Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pabrinex Intravenous High Potency Concentrate for Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each presentation (carton) contains 5 ml ampoules. Each pair of ampoules to be used in treatment is labelled Pabrinex No 1 and Pabrinex No 2.

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

Each No. 2 ampoule (5 ml) contains:
Ascorbic Acid 500 mg
Nicotinamide 160 mg
Glucose (as monohydrate) 1000 mg

Excipients with known effect:
This medicine contains 79 mg sodium per 1 pair of 5 ml ampoules, equivalent to 4% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion

Ampoule No 1
Yellow coloured solution in an amber glass ampoule

Ampoule No 2
Yellow coloured solution in an amber glass ampoule

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

- particularly in alcoholism where a severe depletion of thiamine can lead to Wernicke's encephalopathy.

Wernicke's encephalopathy may also occur as a consequence of other medical conditions.

4.2 Posology and method of administration

Adults and elderly:

Rapid therapy of severe depletion or malabsorption of the water soluble vitamins B and C, particularly in alcoholism, where a severe depletion of thiamine can lead to Wernicke's encephalopathy		
10 ml solution from Ampoule Number 1	***PLUS***	**10 ml solution from Ampoule Number 2**
OR		

15 ml solution from Ampoule Number 1	*PLUS*	15 ml solution from Ampoule Number 2
2 to 3 pairs of 5 ml ampoules (1 pair = ampoule 1 + ampoule 2) diluted with 50 ml to 100 ml infusion solution (physiological saline or glucose 5%) and administered over 30 minutes every 8 hours, or at the discretion of the physician.		

Wernicke's encephalopathy may occur as a consequence of other medical conditions. In these situations the requirements of thiamine may be different to those for patients who suffer with alcoholism.

Method of administration
Pabrinex Intravenous High Potency should be administered by drip infusion. Equal volumes of the contents of ampoules number 1 and 2 should be added to 50 ml to 100 ml physiological saline or 5% glucose and infused over 30 minutes (see sections 6.3 and 6.6).

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, such rare occurrence of serious allergic reactions should not preclude the use of Pabrinex in patients who need treatment by this route of administration - particularly those at risk of Wernicke's encephalopathy - for whom treatment with parenteral thiamine is essential. Initial warning signs of a reaction to Pabrinex 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 Intravenous High Potency is administered. To minimise the risk of such events with Pabrinex Intravenous High Potency, this medicinal product should only be administered by infusion over a period of 30 minutes.

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

Care should be taken to ensure that the product is administered intravenously as intended – reports of unintentional intramuscular administration have been received; these incidents have not been associated with serious adverse reactions.

4.5 Interaction with other medicinal products and other forms of interactions

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

Administration of Pabrinex may induce sneezing or mild asthma in patients receiving repeated injections of Vitamin B1 (thiamine) or, potentially, anaphylaxis if they have become hypersensitive.

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

No studies on the effects on the ability to drive and use machines have been performed. However given the nature of the product, no effects are anticipated.

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
Respiratory, thoracic and mediastinal disorders	Unknown	Bronchospasm
Gastrointestinal disorders	Unknown	Nausea, vomiting
Skin and subcutaneous tissue disorders	Unknown	Sweating
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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

In the unlikely event of overdosage, treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

Not 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
Water for Injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

2 years.
Once mixed or diluted, it should be used immediately.

6.4 Special precautions for storage

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

For storage conditions after dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Pabrinex Intravenous High Potency is supplied in pairs of 5 ml amber Type I glass ampoules.
Packs contain either six or ten pairs of 5 ml ampoules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The two 5 ml ampoules (a No. 1 and a No. 2) each containing sterile yellow coloured aqueous solutions are to be mixed prior to administration. The mixed solution should be further diluted in physiological saline or 5% glucose (refer to section 4.2 for instructions on the administration of this product).

In common with all parenteral products each ampoule should be visually inspected prior to administration.

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA2288/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 August 1987

Date of last renewal: 20 August 2007

10 DATE OF REVISION OF THE TEXT

November 2018