

Package leaflet: Information for the patient

Pabrinex Intravenous High Potency Concentrate for Solution for Infusion

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

- Please 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.

What is in this leaflet:

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

1. What Pabrinex Intravenous is and what it is used for

Pabrinex Intravenous High Potency Concentrate for Solution for Infusion ('Pabrinex Intravenous') provides additional thiamine hydrochloride, riboflavin, pyridoxine hydrochloride and nicotinamide (B vitamins); ascorbic acid (vitamin C); and glucose to correct deficiencies that may have occurred:

- in alcoholism
- through unbalanced diet (malnutrition) or
- poor absorption (malabsorption) of the water soluble vitamins B and C.

Vitamins B and C are important for a number of bodily functions including releasing energy from food and in the formation of healthy skin, bones and teeth.

This medicine will be given to you by a healthcare professional by drip infusion into a vein.

2. What you need to know before you are given Pabrinex Intravenous

You MUST NOT be given Pabrinex Intravenous:

- if you are allergic to any of the ingredients of this medicine (listed in section 6)
- if you have a history of sensitivity to vitamins B and/or C

Warnings and precautions

Talk to your doctor or nurse before you are given Pabrinex Intravenous.

Pabrinex Intravenous should be given with extreme caution if you have:

- ever had a mild allergic reaction (sneezing or mild asthma) to any previous injections of vitamin B1 (thiamine). This could mean that you may have become hypersensitive, and could have a more **severe allergic reaction/anaphylactic shock** if given Pabrinex Intravenous. This may also occur with the first injection.

This **intravenous** medicine must NOT be given into the muscle. Pabrinex is also available as an **intramuscular** injection.

Other medicines and Pabrinex Intravenous

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

The effectiveness of some medicines may be affected by Pabrinex Intravenous, including:

- Levodopa (used in the treatment of *Parkinson's disease*) – Pabrinex Intravenous interferes with the effects of this medicine.
- Vitamin B1 (thiamine) injections - if you are on repeated injections of such preparations, Pabrinex Intravenous may cause sneezing or mild asthma (chest tightness and wheezing) or even anaphylactic shock if you have become hypersensitive.

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 or pharmacist for advice before taking this medicine.

Driving and using machines

Pabrinex is not expected to affect your ability to drive or operate machinery.

Pabrinex contains sodium:

This medicine contains 79 mg sodium (main component of cooking/table salt) in each **1 pair of 5ml ampoules**. This is equivalent to 4% of the recommended daily dietary intake of sodium for an adult.

3. How Pabrinex Intravenous is given

Pabrinex Intravenous will be given to you by drip infusion into a vein by a healthcare professional. The product comes in two ampoules (a No. 1 and a No. 2 – *see section 6 Contents of the pack and other information*), the contents of which are mixed and then diluted with either saline or 5% glucose. The mixed solution is given by infusion over a period of 30 minutes. Once diluted the solution should be used immediately.

This medicine is for injection into a vein only and should not be given by any other route.

Dosage for adults including the elderly:

For rapid therapy of severe depletion or malabsorption of water soluble vitamins B and C, particularly in alcoholism: 2 to 3 pairs of 5 ml ampoules (1 pair = ampoule 1 + ampoule 2) diluted with 50 ml to 100 ml of infusion solution and injected over 30 minutes at intervals decided by your doctor (typically every 8 hours).

The exact dose you will be given will depend on how vitamin deficient you are. Your doctor will monitor your condition and determine what treatment you need. It will usually be no more than nine pairs of ampoules per day. If you feel that you have been given an inappropriate dose or if you would like more information about Pabrinex Intravenous, speak to your doctor.

If you are given too much Pabrinex Intravenous

This product will be given to you under medical supervision. It is therefore unlikely that you will be given too much. However, if you feel unwell, you should tell your doctor or nurse immediately.

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.

- **Allergic reaction** - if following your injection you experience symptoms such as sneezing or mild asthma (chest tightness and wheezing) **tell your doctor immediately**. This may be an indication that you are sensitive to Pabrinex Intravenous and should not be given a repeat dose.
- Severe allergic reaction (anaphylactic shock) - may result from repeated injections of this medicine. Symptoms may include: swelling of the face and or throat, skin rash, severe itching, difficulty in breathing and loss of consciousness due to very low blood pressure
- Low blood pressure, sweating, nausea, vomiting, difficulty in breathing or wheezing (bronchospasm) - can occur in some patients given Pabrinex Intravenous.
- Mild ache, swelling or feeling of 'pins and needles' (mild paraesthesia) - may develop at the site where Pabrinex Intravenous is administered.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

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

5. How to store Pabrinex Intravenous

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Protect from light. Do not freeze.

Once mixed or diluted, it should be used immediately.

Do not use this this medicine after the expiry date which is stated on the ampoule label and the carton after EXP. The expiry date refers to the last day of that month. Each ampoule should be visually inspected prior to administration and should not be used if particulates are present.

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 Pabrinex Intravenous High Potency Concentrate for Solution for Infusion contains

The active substances are:

AMPOULE 1	5 ml
thiamine hydrochloride (vitamin B1)	250 mg
riboflavin (as phosphate sodium) (vitamin B2)	4 mg
pyridoxine hydrochloride (vitamin B6)	50 mg
AMPOULE 2	5 ml
ascorbic acid (vitamin C)	500 mg
nicotinamide	160 mg
glucose (as monohydrate)	1000 mg

The other ingredients are: edetic acid, sodium hydroxide and water for injections.

What Pabrinex Intravenous looks like and contents of the pack

The product is supplied in pairs of amber coloured glass ampoules containing 5 ml of sterile solution. Each pack contains 6 or 10 pairs of 5 ml ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Kyowa Kirin Holdings B.V.
Bloemlaan 2
2132NP Hoofddorp
Netherlands

Manufacturer

Haupt Pharma Wülfing GmbH
Bethelner Landstraße 18
31028 Gronau
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