SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vitamins B+C Intravenous High Potency concentrate for solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each presentation (carton) contains pairs of 5 ml ampoules. Each pair of ampoules to be used in treatment is labelled Vitamins B+C Ampoule 1 and Vitamins B+C Ampoule 2.

Each Ampoule 1 (5 ml) contains:

Thiamine hydrochloride (Vitamin B1) 250 mg

Riboflavin (as Phosphate sodium) (Vitamin B2) 4 mg

Pyridoxine hydrochloride (Vitamin B6) 50 mg

Each Ampoule 2 (5 ml) contains:

Ascorbic acid (Vitamin C) 500 mg

Nicotinamide (Vitamin B3) 160 mg

Glucose (as monohydrate) 1000 mg

Excipients with known effect:

This medicinal product contains 74.39 mg sodium (3.23 mmol sodium) **per each pair of 5 ml ampoules** equivalent to 3.7 % 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 1: Clear yellow solution

Ampoule 2: Clear colorless to pale yellow solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Vitamins B+C Intravenous High potency 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

Posology

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 1	PLUS	10 ml solution from Ampoule 2
OR		
15 ml solution from Ampoule 1	PLUS	15 ml solution from Ampoule 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 1	PLUS	5 ml Ampoule 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 1	PLUS	5 ml Ampoule 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
Vitamins B+C Intravenous 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.
Vitamins B+C Intravenous 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 (sodium chloride 0.9%) 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 Vitamins B+C, such rare occurrence of serious allergic reactions should not preclude the use of Vitamins B+C 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 Vitamins B+C 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 Vitamins B+C Intravenous High Potency is administered. To minimise the risk of such events with Vitamins B+C Intravenous 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 product is administered intravenously as intended – reports of unintentional intramuscular administration 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 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 Vitamins B+C 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

Vitamins B+C Intravenous High Potency concentrate for solution for infusion contains vitamins B1, B2, B6, nicotinamide, vitamin C and glucose.

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

Ampoule 1:

Edetic acid

Water for Injections

Ampoule 2:

Edetic acid

Sodium hydroxide (used as a pH adjusting agent)

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

Before opening

2 years

After dilution

Chemical and physical in-use stability of intravenous high potency vitamins B and C, when added under aseptic conditions to 50 ml and 100 ml of the following infusion fluids has been demonstrated for the number of hours stated below:

At room temperature, both under artificial light and protected from light for 10 hours in the following infusion fluids:

- Glucose 5%
- Physiological saline (sodium chloride 0.9%)
- Sodium lactate M/6;

At room temperature, both under artificial light and protected from light for 6 hours in the following infusion fluids:

- Glucose 4.3% with sodium chloride 0.18%
- Glucose 5% with potassium chloride 0.3%

At 2 – 8◦C, protected from light for 24 hours when diluted with any of the infusion fluids mentioned in section 6.6.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store below 25°C. Keep the ampoules in the outer carton in order to 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

Vitamins B+C Intravenous High Potency concentrate for solution for infusion is supplied in pairs of 5 ml amber Type I glass ampoules.

Packs contain either 5, 6 or 10 pairs of 5 ml ampoules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Compatibility of Vitamins B+C Intravenous High Potency concentrate for solution for infusion has been demonstrated with the following infusion fluids:

- Glucose 5%
- Physiological saline (sodium chloride 0.9%)
- Glucose 4.3% with sodium chloride 0.18%
- Glucose 5% with potassium chloride 0.3%
- Sodium lactate M/6

Please refer to section 6.3 for details regarding storage following dilution in each of these fluids.

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

7 MARKETING AUTHORISATION HOLDER

DEMO PHARMA UK LIMITED

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1 Dover Place, Ashford,

Kent TN23 1FB, England

8 MARKETING AUTHORISATION NUMBER(S)

PL 55035/0019

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/06/2024

10 DATE OF REVISION OF THE TEXT

28/06/2024