

PACKAGE LEAFLET: INFORMATION FOR THE USER
Pabrinex® Intramuscular High Potency, Solution for injection
(Vitamins B & C Injection)

Read all of this leaflet carefully before you start taking 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT PABRINEX INTRAMUSCULAR INJECTION IS AND WHAT IT IS USED FOR

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.

Pabrinex Intramuscular High Potency, Solution for injection ('Pabrinex') provides additional vitamins B and C to correct deficiencies that may have occurred, for example:

- in alcoholism
- after infections
- after operations
- in certain psychiatric states.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN PABRINEX INTRAMUSCULAR INJECTION

You MUST NOT be given Pabrinex Intramuscular injection:

- 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 before taking Pabrinex Intramuscular injection.

Pabrinex 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** if given Pabrinex Intramuscular injection.

Other medicines and Pabrinex Intramuscular injection

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

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

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to become pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medicine.

Driving and using machines

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

Pabrinex Intramuscular contains sodium and benzyl alcohol:

This medicine contains approximately 67 mg sodium (main component of cooking/table salt) in each 7 ml dose (1 pair of ampoules). This is equivalent to 3.4% of the WHO recommended maximum daily intake of 2 g sodium for an adult

This medicine contains approximately 139 mg benzyl alcohol in each 7 ml dose (1 pair of ampoules) which is equivalent to 19.9 mg/ml:

- Benzyl alcohol may cause allergic reactions.
- Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.
- Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.
- Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
- Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

3. HOW PABRINEX INTRAMUSCULAR INJECTION IS GIVEN

Pabrinex Intramuscular, the contents of which are mixed from two ampoules, is usually given by slow injection into your gluteal (bottom) muscle by a healthcare professional.

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

Dosage for adults including the elderly:

7ml of the mixed ampoules (one pair) twice daily for up to 7 days.

Use in children and adolescents: Pabrinex Intramuscular injection is not usually given to children; however, suitable doses according to the child's age are:

Age	Dose
<i>under 6 years</i>	1/4 of the adult dose
<i>6-10 years</i>	1/3 of the adult dose
<i>10-14 years</i>	1/2 to 2/3 of the adult dose
<i>14 years and older</i>	one adult dose

The exact dose you will be given will be decided by your doctor who will monitor your condition and determine what treatment you need. If you feel that you have been given an inappropriate dose or if you would like more information about Pabrinex Intramuscular injection, speak to your doctor.

If you are given more Pabrinex Intramuscular injection than you should

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 immediately.

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

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 Intramuscular injection 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, rash, severe itching, difficulty in breathing and loss of consciousness due to very low blood pressure.
- Low blood pressure and feeling of ‘pins and needles’ (mild paraesthesia) - can occur in some patients given Pabrinex Intramuscular injection
- Mild ache - some swelling may develop at the site where Pabrinex is injected.

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 the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE PABRINEX INTRAMUSCULAR INJECTION

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

Pabrinex Intramuscular injection should be stored in a refrigerator at 2°C to 8°C but not frozen, and protected from light. Do not use this medicine after the expiry date which is stated on the outer carton and ampoule labels 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 medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pabrinex Intramuscular injection contains

The **active** substances are:

AMPOULE 1	5 ml
thiamine hydrochloride (vitamin B1)	250 mg
riboflavin (vitamin B2)	4 mg
pyridoxine hydrochloride (vitamin B6)	50 mg
AMPOULE 2	2 ml
ascorbic acid (vitamin c)	500 mg
nicotinamide	160 mg

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

What Pabrinex Intramuscular injection looks like and contents of the pack

The product is supplied in pairs of amber coloured glass ampoules containing 5 ml or 2 ml of sterile solution. Pack sizes contain 10 pairs of 5 ml and 2 ml ampoules

Marketing Authorisation Holder

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