Scroll down for: Pabrinex (vitamins B & C) IM (UK); and, Pabrinex IV (ROI)

Prescribing Information: UK

PABRINEX® Intravenous High Potency (IVHP), Concentrate for Solution for Infusion

Prescribing Information. Please refer to the full Summary of Product Characteristics before prescribing. **Name:** PABRINEX® Intravenous High Potency (IVHP), Concentrate for Solution for Infusion. **Active Ingredients:** Pabrinex IVHP is presented as a pair of (two) 5ml ampoules (labelled No. 1 and No. 2). Each No. 1 ampoule contains thiamine hydrochloride 250mg, riboflavin 4mg and pyridoxine hydrochloride 50mg. Each No. 2 ampoule contains ascorbic acid 500mg, nicotinamide 160mg and glucose (as monohydrate) 1000mg. **Indications:** Rapid therapy of severe depletion or malabsorption of the water-soluble vitamins B and C, particularly in alcoholism. **Dosage and Administration:** Before administration ensure both the Summary of Product Characteristics and ampoule labels refer to INTRAVENOUS infusion. *Adults:* The contents of 2 to 3 pairs of 5ml ampoules should be diluted with 50 to 100ml physiological saline or 5% glucose, and infused over 30 minutes every eight hours, or at the discretion of the physician. *Elderly:* As for adults. *Children:* Pabrinex IVHP is rarely indicated for administration to children; for further information refer to full SmPC. **Adverse Effects:** Hypersensitivity (including anaphylaxis, rash and urticaria), paraesthesia, hypotension, and injection site reactions. Prescribers should consult the summary of product characteristics for further details of side-effects. **Contraindications:** Known hypersensitivity to any of the active substances or excipients. **Precautions:** Potentially serious allergic reactions such as anaphylactic shock may occur rarely, during or shortly after administration of Pabrinex IVHP. Symptoms such as sneezing or mild asthma are warning signs that further injections may give rise to anaphylactic shock. Facilities for treating anaphylactic reactions should be available whenever Pabrinex IVHP is administered. To minimise risk, infuse over 30 minutes. **Interactions:** The content of pyridoxine may interfere with the effects of concurrent levodopa therapy. **Pregnancy and Lactation:** No adverse effects have been noted during pregnancy or lactation at recommended doses when used as clinically indicated. The potential risk for humans is unknown. Caution should be exercised when prescribing to pregnant women. **Legal category:** POM. **Marketing Authorisation Holder:** Kyowa Kirin Limited, Galabank Business Park, Galashiels, TD1 1QH, UK. **Marketing Authorisation Number:** Pabrinex IVHP: PL 16508/0049. **NHS price:** Pabrinex IVHP as 6 pairs of 5 ml ampoules: £16.23; Pabrinex IVHP as 10 pairs of 5 ml ampoules: £22.53. **Date of prescribing information:** June 2018.

®Pabrinex is a registered trade mark.

KKI/UKIRE/PAB/0183 Date of preparation: June 2023

Adverse Events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse Events should also be reported to Kyowa Kirin Ltd. on +44 (0)1896 664000, email medinfo@kyowakirin.com

IDENTIFY. TREAT. PROTECT.

Pabrinex®

vitamins B & C (high potency)

Prescribing Information: UK

PABRINEX® Intramuscular High Potency (IMHP) solution for injection.

Prescribing Information. Please refer to the full Summary of Product Characteristics before prescribing. **Name:** PABRINEX® Intramuscular High Potency solution for injection. **Active Ingredients:** Pabrinex IMHP is presented as a pair of (two) ampoules (5ml ampoules labelled No. 1 and 2ml ampoules labelled No. 2). The contents of a pair of ampoules (7ml) are mixed immediately prior to use. Each No. 1 ampoule contains: thiamine hydrochloride 250mg, riboflavin 4mg and pyridoxine hydrochloride 50mg. Each No. 2 ampoule contains ascorbic acid 500mg and nicotinamide 160mg. **Indications:** Rapid therapy of severe depletion or malabsorption of the water-soluble vitamins B and C, particularly in alcoholism. **Dosage and Administration:** Before administration ensure both the Summary of Product Characteristics and ampoule labels refer to INTRAMUSCULAR injection. *Adults:* The contents of one pair of ampoules (total 7ml) should be drawn up into a syringe to mix just before use and injected slowly, high into the gluteal muscle 5cm below the iliac crest, twice daily for up to 7 days. *Elderly:* As for adults. *Children:* Pabrinex IMHP is rarely indicated for administration to children. For age-related dose adjustments, refer to the SmPC. Contains benzyl Alcohol therefore: do not give to premature babies or neonates; and, may cause toxic and/or anaphylactoid reactions in infants and children up to 3 years old. **Adverse Effects:** Hypersensitivity (including anaphylaxis, rash and urticaria), paraesthesia, hypotension, and injection site reactions. Prescribers should consult the summary of product characteristics for further details of side-effects. **Precautions:** Potentially serious allergic adverse reactions such as anaphylactic shock may occur rarely during, or shortly after administration. Symptoms such as sneezing or mild asthma are warning signs that further injections may give rise to anaphylactic shock. Facilities for treating anaphylactic reactions should be available whenever Pabrinex IMHP is administered. The content of pyridoxine may interfere with the effects of concurrent levodopa therapy. No adverse effects have been noted during pregnancy or lactation at recommended doses when used as clinically indicated. The potential risk for humans is unknown. Caution should be exercised when prescribing to pregnant women. Pabrinex IMHP contains benzyl alcohol. **Contraindications:** Known hypersensitivity to any of the active constituents or excipients. **Legal category:** POM. **Marketing Authorisation Holder:** Kyowa Kirin Limited, Galabank Business Park, Galashiels, TD1 1QH, UK. **Marketing Authorisation Number:** Pabrinex IMHP: PL 16508/0058. **NHS price:** Pabrinex IMHP as 10 pairs of ampoules: £22.53. **Date of prescribing information:** December 2017.

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KKI/UKIRE/PAB/0183 Date of preparation: June 2023

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IDENTIFY. TREAT. PROTECT.

Pabrinex®

vitamins B & C (high potency)

Prescribing Information: Republic of Ireland

PABRINEX® Intravenous High Potency (IVHP), Concentrate for Solution for Infusion

Prescribing Information. Please refer to the full Summary of Product Characteristics before prescribing.

Name: PABRINEX® Intravenous High Potency (IVHP), Concentrate for Solution for Infusion. **Active Ingredients:** Pabrinex IVHP is presented as a pair of (two) 5ml ampoules (labelled No. 1 and No. 2). Each No. 1 ampoule contains thiamine hydrochloride 250mg, riboflavin 4mg and pyridoxine hydrochloride 50mg. Each No. 2 ampoule contains ascorbic acid 500mg, nicotinamide 160mg and glucose (as monohydrate) 1000mg. **Indications:** Rapid therapy of severe depletion or malabsorption of the water-soluble vitamins B and C, particularly in alcoholism. **Dosage and Administration:** Before administration ensure both the Summary of Product Characteristics and ampoule labels refer to INTRAVENOUS infusion. *Adults:* The contents of 2 to 3 pairs of 5ml ampoules should be diluted with 50 to 100ml physiological saline or 5% glucose, and infused over 30 minutes every eight hours, or at the discretion of the physician. *Elderly:* As for adults. *Children:* Pabrinex IVHP is rarely indicated for administration to children; for further information refer to full SmPC. **Adverse Effects:** Hypersensitivity (including anaphylaxis, rash and urticaria), paraesthesia, hypotension, and injection site reactions. Prescribers should consult the summary of product characteristics for further details of side-effects. **Contraindications:** Known hypersensitivity to any of the active substances or excipients. **Precautions:** Potentially serious allergic reactions such as anaphylactic shock may occur rarely, during or shortly after administration of Pabrinex IVHP. Symptoms such as sneezing or mild asthma are warning signs that further injections may give rise to anaphylactic shock. Facilities for treating anaphylactic reactions should be available whenever Pabrinex IVHP is administered. To minimise risk, infuse over 30 minutes. **Interactions:** The content of pyridoxine may interfere with the effects of concurrent levodopa therapy. **Pregnancy and Lactation:** No adverse effects have been noted during pregnancy or lactation at recommended doses when used as clinically indicated. The potential risk for humans is unknown. Caution should be exercised when prescribing to pregnant women. **Legal category:** POM. **Marketing Authorisation Holder:** Kyowa Kirin Holdings B.V., Bloemlaan 2, 2132NP, Hoofddorp, Netherlands. **Marketing Authorisation Number:** Pabrinex IVHP: PA 2288/001/001. **Date of prescribing information:** November 2018.

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KKI/UKIRE/PAB/0183 Date of preparation: June 2023

Adverse Events should be reported. Information about adverse event reporting can be found at www.hpra.ie. Adverse events should also be reported to Kyowa Kirin Ltd on +44 (0)1896 664000, email medinfo@kyowakirin.com

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