NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Syndrex Intravenous Concentrate for Solution for Infusion

Ampoule No. 1:
Thiamine hydrochloride 50 mg/mL
Riboflavin (as sodium phosphate) 0.8 mg/mL
Pyridoxine hydrochloride 10 mg/mL

Ampoule No. 2:
Ascorbic acid 100 mg/mL
Nicotinamide 32 mg/mL
Glucose (as monohydrate) 200 mg/mL

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each carton contains 6 pairs of 5 ml ampoules. Each pair of ampoules to be used in treatment is labelled Syndrex Ampoule No 1 and Syndrex Ampoule 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:	**5 ml ampoule**
Ascorbic Acid	500 mg
Nicotinamide	160 mg
Glucose (as Monohydrate)	1000 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for Solution for Infusion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Syndrex 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 Dose 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.
* or equivalent volume of 5 ml ampoules

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

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

10 ml of the mixed 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**

10 ml of the mixed 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

Syndrex 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.

Syndrex 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 Syndrex, such rare occurrence of serious allergic reactions should not preclude the use of Syndrex 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 Syndrex 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 Syndrex is administered. To minimise the risk of such events with Syndrex, 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 is intravenous only – 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 medicines 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 Syndrex 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 to https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

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

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Syndrex contains vitamins B1, B2, B6, nicotinamide, vitamin C and glucose.
ATC code: A11EB

This medicine has been given a provisional consent under Section 23 of the Act to address an urgent shortage in the market.

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 data sheet.

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

Before opening: 24 months.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light. Keep the ampoules in the outer carton. Do not freeze.

6.5 Nature and contents of container

Syndrex, is supplied in 5 mL amber glass ampoules.

Each carton contains 6 x Ampoule No. 1 and 6 x Ampoule No 2.

6.6 Special precautions for disposal and other handling

Compatibility 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.

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

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

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9 DATE OF FIRST APPROVAL

1 October 2024

10 DATE OF REVISION OF THE TEXT

1 October 2024

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information