MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Multivitamin liquid for infants (Pentavite®) – 4 September 2023			
Details of affected product(s) Multivitamin liquid for infants (Pentavite) – ARTG 393911			
Reason for communication	Disruption to supply		
Date issue made apparent	22 August 2023		
Supply impact dates	Late September 2023		

Main indications and use

Multivitamin liquid for infants (Pentavite) is a multivitamin supplement used for the prevention of vitamin deficiency in infants born < 35 weeks gestation or < 2 kg birth weight.

Situation

There is a current disruption to the supply of multivitamin liquid for infants (Pentavite) until late September 2023. There are no like-for-like alternatives available on the Australian Register of Therapeutic Goods (ARTG).

Alternative agents

An alternative Australian registered multivitamin liquid that can be used is liquid multivitamin for infants (Brauer®). **Note – as per** the Australasian Neonatal Medicines Formulary recommendations, this alternative should only be used as a substitute when Pentavite® is unavailable.

Precautions, safety issues and other considerations associated with alternatives

While the alternative is a liquid multivitamin registered in Australia, there are differences in active ingredients, dose, frequency, and storage conditions (see **Table 1** on next page for a comparison). Important considerations:

- Note that the Brauer formula supplies betacarotene as the source of vitamin A. Betacarotene may be a suitable source
 of vitamin A in neonates.
- Additionally, the Brauer formula contains 200 IU/1 mL of vitamin D in comparison to the Pentavite formula which contains 400 IU/0.45 mL (Note: IU refers to international units). Therefore, a dose of 1 mL twice a day of the Brauer formula is required to provide a daily dose of 400 IU of vitamin D. Alternatively, 0.2 mL daily of vitamin D3 1000 IU/0.5 mL liquid (Ostelin®) can be given to provide a daily dose of 400 IU.

For further information, refer to the Australasian Neonatal Medicines Formulary (ANMF) consensus drug guidelines for the <u>Pentavite</u>, <u>Brauer</u> and <u>vitamin D</u> formularies.

Liaison with local eMeds/eMR teams may be required to ensure the appropriate products and order sentences/sets are built and available in local electronic Medication Management systems.

Impacts of this communication on clinical practice

Actions to address the disruption to supply of multivitamin liquid for infants (Pentavite) should be coordinated and implemented by the local Drug and Therapeutics Committee in consultation with the relevant clinicians. A different Australian registered product, liquid multivitamin for infants (Brauer) is available and can be utilised by facilities after consideration of the above precautions and safety issues.

Associated regulatory or policy references

PD2022 032 Medication Handling

PD2019 019 Coordination of responses to urgent system-level medicine or medical device issues

Key contacts

Clinical Excellence Commission (Medication Safety) – <u>CEC-MedicationSafety@health.nsw.gov.au</u>
HealthShare NSW (Category Manager – Strategic Procurement) – <u>Noman.Masood@health.nsw.gov.au</u>





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Table 1. Comparison of multivitamin oral liquids (Pentavite and Brauer brands)*

		Multivitamin Liquid for Infants	Liquid Multivitamin for Infants
		(Pentavite) – ARTG ID 393911	(Brauer) - ARTG ID 337233
Presentation		Oral liquid – 30 mL bottle	Oral liquid – 45 mL bottle
NSW Medicines Formulary		Listed – unrestricted ('vitamins')	Listed – unrestricted ('vitamins with
			minerals')
		0.45 mL daily (for preterm infants the	
Dose		dose may be halved (i.e. 0.23 mL) and	1 mL once or twice daily.
		given twice daily to improve tolerability)	Note: dose not weight based.
		Note: dose not weight based.	
Maximum dose per day		0.45 mL	2 mL
Route		Oral or intra-gastric tube	Oral or intra-gastric tube
Administration		Do not shake the bottle.	Shake well before use.
		Administer undiluted or mixed with a	Administer undiluted or mixed with a
		small amount of milk into infant's mouth	small amount of milk into infant's mouth
		through a feeding teat or via intra-	through a feeding teat or via intra-
		gastric tube.	gastric tube.
Storage		Store below 25°C. Protect from light.	Store below 25°C. Protect from light.
		Refrigerate after opening. Use within 9	Product can be used until printed
		weeks after opening.	expiry date.
		Amount per 0.45 mL dose	Amount per 1 mL dose
	Vitamin A	390 micrograms	-
	Betacarotene	-	3 mg (equivalent to retinol/Vitamin A1
	1.00	() () () () ()	250 micrograms)
	Vitamin D3	10.1 micrograms (equivalent to 400 IU)	5 micrograms (equivalent to 200 IU)
	Vitamin B1	540 micrograms	112 micrograms
	Vitamin B2	810 micrograms	150 micrograms
Active ingredients	Nicotinamide	7.1 mg	1 mg
	Vitamin B6	111 micrograms	100 micrograms
	Vitamin B12	-	0.417 micrograms
	Levomefolate	_	144.3 micrograms (equivalent to
	glucosamine		levomefolic acid 80 micrograms)
	Vitamin C	42.8 mg	7.5 mg
	Calcium	-	0.86 mg
	Vitamin E	-	4.04 mg
	Choline	-	37.5 mg
	Biotin	-	1.5 micrograms
Excipients			Ascorbyl palmitate, dl-alpha-
			tocopherol, gelatin, glycerol, maize oil,
		Sodium saccharin, pineapple flavour.	maize starch, potassium sorbate,
			purified water, sucrose, vegetable oil,
			xanthan gum.

^{*}Information obtained from the Australasian Neonatal Medicines Formulary (ANMF) consensus drug guidelines.



