



HSE Recommendations for Pabrinex[®] and Thiamine Prescribing due to International Supply Disruption of Pabrinex[®] IV High Potency Concentrate for Solution for Injection – May 2024

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Approved by: Dr. Mike O'Connor, National Clinical Advisor & Group Lead, Acute Hospitals	Reviewed by: National Clinical Programmes for Gastroenterology & Hepatology, Emergency Medicines and Neurology	Page: 1 of 7



Summary Information

- The Manufacturing Authorisation Holder (MAH) for Pabrinex® IV High Potency Concentrate for Solution for Injection, have advised the Health Products Regulatory Authority (HPRA) there will be a supply disruption from September 2024 until Q3 2025.
- Pabrinex® IV is licensed in adults 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.¹
- **Prescribers are advised to review prescribing to, in order to reserve stock for, only those individuals requiring Pabrinex® for the treatment of life threatening conditions, namely Wernicke’s encephalopathy/Korsakoff psychosis.²**
- All local protocols that include Pabrinex® should be reviewed and updated as appropriate, including electronic prescription order sets.
- Current available stock is being managed at wholesale level on an allocation basis to ensure equitable distribution of remaining stock.
- In addition to this disruption, Pabrinex® Intramuscular (IM) injection (unlicensed in Ireland) will be discontinued. There are no other licensed parenteral alternatives to Pabrinex®.
- Oral supplementation of thiamine should be used as appropriate, when clinically indicated, as first line choice of supplementation.
- Though IV / IM thiamine is unlicensed in Ireland, it may be used in place of Pabrinex®, with supplementation of other vitamins as required.
- Further guidance may be issued as additional information becomes available.
- See information below for prescribing recommendations for the Treatment of Suspected or Established Wernicke’s Encephalopathy, Prophylaxis of Wernicke’s Encephalopathy Associated with Alcohol Use-Disorders and Refeeding Syndrome in Adult and Paediatric Patients

Table 1: Treatment of Suspected or Established Wernicke’s Encephalopathy ^{3,4,5}			
Definition	Wernicke’s encephalopathy is an acute neurological condition caused by the lack of thiamine (vitamin B1). This condition is characterised by: <ul style="list-style-type: none"> • Encephalopathy • Oculomotor dysfunction • Gait ataxia 		
Causes	Wernicke’s encephalopathy can occur as a consequence of medical conditions including: <ul style="list-style-type: none"> • Alcoholism • Malnutrition 		
Diagnosis ³	Wernicke’s encephalopathy is diagnosed in patients with two of the following four Caine criteria: <ul style="list-style-type: none"> • Dietary deficiency • Oculomotor abnormalities • Cerebellar dysfunction • Either altered mental status or mild memory impairment 		
Recommended IV Pabrinex[®] Dose	DOSE	FREQUENCY	DURATION
	ONE pair of 5mL ampoules	THREE times daily	Days 1 – 5*
Recommended Parenteral Thiamine Dose	DOSE	ROUTE and FREQUENCY	DURATION
	200mg	IV THREE times daily	Days 1 – 5*
Other Information	<ul style="list-style-type: none"> • ONE pair = ampoule 1 + ampoule 2 of Pabrinex[®] (250mg of thiamine) • *Minimum 5 days duration, continue treatment until no further improvement in signs and symptoms or Wernicke’s encephalopathy has been excluded.³ • Review need for parenteral treatment regularly with consideration to switching to oral therapy when appropriate. • Pabrinex[®] and parenteral thiamine should be administered before glucose • Route should preferably be via intravenous instead of intramuscular route³ • Oral thiamine 100mg – 300mg daily should be continued after the completion of Pabrinex[®] or parenteral thiamine, until patient is no longer at risk.⁴ • A multivitamin preparation should also be prescribed as necessary. 		

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Table 2: Prophylaxis of Wernicke’s Encephalopathy Associated with Alcohol Use-Disorders^{6,7,8}

Oral Thiamine Recommendations⁵	Prophylactic oral thiamine should be offered to harmful or dependent drinkers: <ul style="list-style-type: none"> • If they are malnourished or at risk of malnourishment or • If they have decompensated liver disease or • If they are in acute withdrawal or • Before and during a planned medically assisted alcohol withdrawal 		
Oral Thiamine Recommended Dose	DOSE	FREQUENCY	DURATION
	100mg	THREE times daily	As long patient is at risk or until adequate nutritional status
Other Information	<ul style="list-style-type: none"> • For use in combination with other local policies for therapeutic management of symptoms of alcohol withdrawal e.g. benzodiazepine tapering etc. 		
Pabrinex® / Parenteral Thiamine Recommendations⁵	Prophylactic parenteral Pabrinex® or thiamine, followed by oral thiamine, should be offered to harmful or dependent drinkers: <ul style="list-style-type: none"> • If they are malnourished or at risk of malnourishment or • If they have decompensated liver disease and in addition • They attend an emergency department or • Are admitted to hospital with an acute illness or injury 		
IV Pabrinex® Recommended Dose	DOSE	FREQUENCY	DURATION
	ONE pair of 5mL ampoules	ONCE daily	Days 1 - 3
Recommended Parenteral Thiamine Dose	DOSE	ROUTE and FREQUENCY	DURATION
	200mg	IV ONCE daily	Days 1 - 3
Other Information	<ul style="list-style-type: none"> • ONE pair = ampoule 1 + ampoule 2 of Pabrinex® (250mg of thiamine) • Review need for parenteral treatment regularly with consideration to switching to oral therapy when appropriate. • Pabrinex® and parenteral thiamine should be administered before glucose • Oral thiamine 100mg – 300mg daily should be continued after the completion of Pabrinex® or parenteral thiamine, until patient is no longer at risk.⁴ • A multivitamin preparation should also be prescribed as necessary. • For use in combination with other local policies for therapeutic management of symptoms of alcohol withdrawal e.g. benzodiazepine tapering etc. 		

Table 3: Refeeding Syndrome in Adult and Paediatric Patients ^{9,10,11}

Adult Patients at Extremely High Risk of Developing Refeeding Problems ⁹	BMI less than 14 kg/m ² with negligible nutrition for more than 15 days		
Adult Patients at High Risk of Developing Refeeding Problems ⁹	Patient has 1 or more of the following: <ul style="list-style-type: none"> • BMI less than 16 kg/m² • Unintentional weight loss greater than 15% within the last 3 to 6 months • Little or no nutritional intake for more than 10 days • Low levels of potassium, phosphate or magnesium before feeding Or Patient has 2 or more of the following: <ul style="list-style-type: none"> • BMI less than 18.5 kg/m² • Unintentional weight loss greater than 10% within the last 3 to 6 months • Little or no nutritional intake for more than 5 days • A history of alcohol abuse or drugs including insulin, chemotherapy, antacids or diuretics. 		
Adult Oral Thiamine Recommendations	<ul style="list-style-type: none"> • Oral thiamine is recommended as first line in patients with refeeding problems without absorption issues and where oral / enteral access is available. 		
Adult Oral Thiamine Recommended Dose	DOSE	FREQUENCY	DURATION
	200 - 300mg	Daily	Days 1 -10*
Other Information	<ul style="list-style-type: none"> • *Management should be accompanied in all cases by a multivitamin preparation and thiamine replacement immediately before and during the first 10 days of refeeding⁹ 		
Pabrinex® / Parenteral Thiamine Recommendations	<ul style="list-style-type: none"> • Intravenous Pabrinex / thiamine replacement should only be used for patients with intestinal failure at high risk or extremely high risk of refeeding syndrome where the oral or enteral route is unavailable.⁹ 		
IV Pabrinex® Recommended Dose	AGE	DOSE	FREQUENCY
	Adults and Children Over 10 Years of Age	ONE pair of 5mL ampoules	ONCE daily
Parenteral Thiamine	AGE	DOSE	DURATION
	Adults and Children Over 10 Years of Age	200mg	ONCE daily
			DAYS: 1 - 3 Or DAYS: 1 - 5 (higher-risk patients)



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	6 – 10 Years of Age	150mg	ONCE daily	DAYS: 1 - 3 Or DAYS: 1 - 5 (higher-risk patients)
	Under 6 Years	100mg	ONCE daily	DAYS: 1 - 3 Or DAYS: 1 - 5 (higher-risk patients)
Other Information	<ul style="list-style-type: none"> Patients should continue to receive multi-ingredient micronutrient preparation(s) whilst receiving parenteral nutrition (PN), either alongside every PN infusion or added to the bag.⁹ 			

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<https://www.nice.org.uk/guidance/cg32/resources/nutrition-support-for-adults-oral-nutrition-support-enteral-tube-feeding-and-parenteral-nutrition-pdf-975383198917>

Appendix I – Qualitative and Quantitative Composition of Pabrinex® Intravenous High Potency Concentrate for Solution for Infusion¹

Each No. 1 ampoule (5 mL) contains:

- Thiamine Hydrochloride 250 mg
- Riboflavin (as Phosphate Sodium) 4 mg
- Pyridoxine Hydrochloride 50 mg

Each No. 2 ampoule (5 mL) contains:

- Ascorbic Acid 500 mg
- Nicotinamide 160 mg
- Glucose (as monohydrate) 1000 mg

Appendix II - Contributors to the guideline

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