

MAGNE B6[®] 48 mg/5 mg coated tablets

magnesium-vitamin B6

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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.

In this leaflet:

1. What Magne B6 48 mg/5 mg coated tablets are and what they are used for
2. Before you take Magne B6 48 mg/5 mg coated tablets
3. How to take Magne B6 48 mg/5 mg coated tablets
4. Possible side effects
5. How to store Magne B6 48 mg/5 mg coated tablets
6. Further information

1. WHAT Magne B6 48 mg/5 mg coated tablets ARE AND WHAT THEY ARE USED FOR

Pharmacotherapeutic group

MINERAL SUPPLEMENTS

Therapeutic indication

This medicinal product is intended for the treatment of magnesium deficiency confirmed by your doctor.

2. BEFORE YOU TAKE Magne B6 48 mg/5 mg coated tablets

If your doctor has told you that you have an intolerance to certain sugars, consult him/her before taking this medicine.

Contraindication

Do not take Magne B6 48 mg/5 mg coated tablets:

- if you are allergic to any of the ingredients in the medicine (see "What Magne B6 48 mg/5 mg coated tablets contain"),
- if you have severe renal insufficiency (kidney failure).

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Appropriate precautions for use; special warnings

Take special care with Magne B6 48 mg/5 mg coated tablets:

Warnings

If you have severe magnesium deficiency, treatment is to be initiated via the intravenous route. This also applies to patients who suffer from malabsorption.

If you also have calcium deficiency, in most cases the magnesium deficiency should be corrected first before calcium is taken.

As this medicine contains sucrose, you must not take it if you have fructose intolerance, glucose and galactose malabsorption syndrome or sucrase-isomaltase deficiency (rare hereditary diseases). Taking high doses of pyridoxine (vitamin B6) over a long period of time (several months or even years) can cause tingling sensations and balance disorders, tremor of the hands and feet, and difficulty coordinating movements. These effects are generally reversible on stopping treatment.

Precautions for use

THIS MEDICINE IS FOR ADULTS AND CHILDREN OVER 6 YEARS OF AGE ONLY.

Pharmaceutical forms are available that are more suitable for use in children under 6 years of age.

If you have moderate kidney failure, precautions should be taken to avoid the risk of an increase in blood magnesium levels.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Using other medicines

TO AVOID POSSIBLE INTERACTIONS BETWEEN DIFFERENT MEDICINES, particularly phosphate or calcium salts, YOU MUST SYSTEMATICALLY INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT YOU MAY BE TAKING.

Pregnancy and breast-feeding

Pregnancy

Use of this medicine may be considered at any stage during pregnancy, if needed. If you discover that you are pregnant during treatment, consult your doctor who alone can determine whether you should continue treatment.

Ask your doctor or pharmacist for advice before using any medicine.

Breast-feeding

Breast-feeding women should not take more than 20 mg/day of vitamin B6.

Ask your doctor or pharmacist for advice before using any medicine.

Excipient with a specific effect

Sucrose.

3. HOW TO TAKE Magne B6 48 mg/5 mg coated tablets

Dosage

FOR ADULTS AND CHILDREN OVER 6 YEARS OF AGE ONLY.

Adults: 6 to 8 tablets per day, in 2 or 3 divided doses during meals.

Children over 6 years of age (weighing approximately 20 kg): 4 to 6 tablets per day, in 2 or 3 divided doses during meals.

Method and route and of administration

Oral use.

The tablets should be swallowed with a large glass of water.

Duration of treatment

Treatment is to be stopped as soon as blood magnesium levels have returned to normal.

If you take more Magne B6 48 mg/5 mg coated tablets than you should

An overdose of magnesium taken orally does not generally lead to toxic reactions in patients with normal kidney function. However, magnesium poisoning can occur in patients with kidney failure.

If you forget to take Magne B6 48 mg/5 mg coated tablets

Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Magne B6 48 mg/5 mg coated tablets can cause side effects, although not everybody gets them them.

- diarrhea,
- abdominal pain,
- skin reactions,
- allergic reactions.

DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

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.

5. HOW TO STORE Magne B6 48 mg/5 mg coated tablets

Keep out of the reach and sight of children.

Do not use Magne B6 48 mg/5 mg coated tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Magne B6 48 mg/5 mg coated tablets contain

The active substances are:

Magnesium lactate dihydrate	470.00 mg
Pyridoxine hydrochloride (vitamin B6)	5.00 mg

for one coated tablet.

The total magnesium content per tablet is 48 mg (1.97 mmol).

The other ingredients are:

Sucrose, heavy kaolin, acacia, carboxypolymethylene, talc, magnesium stearate, titanium dioxide (E171), carnauba wax powder.

What Magne B6 48 mg/5 mg coated tablets look like and contents of the pack

This medicine is available as coated tablets (Box of 50).

Marketing Authorization Holder and Operating Company sanofi-aventis France

1-13, boulevard Romain Rolland
75014 Paris - France

Manufacturer

SANOFI WINTHROP INDUSTRIE
1, rue de la Vierge, Ambarès & Lagrave,
F-33565 Carbon Blanc Cedex, France

This leaflet was last approved in October 2010.

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