INFORMATION FOR MEDICAL PROFESSIONALS

ANCOPIR® Dragées / Ampoules

Composition

Dragée

Active ingredients: cyanocobalamine (Vit. B_{12}), pyridoxine hydrochloride (Vit. B_6), thiamine nitrate (Vit. B_1) / Excipients: coating material for tablets.

Ampoule

Active ingredients: cyanocobalamine (Vit. B_{12}), pyridoxine hydrochloride (Vit. B_6), thiamine hydrochloride (Vit. B_1), 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 cyanocobalamine (Vit. B_{12}), 100mg pyridoxine hydrochloride (Vit. B_6), 200mg thiamine nitrate (Vit. B_1)

Ampoule

1 ampoule of 2ml contains: 1.0mg cyanocobalamine (Vit. B_{12}), 50mg pyridoxine hydrochloride (Vit. B_6), 200mg thiamine hydrochloride (Vit. B_1), 10mg lidocaine hydrochloride

Indications / Application options

Vitamin-B_6-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 B_6 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 B_6 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 B_6 cancel the effect of Levodopa.

Thiosemicarbazone and 5-fluorouracil act as thiamine antagonists and cancel the action of vitamin B_1.

Antacids hinder the absorption of vitamin B_1.

Pregnancy / breastfeeding

Dragées

Vitamins B_1, B_6 und B_{12} 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 B_6 (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 B_{12} can exacerbate existing acne.

Repeated i.v administration and in certain circumstances also repeated i.m. administration of preparations containing B_1 can sometimes result in ana-

phylactic reactions occurring in isolated cases and in patients with a predisposition thereto.

Overdose
If vitamin B_6 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. B_1) acts as a co-factor in many reactions involved in carbohydrate and lipid metabolism. Vitamin-B_1 requirement is directly related to the degree of carbohydrate absorption. B_1 requirement therefore increases if the diet is rich in carbohydrates. At high doses there is evidence of vitamin B_1 having an analgesic effect.
Vitamin B_6 (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 B_{12} (cyanocobalamine) 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 B_{12} exhibits an analgesic effect.
The balanced combination of vitamins B_1, B_6 and B_{12} in Ancopir has antineuritic, 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 B_6 is absorbed from the gastro-intestinal tract after hydrolysis of its phosphorylated derivatives.
The absorption of vitamin B_{12} is dependent on the presence of intrinsic factors in the gastric mucosa.

Distribution
Vitamin B_1 quickly diffuses into organic tissue and fluids, without any significant deposition in any particular organ.
Vitamin B_1 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 B_6 that is circulating.
Vitamin B_6 transfers into the foetus and is expressed in the mother's milk.
Vitamin B_{12} binds to the plasma proteins. Transcobalamine II is responsible for its transport at tissue level. Vitamin B_{12} is stored in the liver and enters the enteropathic circulation. Vitamin B_{12} is actively transported into the foetus and is expressed in the mother's milk.

Metabolism
When a daily dose of 1mg Vitamin B_1 (approx. the normal daily dose) is taken, this is metabolised completely in the tissues. If the daily requirement is exceeded, vitamin B_1 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 B_1 is approx. 0.35 hours.
With a daily intake of approx. 1mg very little, or hardly any, Vitamin B_1 is excreted in the urine. Excess vitamin B_1 is excreted in the urine as unchanged thiamine und pyrimidine, which results from the breakdown of thiamine. More vitamin B_1 is eliminated unchanged the greater excess there is in the body.
Vitamin B_6 is generally eliminated in the urine as 4-pyridoxine acid.
Vitamin B_{12} is eliminated biliarly, partially also renally. Excess vitamin B_{12} 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 Pharmaca
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Last revision of information: April 2006