APPROVED
Order of Ministry of Health
of Ukraine
15.08.2023 No. 1462
Marketing Authorisation
No. UA/20157/01/01

INSTRUCTION
for medical use of medicinal product

SYNDREX®
(SYNDREX)

Composition:
Ampoule No. 1
Active ingredients: thiamine hydrochloride, riboflavin, pyridoxine hydrochloride;
1 ml of the concentrate for infusion solution contains thiamine hydrochloride 50 mg, riboflavin sodium phosphate (as calculated on riboflavin) 0.8 mg, pyridoxine hydrochloride 10 mg;
Excipients: edetic acid, sodium hydroxide, water for injection.
Ampoule No. 2
Active ingredients: ascorbic acid, nicotinamide, glucose;
1 ml of concentrate for solution for infusion contains ascorbic acid 100 mg; nicotinamide 32 mg; glucose monohydrate (as calculated on glucose) 200 mg;
Excipients: edetic acid, sodium hydroxide, water for injection.

Pharmaceutical form
Concentrate for solution for infusion.
Basic physical and chemical properties: clear, yellow liquid.

Pharmacotherapeutic group
Vitamin B-complex with vitamin C.
ATC Code A11E B.

Pharmacological properties
Pharmacodynamics
Syndrex® concentrate for solution for infusion contains vitamins B1, B2, B6, nicotinamide and vitamin C.
Pharmacokinetics
No data

Clinical particulars
Indications
The medicinal product is indicated in adults and children for rapid therapy of severe depletion or malabsorption of the water soluble vitamins B and C:

- in alcoholism, when severe thiamine deficiency can lead to Wernicke's encephalopathy;
- after acute infections;
- post-operatively;
- in psychiatric states.

It is also used to maintain vitamin B and C levels in patients undergoing chronic intermittent haemodialysis.

Contraindications
Hypersensitivity to the active substances, or to any of the excipients.

Interaction with other medicinal products and other forms of interaction

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

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, especially those at risk of developing Wernicke's encephalopathy. Treatment of such patients with parenteral thiamine is important.
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 during intravenous administration, Syndrex® should be administered by infusion over 30 minutes.
This medicine is for intravenous infusion only and should not be administered by any other route
Syndrex® should only be used intravenously – reports of unintentional administration by the wrong route have been received; these incidents have not been associated with serious adverse reactions.
Each ampoule should be visually inspected prior to administration and should not be used if particulates are present.
Sodium
This medicine contains 2.86 mmol (65.78 mg) of sodium in 1 pair of ampoules (ampoule 1 + ampoule 2). Caution should be exercised in patients on a sodium-controlled diet.

Use during 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. The potential risk for humans is unknown.
Caution should be exercised when prescribing to pregnant women.

Effects on speed of reactions when driving or using machinery
No studies on the effects on the ability to drive and use machines have been performed. Due to the composition of the drug, no effects are expected.

Posology and method of administration
For intravenous administration.
Adults and elderly:

- rapid treatment of severe deficiency or malabsorption of water-soluble vitamins B and C, especially in alcoholism, where severe thiamine deficiency can lead to Wernicke's encephalopathy

10 ml of solution from ampoule No. 1	+	10 ml of solution from ampoule No. 2
	or	
15 ml of solution from ampoule No. 1	+	15 ml of solution from ampoule No. 2

Dissolve 2-3 pairs of 5 ml ampoules (1 pair = ampoule No. 1 + ampoule No. 2) in 50-100 ml of infusion solution (saline or 5% glucose), infuse for 30 minutes every 8 hours or as directed by a physician.

- psychosis after anaesthesia or ECT (electroconvulsive therapy); intoxication in acute infections

5 ml of solution from ampoule No. 1	+	5 ml of solution from ampoule No. 2

Dissolve 1 pair of 5 ml ampoules in 50-100 ml of infusion solution (saline or 5% glucose), infuse for 30 minutes twice daily for 7 days.

- haemodialysis

5 ml of solution from ampoule No. 1	+	5 ml of solution from ampoule No. 2

Dissolve 1 pair of 5 ml ampoules in 50-100 ml of infusion solution (saline or 5% glucose), infuse for 30 minutes 1 time in two weeks at the end of dialysis.

Children:

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

Dissolve before use.

Syndrex®, concentrate for infusion solution for intravenous administration, should be administered by drip infusion. Add equal volumes of the contents of ampoules No. 1 and No. 2 to 50-100 ml of saline or 5% glucose solution and administer over 30 minutes.

Compatibility

Syndrex® is compatible with infusion solutions: glucose 5%, saline (sodium chloride 0.9%), glucose 4.3% with sodium chloride 0.18%, glucose 5% with potassium chloride 0.3%, sodium lactate.

The chemical and physical stability of Syndrex® at room temperature is shown in the table below:

Solvent	Light exposure, hours
Glucose 5%	7
Saline (sodium chloride 0.9 %)	7
Glucose 4.3% with sodium chloride 0.18%	4
Glucose 5% with potassium chloride 0.3%	4
Sodium lactate	7

Solutions are expected to be stable for a longer period of time if they are protected from light.

Paediatric population

Syndrex® is administered in paediatric patients (see *Posology and method of administration*).

Overdose

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

Undesirable effects

Adverse reactions that have been reported as having a probable association with the use of the medicinal product are listed in the table below. Adverse reactions are classified by system and frequency: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000) including single reports; not known (cannot be estimated from the available data).

The incidence of adverse reactions reported in the post-marketing period cannot be assessed as they are derived from spontaneous reports, therefore they are classified as unknown.

Systems	Frequency	Adverse reaction
Immune system disorders	Not known	Hypersensitivity (including anaphylaxis, rash and urticaria)
Nervous system disorders	Not known	Paresthesia
Cardiac and vascular disorders	Not known	Hypotension

General disorders and administration site conditions	Not known	Injection site reactions (including pain and swelling)

Reporting of any 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. Medical and pharmaceutical professionals, as well as patients or their legal representatives, should report all cases of suspected adverse reactions and lack of efficacy of the medicinal product through the Automated Pharmacovigilance Information System at the link: https://aisf.dec.gov.ua.

Shelf-life
2 years.
From a microbiological point of view the medicinal product shall 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 °C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Storage
Store below 25 °C in the secondary package. Do not freeze.
Do not freeze diluted solution.
Keep out of the reach and sight of children.

Incompatibilities
This medicinal product must not be mixed with other medicinal products, except those mentioned in section “Posology and method of administration”.

Nature and contents of container
5 ml ampoule.
3 ampoules No. 1 (thiamine hydrochloride + riboflavin + pyridoxine hydrochloride) in a blister.
3 ampoules No. 2 (ascorbic acid + nicotinamide + glucose) in a blister.
2 blisters of ampoules No. 1 and 2 blisters of ampoules No. 2 per carton.
Or 6 ampoules No. 1 (thiamine hydrochloride + riboflavin + pyridoxine hydrochloride) in a blister.
6 ampoules No. 2 (ascorbic acid + nicotinamide + glucose) in a blister.
1 blister of ampoules No. 1 and 1 blister of ampoules No. 2 per carton.
Or 6 ampoules No. 1 (thiamine hydrochloride + riboflavin + pyridoxine hydrochloride) and 6 ampoules No. 2 (ascorbic acid + nicotinamide + glucose) per carton with corrugated inserts

Prescription status
Prescription only.

Manufacturer
JSC Farmak

Location of manufacturer and address of manufacturing site.
JSC Farmak, 74, Kyrylivska Street, Kyiv, 04080 Ukraine

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18.11.2024.