SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pabrinex Intramuscular High Potency, Solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each presentation (carton) contains pairs of 5 ml and 2 ml ampoules. Each pair of ampoules consists of one 5 ml and one 2 ml ampoule to be used in treatment, labelled as Pabrinex No. 1 and Pabrinex No. 2.

Each No. 1 ampoule contains:	5 ml ampoule
Thiamine Hydrochloride	250 mg
Riboflavin (as Phosphate Sodium)	4 mg
Pyridoxine Hydrochloride	50 mg

Each No. 2 ampoule contains:	2 ml ampoule
Ascorbic acid	500 mg
Nicotinamide	160 mg

Excipients with known effect:
Sodium (either as phosphate sodium, or as sodium hydroxide) and benzyl alcohol – please refer to section 4.4 for further details.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Pabrinex IM is indicated in adults and children for rapid therapy of severe depletion or malabsorption of the water soluble vitamins B and C:

- particularly in alcoholism
- after acute infections
- post-operatively
- in psychiatric states.

4.2 Posology and method of administration

Pabrinex is also available as an Intravenous High Potency, Solution for Injection. Therefore before administration ensure that both the Summary of Product Characteristics and ampoule labels refer to the INTRAMUSCULAR injection.

Posology

Adults and elderly: The contents of one pair of ampoules (7ml) twice daily for up to 7 days.

Paediatric population: Pabrinex Intramuscular High Potency is rarely indicated for administration to children, however suitable doses are as follows:

Under 6 years	quarter of the adult dose
6-10 years	third of the adult dose
10-14 years	half to two thirds of the adult dose
14 years and over	as for the adult dose

Method of administration

The contents of one ampoule number 1 and one ampoule number 2 of Pabrinex Intramuscular High Potency (total 7 ml) are drawn up into a syringe to mix them just before use, then injected slowly high into the gluteal muscle, 5cm below the iliac crest.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Although potentially serious allergic adverse reactions such as anaphylactic shock may occur rarely during, or shortly after, parenteral administration of Pabrinex Intramuscular, such rare occurrence of serious allergic reactions should not preclude the use of Pabrinex Intramuscular in patients who need treatment by this route of administration. Initial warning signs of a reaction to Pabrinex Intramuscular are sneezing or mild asthma, and those treating patients need to note that the administration of further injections to such patients may give rise to anaphylactic shock. Facilities for treating anaphylactic reactions should be available whenever Pabrinex Intramuscular High Potency is administered.

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

Care should be taken to ensure that the route of administration used (intramuscular or intravenous) is that intended – reports of unintentional administration by the wrong route have been received; these incidents have not been associated with serious adverse reactions.

In common with all parenteral products each ampoule should be visually inspected prior to administration and should not be used if particulates are present.

This medicinal product contains approximately 67 mg sodium per 7 ml dose (1 pair of ampoules), 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.
- Intravenous administration of benzyl alcohol has been associated with serious adverse events and death in neonates ("gasping syndrome"). The minimum amount of benzyl alcohol at which toxicity may occur is not known.
- Increased risk due to accumulation in young children.
- High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis)

4.5 Interaction with other medicinal products and other forms of interaction

The content of pyridoxine may interfere with the effects of concurrent levodopa therapy.

4.6 Fertility, Pregnancy and lactation

No adverse effects have been reported at recommended doses when used as clinically indicated.

Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). The potential risk for humans is unknown.

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Adverse reactions reported as possibly associated to Pabrinex are presented in the following table by MedDRA System Organ Class (SOC), Preferred Term and frequency. The following frequency categories are used:

Very common (>1/10);
Common (>1/100, <1/10);
Uncommon (>1/1,000, <1/100);
Rare (>1/10,000, <1/1,000);
Very rare (<1/10,000), including isolated reports.

Post-marketing adverse reactions are reported voluntarily from a population with an unknown rate of exposure. Therefore it is not possible to estimate the true incidence of adverse reactions and the frequency is "unknown".

Tabulated summary of adverse reactions

SYSTEM ORGAN CLASS (SOC)	FREQUENCY	ADVERSE REACTION
Immune system disorders	Unknown	Hypersensitivity (including anaphylaxis, rash and urticaria)
Nervous system disorders	Unknown	Paraesthesia
Vascular disorders	Unknown	Hypotension
General disorders and administration site conditions	Unknown	Injection site reactions (including pain and swelling)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose
In the unlikely event of over dosage, treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pabrinex Intramuscular High Potency contains vitamins B1, B2, B6, nicotinamide and vitamin C.

Pharmacotherapeutic group: Vitamin B-complex with vitamin C, ATC code: A11EB

5.2 Pharmacokinetic properties
None supplied.

5.3 Preclinical safety data
There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Edetic acid

Sodium hydroxide

Benzyl alcohol

Water for Injections

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in a refrigerator at 2°C to 8°C. Keep the container in the outer carton. Do not freeze.

6.5 Nature and contents of container

Pabrinex Intramuscular High Potency is supplied in pairs of (5ml and 2ml) amber glass ampoules in packs of 10 pairs.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Kyowa Kirin Limited
Galabank Business Park
Galashiels
TD1 1QH
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 16508/0058

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: October 1993

Date of the latest renewal: October 2003

10 DATE OF REVISION OF THE TEXT

27/09/2018