

**From the Chief Medical Officer  
Professor Sir Michael McBride**



**HSS(MD) 22/2024**

**FOR ACTION**

Chief Executives, Public Health Agency/HSC Trusts/NIAS  
Deputy Secretary SPPG  
GP Medical Advisers, SPPG  
All General Practitioners and GP Locums (for onward  
distribution to practice staff)  
OOHs Medical Managers (for onward distribution to staff)

**PLEASE SEE ATTACHED FULL CIRCULATION LIST**

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Dear Colleague

**MEDICINE SUPPLY NOTIFICATION - PABRINEX® (VITAMINS B AND C)  
INTRAVENOUS AND INTRAMUSCULAR HIGH POTENCY SOLUTION FOR  
INJECTION AMPOULES**

On 5 May 2024, the Department of Health and Social Care (DHSC) issued a Tier 3, high impact, Medicine Supply Notification for Pabrinex® (Vitamins B and C) intravenous and intramuscular high potency solution for injection ampoules.

Whilst this Medicine Supply Notification would have been distributed through the usual channels to HSC pharmacy procurement leads, we are writing to highlight the need for all clinicians and pharmacy teams involved in the prescribing, dispensing and administering of these products to be aware of the advice and actions contained within this guidance. As Pabrinex® IV stock is expected to be exhausted from August 2024 and Pabrinex® IM from December 2024 and with allocations now in place for these products, an executive lead (or equivalent role in organisations without executive boards) should co-ordinate the implementation of this guidance, ensuring the implementation has been supported by relevant clinicians and pharmacy teams.

The most up-to-date guidance relating to the supply of Pabrinex® IV and IM injections is summarised below.

### Advice and actions for clinicians

- **Clinicians, considering clinical guidance on alcohol dependence and refeeding syndrome (see Supporting information and links to further information below),** should urgently review where and how Pabrinex® IV and IM are used in their local health system to ensure it is only being used where clinically necessary in terms of dose and length of course. The aim should be to reduce usage of Pabrinex® IV and IM injections and maintain stocks for essential use only.
- Clinicians should not seek to replace Pabrinex® IV with supplies of Pabrinex® IM as it cannot support an uplift in demand and is required in non-hospital settings where Pabrinex® IV cannot be administered.
- Should clinicians consider that prescribing unlicensed thiamine injections is clinically appropriate, prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary.

### Advice and actions for pharmacy teams

- Pabrinex® injection is only distributed via the wholesalers AAH Pharmaceuticals.
- AAH accounts with historical usage of **Pabrinex® IM injections should continue to be allocated stock to cover 100% of their average historic demand.**
- AAH accounts with historical usage of **Pabrinex® IV injections have been allocated stock to cover 80% of their average historical demand (please note this has decreased from the 100% allocations applied in April 2024).** This quota is reviewed monthly.
- **Excessive orders should not be made. Orders should be placed in line with previous ordering patterns to ensure equitable distribution of stock.**
- Trusts should review where Pabrinex® IV and IM is stocked in order to consolidate supply.
- **Supplies of Pabrinex® IM should be reserved for settings that are only able to supply or administer Pabrinex® IM with a Patient Group Direction (PGD), where possible. All other settings should consider prescribing unlicensed thiamine injections (intramuscular preparations are available) where clinically appropriate and suitable, considering clinical guidance (see Supporting information).**
- Where there is insufficient stock in Trusts, and where clinical judgement determines that a patient should be prescribed Pabrinex® IV or IM injections, liaise with pharmacy services to request mutual aid, facilitated by the Regional Pharmaceutical Procurement Service for consideration of additional supply.
- All other accounts should escalate their queries to AAH Pharmaceuticals for consideration.

## Supporting information

### Clinical information

Pabrinex® IV and IM injections are both indicated for rapid therapy of severe depletion or malabsorption of the water-soluble vitamins B and C, particularly in alcohol dependent patients, where a severe depletion of thiamine can lead to Wernicke's encephalopathy ([see NICE CG100 Alcohol use disorders: diagnosis and management of physical complications](#)).

They are indicated for use after acute infections, post-operatively and in psychiatric states. Pabrinex® IV is used to maintain levels of vitamin B and C in patients on chronic intermittent haemodialysis.

### Treatment of alcohol dependence

DHSC and NHS England convened a clinical working group of key stakeholders to develop and share additional guidance. In the treatment of alcohol dependence, clinicians should consider prescribing the equivalent dose of unlicensed injectable thiamine where Pabrinex® is unavailable (which contains 250mg thiamine), where deemed clinically appropriate.

Please see further guidance on [using and prescribing thiamine in alcohol dependence](#)

### Critical Care

Following discussions with critical care experts and a review of the data, it was agreed that there is no evidence to support the use of Pabrinex® for treating delirium in critical care.

In practice, Pabrinex® should be used in critical care for the management of refeeding syndrome or related to complications of alcohol dependence. Further clinical guidance can be found on [prescribing thiamine for patients at risk of refeeding syndrome](#) and [alcohol dependence](#) pages.

If you consider Pabrinex® is clinically appropriate, prescribe the equivalent dose of unlicensed injectable thiamine.

### Off-label use

In practice, Pabrinex® IV is used in patients with or at risk of malnourishment or refeeding syndrome (where oral/enteral route is not available or suitable), see further [guidance on prescribing thiamine for patients at risk of refeeding syndrome](#).

Further dosing and extended duration of treatment of suspected or established Wernicke's encephalopathy is off-label, see BNF for further information.

<b>Composition of Pabrinex® IV injection ampoules</b>	<b>Composition of Pabrinex® IM injection ampoules</b>
Each presentation (carton) contains pairs of 5 ml ampoules. Each pair of ampoules to be used in treatment is labelled Pabrinex® No.1 and Pabrinex® No.2.	Each presentation (carton) contains pairs of 5 ml and 2 ml ampoules. Each pair of ampoules consists of one 5 ml and one 2 ml ampoule to be used in treatment, labelled as Pabrinex® No.1 and Pabrinex® No. 2.
<u>Each No. 1 ampoule contains: 5 ml ampoule</u>	<u>Each No. 1 ampoule contains: 5 ml ampoule</u>
Thiamine Hydrochloride 250 mg	Thiamine Hydrochloride 250 mg
Riboflavin (as Phosphate Sodium) 4 mg	Riboflavin (as Phosphate Sodium) 4 mg
Pyridoxine Hydrochloride 50 mg	Pyridoxine Hydrochloride 50 mg
<u>Each No. 2 ampoule contains: 5 ml ampoule</u>	<u>Each No. 2 ampoule contains: 2 ml ampoule</u>
Ascorbic acid 500 mg	Ascorbic acid 500 mg
Nicotinamide 160 mg	Nicotinamide 160 mg
Glucose (as Monohydrate) 1000 mg	
<u>Excipients with known effect:</u>	<u>Excipients with known effect:</u>
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.	This medicinal product contains 67 mg sodium per 1 pair of ampoules, equivalent to 3.4% of the WHO recommended maximum daily intake of 2 g sodium for an adult. It also contains benzyl alcohol.

### Alternatives

Thiamine 50mg and 100mg tablets remain available and should be used where clinically appropriate.

Solivito® N powder for concentrate for solution for infusion vials cannot support an uplift in demand.

The following specialist importers have confirmed they can source unlicensed thiamine 50mg/ml or 100mg/ml solution for injection for intramuscular and/ or intravenous use (please note there may be other companies that can also source supplies):

- Alium Medical
- Ascot labs
- Chapper Healthcare
- Clinigen
- Genetech
- Mawdsleys Unlicensed
- Qmed Pharmaceuticals
- Smartway
- Target Healthcare

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and HSC Trust or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.

**CAUTION:** Prescribers should be aware that some of these products may contain benzyl alcohol, and/or monothioglycerol. Other products do have a standard warning about aluminum content, which is linked to an FDA guidance around small volume injectables for parenteral nutrition. There should be particular caution when prescribing for paediatric patients that could be affected by certain excipients.

### **Guidance on ordering and prescribing unlicensed imports**

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and HSC Trust or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.

Please see the links below for further information:

- [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
- [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society (RPS)
- [Prescribing unlicensed medicines](#), General Medical Council (GMC)

### **References**

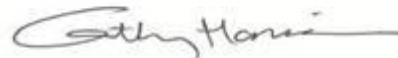
- [SmPC Pabrinex Intramuscular High Potency Injection](#)

- [SmPC Pabrinex Intravenous High Potency, Concentrate for Solution for Infusion](#)
- [BNF Vitamin B substances with ascorbic acid](#)
- [NICE CG100 Alcohol-use disorders: diagnosis and management of physical complications](#)
- [NICE CG32 Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition](#)
- [Guidance on prescribing thiamine for patients at risk of refeeding syndrome](#)
- [Using and prescribing thiamine in alcohol dependence](#)

Yours sincerely



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Chief Medical Officer



**PROFESSOR CATHY HARRISON**  
Chief Pharmaceutical Officer

### **Circulation List**

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