



INFORMATION FOR MEDICAL PROFESSIONALS

ANCOPIR® Dragées / Ampoules

Composition

Dragée

Active ingredients: cyanocobalamin (Vit. B₁₂), pyridoxine hydrochloride (Vit. B₆), thiamine nitrate (Vit. B₁) / Excipients: coating material for tablets.

Ampoule

Active ingredients: cyanocobalamin (Vit. B₁₂), pyridoxine hydrochloride (Vit. B₆), thiamine hydrochloride (Vit. B₁), lidocaine hydrochloride. Excipients: Sorbitol; Preservative: E 218 1.6mg, enough water for injection of 2ml of product.

Galenic form and active ingredient content per unit

Dragée

1 dragée contains: 0.3mg cyanocobalamin (Vit. B₁₂), 100mg pyridoxine hydrochloride (Vit. B₆), 200mg thiamine nitrate (Vit. B₁)

Ampoule

1 ampoule of 2ml contains: 1.0mg cyanocobalamin (Vit. B₁₂), 50mg pyridoxine hydrochloride (Vit. B₆), 200mg thiamine hydrochloride (Vit. B₁), 10mg lidocaine hydrochloride

Indications / Application options

Vitamin-B₆-symptoms of deficiency, adjuvant in neuralgia and neuritis, sciatica, lumbago.

In cases of chronic intoxication, particularly alcoholism.

As an adjuvant in radiation sickness.

Dosage / Application

Adults

1-2 dragées per day to be taken with fluid.

1 ampoule per day, to be administered intramuscularly.

Children

Because of their high vitamin B₆ content Ancopir dragées and ampoules are not recommended for the treatment of children.

Contraindications

Ancopir may not be given to patients who are known to be hypersensitive to one or more constituents of the preparation.

Ancopir is contraindicated for patients with psoriasis.

Administration of high doses of Vitamin B₆ is contraindicated for patients taking Levodopa.

Precautions

Parenteral administration is not recommended for patients with a known allergic disposition.

In certain circumstances and in isolated cases an anaphylactic reaction can occur after repeated intramuscular injections of thiamine-containing preparations in pre-disposed patients. The administration of glucocorticoid and antihistamine preparations act as countermeasures.

Interactions

High doses of vitamin B₆ cancel the effect of Levodopa.

Thiosemicarbazone and 5-fluorouracil act as thiamine antagonists and cancel the action of vitamin B₁.

Antacids hinder the absorption of vitamin B₁.

Pregnancy / breastfeeding

Dragées

Vitamins B₁, B₆ and B₁₂ can be taken in a quantity corresponding to the daily requirement. There are no controlled studies available on either animals or pregnant women stating whether Ancopir can be given as a daily dose. Ancopir dragées should not be given during pregnancy unless there are clear indications that this is necessary.

Ampoules

There are again no controlled studies available on animals or pregnant women.

Ancopir ampoules should not be administered during pregnancy unless there are clear indications that this is necessary.

Breastfeeding

The active ingredients are passed to the child in the mother's milk. Ancopir should therefore not be taken while breastfeeding unless there are clear indications that it is necessary.

Effect on the ability to drive and operate machinery

No relevant studies have been carried out.

Undesirable effects

When high doses of B₆ (more than 2g in 24h) are taken and/or when it is prescribed over a long period (more than 6 months) extraordinary neurological symptoms have been observed (paraesthesia, peripheral neuropathy); these symptoms disappear after stopping treatment. These paraesthesia/sensitivity disturbances have on occasion already been observed during long term administration of daily doses of 200mg (and below).

Vitamin B₁₂ can exacerbate existing acne.

Repeated i.v. administration and in certain circumstances also repeated i.m. administration of preparations containing B₁ can sometimes result in ana-

phyllactic reactions occurring in isolated cases and in patients with a pre-disposition thereto.

Overdose

If vitamin B₁₂ is taken in huge doses (over 2g/24h) for a short period or in daily doses of 200mg over a period of months, this can occasionally lead to peripheral sensory neuropathy, although this is generally reversible when the patient stops taking the drug.

Properties/Effects

ATC-Code: A11DB

The active ingredients of Ancopir are of great importance for energy production as well as for the metabolism of protein and nucleic acid in cells.

Thiamine (Vit. B₁) acts as a co-factor in many reactions involved in carbohydrate and lipid metabolism. Vitamin-B₁ requirement is directly related to the degree of carbohydrate absorption. B₁ requirement therefore increases if the diet is rich in carbohydrates. At high doses there is evidence of vitamin B₁ having an analgesic effect.

Vitamin B₆ (pyridoxine) acts as a co-enzyme for numerous enzymes that are involved in protein and amino acid metabolism. The most marked form of deficiency manifests itself as neurological symptoms.

Vitamin B₁₂ (cyanocobalamin) fulfils an important metabolic function in lipid and carbohydrate metabolism. It is required for the production of methionine and subsequently for folic acid metabolism as well as for the synthesis of DNA.

In high doses Vitamin B₁₂ exhibits an analgesic effect.

The balanced combination of vitamins B₁, B₆ and B₁₂ in Ancopir has anti-neuritic, detoxifying and anti-anaemic properties.

Pharmacokinetics

Absorption

Oral intake

The absorption of vitamin B1 occurs in the gastro-intestinal tract by Na⁺-dependent active transport; in higher concentrations it also occurs by passive diffusion.

Vitamin B₆ is absorbed from the gastro-intestinal tract after hydrolysis of its phosphorylated derivatives.

The absorption of vitamin B₁₂ is dependent on the presence of intrinsic factors in the gastric mucosa.

Distribution

Vitamin B₁ quickly diffuses into organic tissue and fluids, without any significant deposition in any particular organ.

Vitamin B₆ transfers into the foetus and is expressed in the mother's milk.

There is almost no binding of pyridoxine to plasma proteins. However, pyridoxal phosphate makes up at least 60 % of the vitamin B₆ that is circulating. Vitamin B₆ transfers into the foetus and is expressed in the mother's milk.

Vitamin B₁₂ binds to the plasma proteins. Transcobalamin II is responsible for its transport at tissue level. Vitamin B₁₂ is stored in the liver and enters the enteropathic circulation. Vitamin B₁₂ is actively transported into the foetus and is expressed in the mother's milk.

Metabolism

When a daily dose of 1mg Vitamin B₁ (approx. the normal daily dose) is taken, this is metabolised completely in the tissues. If the daily requirement is exceeded, vitamin B₁ is first deposited in the tissues.

Due to the effect of hepatic aldehyde oxidase the free pyridoxine is converted into 4-pyridoxine acid.

Vitamin B12 is not metabolised.

Elimination

The half-life period for the elimination of vitamin B₁ is approx. 0.35 hours.

With a daily intake of approx. 1mg very little, or hardly any, Vitamin B₁ is excreted in the urine. Excess vitamin B₁ is excreted in the urine as unchanged thiamine and pyrimidine, which results from the breakdown of thiamine. More vitamin B₁ is eliminated unchanged the greater excess there is in the body. Vitamin B₆ is generally eliminated in the urine as 4-pyridoxine acid.

Vitamin B₁₂ is eliminated bilially, partially also renally. Excess vitamin B₁₂ is eliminated in the urine, usually within the first 8 hours after being taken.

Pre-clinical data

There is no relevant pre-clinical data regarding administration available.

Other information

Storage life / storage

Store under dry conditions at room temperature (15–25°C), and out of reach of children. The drug should not be used after the exp. date printed on the container.

Marketing authorisation

28'486 ampoules (Swissmedic), 34'662 dragées (Swissmedic)

Packs

5 Ancopir ampoules (B), 20 Ancopir dragées (B)



Marketing authorisation holder

Dr. Grossmann AG Pharmacia
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