Pabrinex Intravenous High Potency Solution for Injection or Infusion

Read all of this leaflet carefully before you are given 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 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.

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

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

Pabrinex Intravenous High Potency Solution for Injection or Infusion ('Pabrinex Intravenous Injection') 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 either a drip infusion or an injection into a vein.

2. What you need to know before Pabrinex Intravenous Injection is given

You MUST NOT be given Pabrinex Intravenous Injection if you have:
- an allergy (hypersensitivity) to any of the ingredients in the product (see Section 6 ‘Contents of the pack and other information’)

Warnings and precautions
Talk to your doctor or nurse before you are given Pabrinex Intravenous Injection 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 Injection. This may also occur with the first injection.

This intravenous injection must NOT be given into the muscle.

Other medicines and Pabrinex Intravenous Injection
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

The effectiveness of some medicines may be affected by Pabrinex Intravenous Injection, including:
- Levodopa (used in the treatment of Parkinson’s disease) – Pabrinex Intravenous Injection interferes with the effects of this medicine.

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 for advice before you are given this medicine.

3. How Pabrinex Intravenous Injection is given

Pabrinex Intravenous Injection is usually given by drip infusion into a vein by a healthcare professional. The product comes in two vials (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.

Alternatively, Pabrinex Intravenous Injection can be given undiluted by mixing the contents of each vial in a syringe just before use and injecting slowly into a vein over a period of not less than 30 minutes.

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 vials per day. If you feel that you have been given an inappropriate dose or if you would like more information about Pabrinex Intravenous Injection, speak to your doctor.

If you are given too much Pabrinex Intravenous Injection
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 Injection and should not be given a repeat dose.
- Severe allergic reaction (anaphylactic shock) - may result from repeated injections of this product. 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 Injection.
- Mild ache, swelling or feeling of ‘pins and needles’ (mild paraesthesia) - may develop at the site where Pabrinex Intravenous Injection is administered.

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

**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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie.

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

5. How to store Pabrinex Intravenous Injection
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 vial label and the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

**What Pabrinex Intravenous High Potency Solution for Injection or Infusion contains**

The **active** ingredients are:

<table>
<thead>
<tr>
<th>VIAL 1</th>
<th>5ml</th>
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<tbody>
<tr>
<td>thiamine hydrochloride (vitamin B₁)</td>
<td>250mg</td>
</tr>
<tr>
<td>riboflavin (vitamin B₂)</td>
<td>4mg</td>
</tr>
<tr>
<td>pyridoxine hydrochloride (vitamin B₆)</td>
<td>50mg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VIAL 2</th>
<th>5ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>ascorbic acid (vitamin C)</td>
<td>500mg</td>
</tr>
<tr>
<td>nicotinamide</td>
<td>160mg</td>
</tr>
<tr>
<td>anhydrous glucose</td>
<td>1g</td>
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The **other** ingredients are: edetic acid, sodium hydroxide and water for injections.

**What Pabrinex Intravenous Injection looks like and contents of the pack**

The product is supplied in pairs of yellow coloured glass vials containing 5ml of sterile solution. Packs contain 10 pairs of 5ml vials.

**Marketing Authorisation Holder**
Archimedes Pharma UK Limited
250 South Oak Way
Green Park
Reading
RG2 6UG, UK.

**Manufacturer**
Haupt Pharma Wülfing GmbH
Bethelner Landstraße 18
31028 Gronau
Germany.

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