



UPDATE:

Update to communications issued 3rd April 2024. Material updates are shown in **bold**.

Medicine Supply Notification

MSN/2024/038U

Pabrinex[®] (Vitamins B and C) Intravenous and Intramuscular High Potency solution for injection ampoules

Tier 3 – High impact*

Date of issue: 08/05/2024

Link: [Medicines Supply Tool](#)

Summary

- Pabrinex[®] Intravenous (IV) injection will be out of stock from August 2024 with a **resupply date to be confirmed**.
- Pabrinex[®] Intramuscular (IM) injection is being **discontinued**, with stock exhaustion expected from December 2024.
- **Trusts should not seek to replace Pabrinex[®] IV with supplies of Pabrinex[®] IM as it cannot support an uplift in demand.**
- **Supplies of Pabrinex[®] IM should be reserved for settings where a Patient Group Direction (PGD) is required to supply or administer Pabrinex[®] IM, where possible.**
- There are no other licensed parenteral alternatives to Pabrinex[®] IV and IM injections.
- Thiamine 50mg and 100mg tablets remain available and should be used where clinically appropriate.
- **Unlicensed imports of thiamine injections have been sourced.**

Actions Required

Clinicians and pharmacy teams should be aware of the following guidance:

- Pabrinex[®] injection is only distributed via the wholesalers AAH Pharmaceuticals.
- AAH accounts with historical usage of **Pabrinex[®] IM injections continue to be allocated stock to cover 100% of their average historical 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% allocation applied in April 2024).** This quota will be 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, working with clinicians **and 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;

*Classification of Tiers can be found at the following link:

<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

- Trusts should review where Pabrinex® IV and IM is stocked in order to consolidate supply;
- Trusts 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;
- **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 their Regional Pharmacy Procurement Specialist or for consideration of additional supply.
- All other accounts should escalate their queries to AAH Pharmaceuticals for consideration; and
- **Trusts should otherwise consider prescribing unlicensed thiamine injections where clinically appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary.**

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

Treatment of alcohol dependence

The Department of Health and Social Care 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. Further guidance will be provided.

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.

| Composition of Pabrinex® Intravenous (IV) injection ampoules | Composition of Pabrinex® Intramuscular (IM) injection ampoules |
|--|---|
| 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 Pyridoxine Hydrochloride 50 mg | Riboflavin (as Phosphate Sodium) 4 mg Pyridoxine Hydrochloride 50 mg |
| <u>Each No. 2 ampoule contains: 5 ml ampoule</u> Ascorbic acid 500 mg Nicotinamide 160 mg Glucose (as Monohydrate) 1000 mg | <u>Each No. 2 ampoule contains: 2 ml ampoule</u> Ascorbic acid 500 mg Nicotinamide 160 mg |
| <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. | <u>Excipients with known effect:</u> 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. |

Imports of unlicensed thiamine solution for injection

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 aluminium 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

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**
- **Genetech**
- **Qmed Pharmaceuticals**
- **Smartway**
- **Target Healthcare**

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS 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
- [Prescribing unlicensed medicines](#), General Medical Council (GMC),

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:

- Thiamine 50mg/ml solution for injection (imported)
- Thiamine 100mg/ml solution for injection (imported)

Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: “special order”.

[Links to further information](#)

[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](#)

Enquiries

Enquiries from NHS Trusts in England should in the first instance be directed to your Regional Pharmacy Procurement Specialist (RPPS) or Associate RPPS, who will escalate to national teams if required.

| REGION | Lead RPPS | Email | Associate RPPS | Email |
|--------------------------|-----------------|--|----------------|--|
| Midlands | Andi Swain | andi.swain@nhs.net | Vacant | |
| East of England | James Kent | james.kent@nhs.net | Tracy McMillan | tracy.mcmillan2@nhs.net |
| London | Jackie Eastwood | jacqueline.eastwood@gstt.nhs.uk | Daniel Johnson | Daniel.Johnson@gstt.nhs.uk |
| North East and Yorkshire | David Allwood | davidallwood@nhs.net | Penny Daynes | penny.daynes@nhs.net |
| North West | Richard Bateman | richard.bateman@liverpoolft.nhs.uk | Andy Stewart | Andrew.stewart@liverpoolft.nhs.uk |
| South East | Alison Ashman | Alison.Ashman@berkshire.nhs.uk | Melanie Renney | melanie.renney@berkshire.nhs.uk |
| South West | Danny Palmer | danny.palmer@uhbw.nhs.uk | Natalie Bryson | Natalie.Bryson@uhbw.nhs.uk |

Scotland

nss.nhssmedicineshortages@nhs.scot

Wales

MedicinesShortages@gov.wales

Northern Ireland

RPHPS.Admin@northerntrust.hscni.net

All other organisations should send enquiries about this notice to the DHSC Medicine Supply Team quoting reference number MSN/2024/038U.

Email: DHSCmedicinesupplyteam@dhsc.gov.uk.