Summary of product characteristics

1. NAME OF THE MEDICINAL PRODUCT

PABIOVITE High Potency 1 & 2 Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The combi pack of Pabiovite 1 & 2 contains,

Ampoule 1:

Each 5 ml contains:

Thiamine Hydrochloride BP……250 mg

Riboflavin sodium phosphate BP……4 mg

Pyridoxine Hydrochloride BP……..50 mg

Nicotinamide BP……..160 mg

Water for Injection BP……..Q.S

Ampoule 2:

Each 5 ml contains:

Ascorbic acid BP……500 mg

Glucose BP……1000 mg

Water for Injection BP……....Q.S

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection

PABIOVITE injection Ampoule 1 is a yellow colour solution.

PABIOVITE injection Ampoule 2 is a clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

PABIOVITE injection 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, where a severe depletion of thiamine can lead to Wernicke's encephalopathy

- after acute infections
- post-operatively
- in psychiatric states

Also used to maintain levels of vitamin B and C in patients on chronic intermittent haemodialysis.

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.

Psychosis following narcosis or E.C.T; toxicity from acute infections

5 ml Ampoule Number 1	**PLUS**	**5 ml Ampoule Number 2**

1 pair of 5 ml ampoules diluted with 50 ml to 100 ml infusion solution (physiological saline or glucose 5%) administered over 30 minutes twice daily for up to 7 days.

Haemodialysis

5 ml Ampoule Number 1	**PLUS**	**5 ml Ampoule Number 2**

1 pair of 5 ml ampoules diluted with 50 ml to 100 ml infusion solution (physiological saline or glucose 5%) administered over 30 minutes once every two weeks at the end of dialysis.

Paediatric population

Pabiovite High Potency, Concentrate for Solution for Infusion 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

Dilute before use.

Pabiovite High Potency, Concentrate for Solution for Infusion 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 Pabiovite injection, such rare occurrence of serious allergic reactions should not preclude the use of Pabiovite injection 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 Pabiovite injection 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 Pabiovite High Potency is administered. To minimise the risk of such events with Pabiovite High Potency, this medicinal product should 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 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.

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 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 the 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
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 overdosage, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group	: vitamins B1, B2, B6, nicotinamide, vitamin C and glucose.
ATC Code	: A11EB

5.2 Pharmacokinetic properties

Riboflavin is bound to plasma proteins. A little is stored in organs such as liver and kidneys, and amounts in excess of the body's requirements are excreted in the urine. Thiamine is fundamentally associated with carbohydrate metabolism. By combining with the pyrophosphoric acid in nucleated cells, particularly in the liver, kidneys and white blood cells it is converted in the body to its pyrophosphate which acts as coenzyme in such reactions as the decarboxylation of alpha-keto acids, particularly of pyruvate and alpha-keto-glutarate. In the presence of thiamine deficiency pyruvic and lactic acids accumulate in the tissues.

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 SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Ampoule 1:

Benzyl alcohol
EDTA
Tween 80
Triethanolamine and
Water for Injection

Ampoule 2:

Sodium Metabisulphite
EDTA
Sodium Bicarbonate and
Water for Injection

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:

Shelf life: 24 Months

6.4 Special Precautions for storage:

Store below 25°C (do not freeze), away from light. Keep the injection in their original pack.

6.5 Nature and contents of container:

The product is supplied in pairs of amber coloured glass ampoules containing 5 ml of sterile solution. PABIOVITE ampoules are supplied in a Carton of 10 ampoules of PABIOVITE 1 and 10 ampoules of PABIOVITE 2 along with patient information leaflet.

PABIOVITE injection Ampoule 1 is a yellow colour solution.
PABIOVITE injection Ampoule 2 is a clear colourless solution.

6.6 Special precautions for disposal and other handling:

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

7. Marketing authorisation holder and manufacturing site addresses

EXETER HEALTH LIMITED
Queensgate House, 48,
Queen Street Exeter,
Devon EX4, 3SR, United Kingdom.

8. Marketing authorisation number
FDA/SD.255-040586

9. Date of first authorisation or renewal
4/11/2025

10. Date of Revision of the Test
9th July,2025.