Summary Product Characteristic for Pharmaceutical Product

1. Name of the medicinal product

Tasrinex 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 Tasrinex IVHP No 1 and Tasrinex IVHP 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

Excipients with known effect:
This medicinal product 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

4. Clinical particulars

4.1 Therapeutic indications

Therapeutic indications

Tasrinex 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

Before administration, ensure that both the Summary of Product Characteristics and ampoule labels refer to the INTRAVENOUS form.

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 number 1 + ampoule number 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

Tasrinex Intravenous High Potency, Concentrate for Solution for Infusion is rarely indicated for administration to children; however, suitable doses are as follows:

Age (years)	Dosage
Under 6	quarter of the adult dose
6 - 10	third of the adult dose
10 - 14	half to two thirds of the adult dose
14 and over	as for the adult dose

Method of administration

Dilute before use.

Tasrinex 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 or 5% glucose and infused over 30 minutes (see sections 6.3 and 6.6).

4.3 Contraindications

Hypersensitivity to the active substance 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 Tasrinex, such rare occurrence of serious allergic reactions should not preclude the use of Tasrinex 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 Tasrinex 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 Tasrinex Intravenous High Potency is administered. To minimise the risk of such events with Tasrinex 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 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 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

Tabulated summary of adverse reactions
Adverse reactions reported as possibly associated to Tasrinex are presented in the following table by MedDRA System Organ Class (SOC), Preferred Term and frequency. The following frequency categories are used:

Term	Frequency of occurrence
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)

Not known	(Cannot be estimated from the available data)

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 "Not known".

System Organ Class	Frequency	Undesirable effects
Immune system disorders	Not Known	Hypersensitivity (including anaphylaxis, rash and urticaria)
Nervous system disorders	Not Known	Paraesthesia
Vascular disorders	Not Known	Hypotension
General disorders and administration site conditions	Not Known	Injection site reactions (including pain and swelling)

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

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

5. Pharmacological properties

5.1 pharmacodynamic properties

ATC code: A11EB
Vitamin B-complex with vitamin C

Tasrinex Intravenous High Potency contains vitamins B1, B2, B6, nicotinamide, vitamin C and glucose.

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

Disodium Edetate
Sodium hydroxide
Hydrochloric acid
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.

After opening:
Chemical and physical in-use stability of intravenous high potency vitamins B and C has been demonstrated in the following intravenous infusion fluids for the number of hours stated in the table below, at room temperature:

Intravenous infusion fluid	**In the light**
Glucose 5%	7 hours
Physiological saline (sodium chloride 0.9%)	7 hours
Glucose 4.3% with sodium chloride 0.18%	4 hours
Glucose 5% with potassium chloride 0.3%	4 hours
Sodium lactate M/6	7 hours

Although no further specific data are available, the solutions are expected to be stable for longer periods when protected from light.

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°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

The diluted solutions should not be frozen.

6.4 Special precautions for storage

Do not store above 30°C. Keep the container in the outer carton 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

Tasrinex Intravenous High Potency, Concentrate for Solution for Infusion is supplied in pairs of glass ampoules of 5 ml. Packs contain five pairs of 5 ml ampoules.

6.6 Special precautions for disposal and other handling

Compatibility of Tasrinex Intravenous High Potency 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 and manufacturing site addresses

Marketing authorisation holder

Tasa Pharma Limited
Unit C1-C3, Kay complex
Mombasa Road
Nairobi, Kenya.

Manufacturing Site Addresses

Tasa Pharma Limited
Unit C1-C3, Kay complex
Mombasa Road
Nairobi, Kenya.

8. Marketing authorisation number(s)

H2024/CTD10596/24006

9. Date of first authorisation/renewal of the authorisation

Date of first authorization: 23-Feb.-2024

10. Date of revision of the text

Nov-2024