient colecalciferol.Colecalciferol is a form of vitamin D used in the initial treatment of clinically relevant vitamin D deficiency conditions in adults.

2. What you need to know before you take Aviticol Capsules
If you are allergic (hypersensitive) to colecalciferol or any of the other ingredients in the capsules (these are listed in section 6, Contents of the pack and other information) you should not take this medicine. If you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria) you should not take this medicine. If you suffer from severe renal impairment you should not take this medicine. If you already take other medicines containing vitamin D (e.g. multivitamin preparations) you should not take this medicine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Aviticol if you are allergic (hypersensitive) to colecalciferol or any of the other ingredients in the capsules (these are listed in section 6, Contents of the pack and other information). If you suffer from heart disease or narrowing of the arteries you should not take this medicine. If you suffer from sarcoidosis (a multisystem chronic inflammatory condition which can affect your lungs, heart and kidneys), then there is a risk of increased conversion of vitamin D into its active form. If you are taking medicines containing vitamin D, or eating foods or drinking milk enriched with vitamin D you should not take this medicine. If your renal function is impaired you should not take this medicine. If you have a tendency to form calcium- containing kidney stones you should not take this medicine. If you have taken or might be taking any other medicines leading to metabolic acidosis (e.g. phenobarbital, phenytoin, primidone) you should not take this medicine. If you have take a medicine to treat fungal infections i.e ketoconazole, itraconazole you should not take this medicine. If you have take a medicine used to treat some forms of cancer) as it may interfere with the metabolism of vitamin D you should not take this medicine. If you have take a medicine removing excess calcium from the blood (e.g. hydrocortisone or prednisolone) you should not take this medicine.

Do not take Aviticol

3. How to take Aviticol Capsules
Always take this medicine exactly as your doctor or pharmacist has told you and as written on the label. This also applies to patients who are particularly susceptible to the formation of kidney stones that contain calcium. During pregnancy Aviticol should be taken only when strictly indicated and dosed only as it is absolutely necessary to correct the vitamin D deficiency.

Children and adolescents
This product should not be used in young children and adolescents aged up to 18.

Other medicines and Aviticol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines which you have bought without a prescription. You must tell your doctor or pharmacist if you are taking any of the following medicines: medicines for epilepsy such as barbiturates or other anti-convulsants (e.g. carbamazepine, phenobarbital, phenytoin, primidone) other vitamin D containing medicines including multi-vitamins cardiac glycosides for the treatment of cardiovascular disease (e.g. digoxin, digitoxin) thiazide diuretics (water tablets) such as hydrochlorothiazide calcium supplements medicines to treat tuberculosis e.g rifampicin, isoniazid medicines leading to fat malabsorption e.g orlistat, cholestyramine, liquid paraffin medicines to treat fungal infections i.e ketoconazole, itraconazole actinomycin (a medicine used to treat some forms of cancer) as it may interfere with the metabolism of vitamin D glucocorticosteroids (steroid hormones such as hydrocortisone or prednisolone).

Aviticol Capsules with food and drink
Aviticol should preferably be taken together with food and drink.

Pregnancy, breast-feeding and fertility
Pregnancy During pregnancy Aviticol should be taken only when strictly indicated and dosed only as it is absolutely necessary to correct the vitamin D deficiency. Overdoses of vitamin D must be avoided during pregnancy, as prolonged hypercalcaemia (increased blood level of calcium) may lead to physical and mental disability as well as to congenital heart and eye diseases in the child.

Breast-feeding
Vitamin D and its metabolites are excreted in human milk. There have been no observed cases of overdose produced in this way among infants. This should, however, be borne in mind when administering additional vitamin D to the child. Treatment with high-dose vitamin D in breast-feeding women is not recommended.

Fertility
Normal endogenous levels of vitamin D are not expected to have any adverse effects on fertility.

Driving and using machines
Aviticol should not affect your ability to drive or operate machinery.

4. Possible side effects
Aviticol should not affect your ability to drive or operate machinery.

Recommended Dose and Dosage Schedules
Adults Initial treatment of clinically relevant vitamin D deficiency.

Package leaflet: Information for the Patient

Aviticol 20 000 IU Capsules
Colecalciferol (Vitamin D3), hard capsule

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is this medicine used for?
Aviticol 20 000 IU Capsules contain the equivalent of 500 micrograms vitamin D3 which is involved in bone formation. The active ingredient, colecalciferol, is identical to the vitamin D3 that is found in the human body. Deficiency of vitamin D may occur when your diet is found in the human body.

Where can I get more information?
If you have any further questions, ask your doctor, pharmacist or nurse.
Keep this medicine out of the sight and reach of children.

Store below 25°C. Store blister foil in the original container in order to protect from light.

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.

5. How to store Aviticol Capsules

6. Contents of the pack and other information

What Aviticol Capsules contain
The active substance is colecalciferol (vitamin D₃).

The other ingredients are medium-chain triglycerides, butylated hydroxytoluene (BHT), colloidal silicon dioxide, titanium dioxide E171, yellow iron oxide E172 and gelatin.

What Aviticol 20 000 IU Capsules look like and contents of the pack
Aviticol 20 000 IU Capsule is an ivory unprinted hard gelatin capsule containing a clear, slightly oily liquid. It is available in Germany in blister packs containing 14 hard capsules, and in UK and Malta in blister packs containing 10, 14, 20, 28, 30, 56, 60, 84 and 100 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Colonis Pharma Limited
Quantum House
Hobson Industrial Estate
Burnopfield
County Durham
NE16 6EA

United Kingdom
E-mail: medinfo@colonis.co.uk

Manufacturers
MW Encap Limited
Oakbank Park
Building 1
Units 4, 5 & 6
Livingston
West Lothian
EH53 0TH

United Kingdom
mibe GmbH Azneimittel
Münchener Straße 15
06796 Brehna

Germany

This medicinal product is authorised in other Member States of the EEA under the following names:

Malta:
Aviticol 20 000 IU Capsules
Colecalciferol 20 000 IU Capsules

Germany: Dekristol 20.000 IE N

This leaflet was last revised in May 2018.

4. Possible side effects

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

Side effects with Aviticol may include:

Uncommon side effects
(affecting less than 1 in 100 people)
- too much calcium in your blood
  (hypercalcaemia). You may feel or be sick, lose
  your appetite, have constipation, stomach
  ache, feel very thirsty, have muscle weakness,
  drowsiness or confusion
- too much calcium in your urine (hypercalciuria).

Rare side effects
(affecting less than 1 in 1000 people)
- skin rash
- itching
- raised itchy rash (hives)

Tell your doctor or pharmacist if any of the side effects become serious or if you notice any side effects not listed.

Reporting of side effects

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

You can also report side effects directly to the relevant medicine authority (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom:
The Yellow Card Scheme
Medicines and Healthcare Products Regulatory Agency
151 Buckingham Palace Road
Victoria
London, SW1W 9SZ

United Kingdom
Website: www.mhra.gov.uk/yellowcard