



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

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While these recommendations are intended to strengthen clinical management of patients, it does
not replace clinical judgment or specialist consultation.

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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 9

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 December 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 ^{3,4,5,6}

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 • Gastric sleeve or other weight loss interventions 		
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 – TWO* pair(s) of 5mL ampoules	THREE times daily	Days 1 – 5**
Recommended Parenteral Thiamine Dose³	DOSE	ROUTE and FREQUENCY	DURATION
	300 - 500mg*	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) • * Higher dose recommended in treatment of Suspected or Established Wernicke's Encephalopathy in patients with alcohol dependence. Lower treatment doses, e.g thiamine 200mg, or Pabrinex[®] ONE pair, THREE times daily, recommended in patients without alcohol dependence. • **Minimum 5 days duration, continue treatment until no further improvement in signs and symptoms or Wernicke's encephalopathy has been excluded.⁴ • Higher dose recommended in treatment of Suspected or Established Wernicke's Encephalopathy in patients with alcohol dependence. Lower treatment doses, e.g thiamine 200mg, or Pabrinex[®] ONE pair, THREE times daily, are recommended in patients without alcohol dependence. • 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 route⁴ • Oral thiamine 100mg – 300mg daily should be continued after the completion of Pabrinex[®] or parenteral thiamine, until patient is no longer at risk.⁵ • A multivitamin preparation should also be prescribed as necessary. 		

Table 2: Prophylaxis of Wernicke's Encephalopathy Associated with Alcohol Use-Disorders^{3,7,8,9}

Oral Thiamine Recommendations⁶	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 Recommendations⁶	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 Dose⁸	DOSE	FREQUENCY	DURATION
	ONE pair of 5mL ampoules	ONCE daily	Days 1 – 3*
Recommended Parenteral Thiamine Dose³	DOSE	ROUTE and FREQUENCY	DURATION
	200mg – 300mg	IM / 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) • * Expert clinical opinion • 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.⁵ • 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 ^{10,11,12}

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Adult Patients at Extremely High Risk of Developing Refeeding Problems ¹⁰	BMI less than 14 kg/m ² with negligible nutrition for more than 15 days			
Adult Patients at High Risk of Developing Refeeding Problems ¹⁰	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 refeeding¹⁰			
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.¹⁰			
IV Pabrinex® Recommended Dose	AGE	DOSE	FREQUENCY	DURATION
	Adults and Children Over 10 Years of Age	ONE pair of 5mL ampoules	ONCE daily	DAYS: 1 - 3 Or DAYS: 1 - 5 (higher-risk patients)
Parenteral Thiamine	AGE	DOSE	FREQUENCY	DURATION
	Adults and Children Over 10 Years of Age	200mg	ONCE daily	DAYS: 1 - 3 Or DAYS: 1 - 5 (higher-risk patients)

	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.¹⁰ 			

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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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Appendix III – Summary of Amendments

Section	Amendment
Table 1: Treatment of Suspected or Established Wernicke's Encephalopathy	Included reference no. 3 dosing of thiamine for treatment of Wernicke's Encephalopathy in alcoholic dependent patients.
Table 2: Prophylaxis of Wernicke's Encephalopathy Associated with Alcohol Use-Disorders	Included reference no. 3 dosing and duration of thiamine for prophylaxis of Wernicke's Encephalopathy in alcohol dependence