

# Pharmacy Informer

Children's and Women's Health Centre of BC, Department of Pharmacy

Fall 2016

## Updates from C&W Pharmacy, Therapeutics and Nutrition (PT&N) Committee

**Jennifer Kendrick, BScPharm, PharmD**

The C&W PT&N Committee serves as the Pediatric subcommittee to the Provincial Pharmacy and Therapeutics Committee. We continue to have representation from other Health Authorities, in addition to our membership from C&W.

### 1. Policies & Procedures

The following new or updated policies & procedures have been approved and are posted on the C&W intranet:

The **Allergy Documentation** policy has been updated to clarify the pharmacist's role in updating a patient's allergy status.

The **BC Children's Hospital Empiric Antimicrobial Guide** has been updated to the 4<sup>th</sup> Edition. [More detailed information](#) on the updates appears in this issue.

The **Continuous Opioid Infusion For Patients Greater Than 3 Months of Age** policy has been updated to provide guidance for patients receiving high dose opioids outside of critical care areas. The Comfort Profile in the Alaris® pump should be used for patients that require high dose opioids under the guidance of the Acute Pain Service. The use of the Comfort Profile is not limited to palliative patients.

The **Investigational Medications** policy has been updated to reflect the changes to the local research institutes and to meet Accreditation standards.

### 2. Drug Dosage Handbook Updates

**Amphotericin B liposomal:** addition of the inhaled route.

**Levetiracetam** and **Valproic Acid:** addition of intravenous dosing (Special Access Program only).

**Dextrose, Insulin and Calcium** monographs now contain dosing information for the management of hyperkalemia. Additionally, the **insulin** monograph now has a section comparing the various formulations of insulin.

**Lidocaine (systemic):** addition of dosing for intradermal infiltration for PICC line.

**Lidocaine topical** now has dosing information for how to apply lidocaine 5% cream prior to painful procedures (e.g. IV start, lumbar puncture, bloodwork). Lidocaine 5% cream is an alternative to lidocaine-prilocaine (EMLA®) or tetracaine (Ametop®).

**Posaconazole** – addition of dosing for the extended release tablet, which is different from the dosing for the liquid formulation.

**Sodium chloride 3% and 7%** – change of name from 'hypertonic saline' and addition of dosing for sodium chloride 3% nebulized as an option for bronchiolitis.

**Sodium polystyrene sulfonate** (Kayexalate®) now includes instructions for how to administer it with feeds.

### 3. Medication Backorders

We continue to be facing medication shortages and the Pharmacy Department continues to monitor supplies and usage. We appreciate all the assistance in reviewing options to mitigate

the shortages (using oral/rectal routes, changing to alternative medications, changing to other brands and strengths, etc).

**Salbutamol** 2.5 mg and 5 mg nebulas are on backorder. Limited quantities may be available on emergency release. Salbutamol 5 mg/mL nebulizer solution continues to be available.

**Gentamicin** is now available. The PT&N Committee has approved removal of the automatic substitution to tobramycin. Gentamicin is the formulary aminoglycoside of choice for most patients. Prescribers have access to both gentamicin and tobramycin.

### 6. Pre-printed Orders

The following C&W pre-printed orders have been approved since May 2016:

**CARE: Sedation: Bariatric**

**NEPH: Kidney Transplant Admission Pre-Op;  
Post-Op PICU;  
Post-Op Ward**

**NICU: IVIG for Transfusion;  
Blood Administration;  
Inborn Admission;  
Outborn Admission**

**PEDS: ED Asthma**

**PICU CARD SURG:  
Post-Op Admission;  
Post-Op Day 1 Ward Transfer;  
Post-Op Day 2 onwards Ward Transfer**

**PICU: ECLS Initiation;  
Suspected Head Trauma;  
Transfer of Stable Long Term Ventilation  
Patients from PICU**

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## Review of References and Resources for Medication Use in Lactation

Joane Tang, BScPharm, ACPR

Reviewed by

Vanessa Paquette, BScPharm, ACPR, PharmD  
and Elaine Wong, BScPharm, ACPR

Breastfeeding is the recommended method for infant nutrition and has numerous benefits for both the mother and the baby.<sup>[1,2]</sup> However, breastfeeding mothers who are taking prescribed medications are often discouraged to breastfeed due to the insufficient information on manufacturer's product inserts and/or misinformation on the perceived harm to infants from medication transfer into breast milk. Many mothers, as well as clinicians, may not realize that most medications are considered compatible while breastfeeding, thus an adequate evaluation of each medication is crucial to prevent unnecessary avoidance of breastfeeding or non-compliance with prescribed medications. With medications that have a paucity of available information, it is important to incorporate patient factors of both the mother and baby with the best scientific literature available and the lactational pharmacology of the medication. One should consider factors that affect the transfer of a medication from serum into milk including: half-life, oral bioavailability, molecular weight, protein binding, pKa, and lipid solubility.<sup>[1,3]</sup>

With the ability to critically review literature and the knowledge of pharmacology, pharmacists play an integral role in supporting mothers and other health care professionals in making informed decisions about medication use in lactation. There are several resources available for pharmacists when faced with questions regarding the safety of medication use in breastfeeding. However, the recommendations from each reference do not always align so it is important to review more than one resource.<sup>[4]</sup> In this article, we will review some of the references available.

**Medications and Mothers' Milk**<sup>[3]</sup> is a comprehensive reference published every 2 years that uses a rating system to categorize lactation risk for each medication (L1 compatible to L5 hazardous). It contains monographs featuring information such as pharmacologic characteristics, summary findings in primary studies, and monitoring parameters. Relevant infant dose is included if known. Monographs often contain recommendations on alternative agents within the same class that are preferred in breastfeeding.

**LactMed**<sup>[5]</sup> is a free online database from the National Institute of Health National Library of Medicine that is

peer-reviewed by a panel of experts to ensure the information is accurate and current. LactMed has an extensive variety of monographs with summaries of primary research and information on drug levels found in breast milk and infant blood, and possible adverse effects in the nursing infant. LactMed does not have a rating system and instead provides a summary of recommendations at the top of each monograph.

**Drugs in Pregnancy and Lactation**<sup>[6]</sup> is typically the preferred resource for determining medication compatibility in pregnancy. However, this may not be the most comprehensive reference for determining the safety of drugs during lactation. Monographs typically include brief mentions of some primary studies and contain general statements for compatibility in lactation as deemed by the American Academy of Pediatrics.

**MotheRisk**<sup>[7]</sup> is a teratology service based at the Toronto Hospital for Sick Children. It provides information via clinic appointment (Toronto only), telephone and via its website on medication and other exposures in pregnancy and breastfeeding for health professionals and the public. The website features links to previous studies conducted by the MotheRisk team.

**MotherToBaby by OTIS (The Organization of Teratology Information Specialists)**<sup>[8]</sup> is a teratology information service which allows health care professionals and the public to access information on medication in pregnancy and lactation via telephone/text, email, a live web chat, or via their website. The website contains printable Fact Sheets that are suitable for providing to patients. In addition to medication, information is also available on herbal supplements, chemicals and beauty products.

If there are any further questions or concerns regarding medication use in lactation, after reviewing the available references, please contact the clinical pharmacists at BC Women's Hospital for assistance.

### References

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- MotheRisk. The Hospital for Sick Children. (accessed 2016 Aug 26). [Link](#)
- MotherToBaby. The Organization of Teratology Information Specialists. (accessed 2016 Aug 26). [Link](#)

**Table 1. Useful References for Medication Use in Lactation**

Reference	Access/Availability	Comments
<b>Medications and Mothers' Milk</b>	• In print and online (annual subscription)	• Online version updated daily
<b>LactMed</b>	• Online and App (free): <a href="https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm">https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm</a>	• Updated monthly
<b>Drugs in Pregnancy and Lactation</b>	• In print and online (UBC library)	• Published approximately every 3 years
<b>MotheRisk</b>	• Online (free): <a href="http://www.motherisk.org/">http://www.motherisk.org/</a>	Telephone: <b>1-877-439-2744</b>
<b>OTIS</b>	• Online (free): <a href="http://mothertobaby.org/">http://mothertobaby.org/</a>	Telephone: <b>1-866-626-6847</b> Text: <b>1-855-999-3525</b>
<b>Micromedex</b>	• Online (intranet): Search drug → Click on "Toxicology" on the right side of webpage → Scroll down to "Reproductive Risk Information"	• Contains TERIS <sup>a</sup> , Shepard's Catalog of Teratogenic Agents, and REPROTOX <sup>b</sup> databases
<b>InfantRisk Centre</b>	• App (subscription required)	• Mobile drug database for health professionals developed by the Texas Tech University

<sup>a</sup>TERIS, Teratogen Information System; <sup>b</sup>REPROTOX, Reproductive Toxicology Center



**BC Children's Hospital Empiric Antimicrobial Guidelines 2016 Update**  
**Karen Ng, BScPharm, PharmD, BCPS**  
**Reviewed by Dr. Joshua Osowicki, Infectious Diseases and Antimicrobial Stewardship**

After an annual review of available evidence and guidelines, the Antimicrobial Stewardship Program has updated the BC Children's Hospital Empiric Antimicrobial Guidelines, now posted onto [Medworxx](#). Therapeutic updates in this version include:

- **Sepsis <4 and ≥4 weeks:** references were updated to include the AAP guidelines[1] for neonatal sepsis and International Surviving Sepsis Campaign guidelines.[2]
- **Bacterial acute otitis media:** Updated February 2016 CPS guidelines have been added as a reference.[3] Amoxicillin remains the empiric drug of first choice. Amoxicillin-clavulanate should be reserved for children with amoxicillin exposure in the previous 30 days, non-response to amoxicillin, and for children who also have purulent conjunctivitis (*Haemophilus influenzae* and *Moraxella catarrhalis* more common).
- **Mastoiditis:** Empiric therapy has been changed from cefotaxime\* ± vancomycin ± metronidazole to cefotaxime\* ± vancomycin (without metronidazole). The most common bacterial pathogens are *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Streptococcus pyogenes* and *H. influenzae*. *Pseudomonas aeruginosa* is generally only seen in patients who also have chronic suppurative otitis media or otitis externa. Empiric anaerobic coverage is generally unnecessary. Vancomycin should be reserved for patients with colonization or a history of MRSA infection.[4]
- **Sinusitis:** Amoxicillin has been added as a first-line treatment for uncomplicated sinusitis. Amoxicillin-clavulanate remains an option for first-line treatment for children <2 years of age, attending child care, after recent amoxicillin treatment, for coverage of β-lactamase-producing *H. influenzae* and *M. catarrhalis*. [5-7]
- **Cervical lymphadenitis:** vancomycin has been deleted as empiric therapy, leaving cephalexin PO or ceftazolin IV as first-line options and clindamycin for MRSA coverage. The clinical presentation of cervical lymphadenitis is generally less severe, thus vancomycin can be reserved for targeted therapy or in rare cases of clinical deterioration.
- **Preseptal cellulitis:** cephalexin has replaced amoxicillin-clavulanate as empiric therapy, and ceftazolin ± vancomycin has been changed to ceftazolin OR vancomycin. The most likely organisms in preseptal cellulitis are *S. pneumoniae* and *S. aureus*, while *H. influenzae* has become rare, thus cephalexin or clindamycin (for MRSA coverage) is generally sufficient.[8] Empiric combination antibiotics for preseptal cellulitis is unnecessary (i.e. vancomycin monotherapy rather than vancomycin combined with ceftazolin is sufficient if MRSA is suspected but not confirmed).
- **Orbital cellulitis:** empiric therapy has been changed from cefotaxime\* ± vancomycin ± metronidazole to cefotaxime\* ± vancomycin (without metronidazole). Guidelines for the management of orbital cellulitis are lacking, but available evidence was reviewed during a meeting between ENT/Otolaryngology and AMS/ID in May 2016. Empiric anaerobic coverage is not necessary for most patients, but should be considered in patients with chronic sinusitis and abscess formation.[8-11] Empiric addition of vancomycin for MRSA should be considered for patients who have a history of MRSA colonization or infection, have evidence of abscess or bone involvement, orbital trauma, recent ophthalmic surgery or severe infection.
- **UTI (< 2 mo and severe >2 mo):** for penicillin-allergic patients < 2 months of age and for severe UTI in children >2 months of age, the empiric regimen has been changed from cefotaxime\* ± gentamicin to cefotaxime\* OR gentamicin. Monotherapy for UTI is sufficient; combination cefotaxime\* and gentamicin provides unnecessary overlapping coverage.

- **Ascending Cholangitis:** empiric therapy has been changed from ampicillin + cefotaxime\* + metronidazole to ampicillin + cefotaxime\* ± metronidazole, as agreed on between GI and AMS/ID in June 2016. Empiric anaerobic coverage should be considered only in the presence of biliary-enteric anastomosis.[12]
- **Cellulitis (mild):** monotherapy of cephalexin OR trimethoprim-sulfamethoxazole has replaced the previous recommendation for cephalexin ± trimethoprim-sulfamethoxazole. Either agent alone provides adequate coverage for Group-A Streptococci and *S. aureus* for this indication. Trimethoprim-sulfamethoxazole can be used instead of cephalexin if MRSA is suspected.
- **Osteomyelitis or septic arthritis:** empiric monotherapy of ceftazolin OR vancomycin has replaced the previous recommendation for ceftazolin ± vancomycin. Combination overlapping therapy for osteomyelitis/septic arthritis is generally unnecessary except in patients with severe sepsis. Vancomycin monotherapy can be used if MRSA is suspected.

\* As noted in previous updates, ceftriaxone may be substituted for cefotaxime for children over 30 days old and not on calcium-containing parenteral products (e.g. TPN).

New lanyard cards with the 2016 updates are available. If you would like a card for you and/or your division, please contact Karen Ng ([Karen.Ng2@cw.bc.ca](mailto:Karen.Ng2@cw.bc.ca)) with your location and number of cards desired.

INFECTION	FIRST CHOICE THERAPY
Sepsis (<4 weeks)	Ampicillin + (Gentamicin or Cefotaxime) ± Acyclovir
Sepsis (≥4 weeks)	Cefotaxime ± Vancomycin
Meningitis (<4 weeks)	Ampicillin + Cefotaxime + Acyclovir
Meningitis (≥4 weeks)	Cefotaxime + Vancomycin ± Acyclovir
Strep pharyngitis/tonsillitis	Penicillin V or Amoxicillin or Penicillin G
Acute otitis media	Amoxicillin or Amox-clav
Mastoiditis	Cefotaxime + Vancomycin
Sinusitis	Amoxicillin or Amox-clav or as mastoiditis if IV needed
Cervical lymphadenitis	Cephalexin or Clindamycin or Ceftazolin
Preseptal cellulitis	Cephalexin or Clindamycin or (Ceftazolin or Vancomycin)
Orbital cellulitis	Cefotaxime + Vancomycin
Dental abscess	Amox-clav or (Penicillin G + Metronidazole)

\*[http://bccwhcems.medworxx.com/Site\\_Published/bcc/PolicyManualView.aspx](http://bccwhcems.medworxx.com/Site_Published/bcc/PolicyManualView.aspx)  
 Empiric antimicrobial therapy at BCHH, Version 4.0, dated June 21, 2016

\*Note Mastoiditis and Orbital cellulitis recommendations have changed since the printing of the lanyard card. Please refer to above text for current recommendations.

**References**

1. Polin RA, Committee on Fetus and Newborn. Management of neonates with suspected or proven early-onset bacterial sepsis. *Pediatrics* 2012; 129: 1006-15. [Full Text](#)
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## Chlorpromazine Injection Discontinued from Canadian Market

Dean Elbe, BScPharm, PharmD, BCPP

Reviewed by Dr. Tyler Black, MD, FRCP(C), Medical Director, BCCH CAPE Unit

In June 2016, Sandoz Canada advised that chlorpromazine injection was being discontinued from the Canadian market.<sup>[1]</sup> Sandoz was the only source of chlorpromazine injection in Canada. A small amount of chlorpromazine injection stock remains on hand in the BC Children's Hospital Pharmacy Department at present, though **all remaining stock of chlorpromazine injection expires at the end of October 2016**. After this time, orders for intramuscular (IM) chlorpromazine cannot be supplied. Chlorpromazine tablets for oral use remain available.

Chlorpromazine is a low-potency first-generation antipsychotic. It offers a balance of sedation, lack of propensity to cause paradoxical agitation (as is sometimes observed with use of benzodiazepines in young children) and low dopamine D2 receptor blockade (resulting in a lower risk of acute dystonia and other extrapyramidal side effects (EPS)). These properties made chlorpromazine an ideal treatment for many agitated children and adolescents in the emergency department and our mental health inpatient units. The ability to administer chlorpromazine via IM injection was a very important treatment option for agitated children and adolescents who were unable or unwilling to take oral medication.

Selected alternative options for IM antipsychotic drug administration for children and adolescents in Canada are shown in the table below. Use of any of these agents in the pediatric age group in Canada is done on an off-label basis.<sup>[2]</sup>

**Methotrimeprazine** injection most closely mimics the sedating properties and low risk for EPS of chlorpromazine. Methotrimeprazine injection is used in some pediatric critical care settings, but it has been infrequently used for agitated children and adolescents in our emergency room and mental health programs. This product has been on manufacturer back-order previously, and as with chlorpromazine injection, there is only a single Canadian manufacturer.

**Loxapine** injection offers a balance of moderate sedation and low to moderate risk of EPS with low doses. There is considerable experience with use of loxapine injection in our mental health programs, and it had previously become the second-stage injectable antipsychotic choice in the inpatient mental health programs if chlorpromazine injection was not effective or not tolerated. There are currently three Canadian manufacturers of loxapine injection.

**Haloperidol** injection is the most evidence-based choice for managing agitation and aggression in children and adolescents. However, many of these publications pre-date the availability of 2<sup>nd</sup> generation antipsychotic medications.<sup>[3-6]</sup> Clinicians in our mental health programs have observed an unacceptably high rate of acute dystonia in patients treated with haloperidol injection at other centers who have been subsequently transferred to our inpatient psychiatry programs for ongoing

management. Haloperidol use should be reserved for the most extremely agitated patients in our program, when other agents have failed to control agitation.

**Zuclopendixol** Acuphase® injection has the unique property amongst injectable antipsychotics of a very long duration of action (typically 48-72 hours). It has been used to treat severely agitated adolescents who have required multiple IM antipsychotic injections, and are previously known to tolerate antipsychotic medications. This drug should not be used in patients who are acutely intoxicated or who have never received and tolerated short-acting oral or injectable antipsychotic medications previously. Profound sedation lasting 6-12 hours is typically observed within 1 hour following zuclopendixol Acuphase® IM injection.

**Olanzapine** injection is the only short-acting injectable 2<sup>nd</sup> generation antipsychotic agent available in Canada. Sedation and low risk of EPS with this drug are desirable properties. Administration within 1 hour of a parenteral benzodiazepine is contraindicated, due to documented risk for death from cardiorespiratory collapse.<sup>[2,7]</sup> Following genericization, the cost of this drug is now closer to the available 1<sup>st</sup> generation injectable antipsychotic agents than when it first became available in Canada. This drug remains non-formulary at BCCH.

After discussion with the staff and psychiatrists in the BCCH Child and Adolescent Psychiatric Emergency (CAPE) Unit, it was agreed that in light of the discontinuation of injectable chlorpromazine, the preferred first-choice injectable antipsychotic for treatment of agitation and aggression would become loxapine injection. Loxapine doses of 5 to 10 mg IM are approximately comparable in potency to previous typically used chlorpromazine doses of 25 to 50 mg IM. The draft CAPE aggression algorithm will be updated to reflect this change and the market removal of chlorpromazine injection. For higher or repeated doses of loxapine injection, co-administration of an anticholinergic drug such as benztropine or diphenhydramine may be necessary to prevent EPS and dystonic reactions.

### References

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- Eli Lilly Canada, Inc. (2013). Zyprexa Intramuscular product Monograph. Toronto, ON: Eli Lilly Canada, Inc. [Link](#)

Drug Name, D2 receptor blockade "potency"	Approximate dosage equivalence [2]* to chlorpromazine 25 mg IM	Comments
<b>methotrimeprazine</b> low to moderate potency	20 mg \$3.46/ampoule (BCCH)	- very sedating - low-moderate risk for acute dystonia - risk for hypotension and syncope with higher doses - single source Canadian injectable formulation
<b>loxapine</b> moderate potency	5 mg \$10.74/ampoule (BCCH)	- balanced sedation, low-moderate risk for acute dystonia - "atypical" properties similar to 2 <sup>nd</sup> generation agents - <b>CAPE Unit preferred first-choice IM antipsychotic</b>
<b>haloperidol</b> high potency	0.5 mg \$1.16/ampoule (BCCH)	- minimally sedating - high risk for acute dystonia in children & adolescents - reserve for severe agitation, after other agents failed
<b>zuclopendixol</b> Acuphase® high potency	n/a (usually 25-50 mg IM, may repeat after 48-72 hrs) \$14.85/ampoule (BCCH)	- very sedating for 6-12 hours following injection - longest acting (48-72 hrs) injectable antipsychotic - not in antipsychotic naive patients/acute intoxication - high risk for acute dystonia in children & adolescents
<b>olanzapine</b> moderate potency	2.5 mg \$16.54/single-use vial (non-formulary at BCCH))	- moderately sedating, low risk for acute dystonia - Only Canadian 2 <sup>nd</sup> generation IM antipsychotic - Parenteral benzodiazepine administration within 1 hour of olanzapine is contraindicated [2,7]

\*dosages rounded to clinically usable amounts



# FloraBABY® for Prevention of Necrotizing Enterocolitis

**Nicole Primus, BScPharm, PharmD**  
**Al McDougal, BScPharm**

### **Why is FloraBABY® now on Formulary? (Background)**

Necrotizing enterocolitis (NEC) is the most common gastrointestinal medical/surgical emergency occurring in neonates. It is an acute inflammatory necrosis of the bowel primarily affecting preterm infants although 5 to 25% of cases occur in term infants.[1] The pathogenesis of NEC is incompletely understood, but it is speculated that NEC coincides with two of the three pathologic events of intestinal ischemia, colonization of the intestine by pathologic bacteria, and excess protein substrate in the intestinal lumen.

Probiotics are live microorganisms which when administered in adequate amounts promote intestinal health and protect against inflammatory responses. The intestine of the term breastfed infant is rapidly colonized with a number of probiotic organisms, in particular *Bifidobacteria* and *Lactobacilli*. In contrast in the preterm infant's intestine these organisms are distinctly uncommon. Instead their intestine becomes colonized by different microorganisms, predominantly coliforms, *Enterococci*, and other *Bacteroides* species with much inter-individual variation. These features of the bacterial flora, unique to the preterm infant, are believed to be responsible for the initiation of pro-inflammatory responses in the context of intestinal ischemia and deficient mucosal immune responses. The mortality and long term morbidity rates for NEC are high in preterm infants. Preventing NEC through the administration of probiotic organisms is supported by extensive published clinical evidence, and clearly has a favourable benefit to risk ratio.[2]

### **Clinical Evidence [1]**

A Cochrane review of clinical trials on probiotics for the prevention of NEC in preterm infants reviewed 24 eligible trials and reported outcomes on 2761 infants treated with probiotics and 2676 control infants. The primary objective was to compare the efficacy and safety of prophylactic enteral probiotics versus placebo or no treatment in the prevention of severe (> stage II) NEC or sepsis or both, in preterm infants. Only randomized and quasi-randomized trials were included. Participants were preterm infants. The authors concluded that, based on the available evidence, the enteral administration of probiotics reduces the occurrence of severe NEC (RR 0.43, NNTB 30) and all-cause mortality (RR 0.65, NNTB 41) in preterm infants weighing less than 1500 grams.

### **Product information [3]**

As per Table 1, FloraBABY® is a blend of 5 strains of probiotics normally found in children: *Bifidobacterium breve*, *Lactobacillus rhamnosus*, *Bifidobacterium bifidum*, *Bifidobacterium infantis* and *Bifidobacterium longum*. FloraBABY PRO and FloraBABY are the same product according to the manufacturer. They are supplied as a powder in unit dose sachets, packaged in a plastic jar.

1 SACHET (0.5 GRAMS)= THE BELOW COMPOSITION		
<b>Active:</b>		<b>Colony Forming Units (CFU)</b>
<i>Bifidobacterium breve</i>	HA-129	600 Million CFU
<i>Bifidobacterium bifidum</i>	HA-132	400 Million CFU
<i>Bifidobacterium infantis</i>	HA-116	300 Million CFU
<i>Bifidobacterium longum</i>	HA-135	200 Million CFU
<i>Lactobacillus rhamnosus</i>	HA-111	500 Million CFU
<b>NON-MEDICINAL INGREDIENTS:</b>		
Ascorbic Acid		
Maltodextrin		



**Table 1. FloraBABY® Composition**

**FloraBABY® Unit Dose Sachet and 50 Sachet Jar**

### **Patient Eligibility [4]**

Newborn infants with birth weight less than 1500 grams

#### **Exclusion Criteria:**

- Congenital gastrointestinal malformations (esophageal atresia/tracheo-esophageal fistula, gastroschisis, malrotation, intestinal atresia, Hirschprung's disease, other intestinal obstruction)
- Treatment of NEC
- Gastrointestinal perforation
- Within 72 hours of gastrointestinal surgery
- Infants who are NPO for reason other than above may have an initial dose on day of birth as ordered by attending physician

#### **Relative Contraindications requiring Case-by-Case Review:**

- Confirmed sepsis during treatment
- Short gut syndrome
- Maternal human immunodeficiency virus (HIV) disease
- Family history of immunodeficiency
- Cow's milk allergy (product has come into contact with milk and soy from fermentation ingredients)
- Corticosteroid therapy exceeding:
  - 2 weeks of dexamethasone for bronchopulmonary dysplasia (BPD)
  - Prolonged stress dose hydrocortisone

...Cont'd on [Page 6](#)



## FloraBABY continued from Page 5...

### **Dosing [5]**

- FloraBaby 0.5 grams (1 sachet) daily, beginning on day of birth (unless contraindicated)
- Administer via feeding tube or orally
- Discontinue at 35 weeks corrected gestational age (Postmenstrual Age)

### **Preparation and administration [3,4]**

- Reconstitute sachet with 1 mL of sterile water and administer via feeding tube or orally
- May mix into warm or cool drinks such as infant formula, water, juice and milk, or soft foods such as yogurt or applesauce
- Do not mix with hot liquids or hot foods
- Requires refrigeration

### **Safety considerations/Adverse effects [6]**

There is a theoretical risk of bacteremia secondary to specific enterally administered probiotic strains, though few data support this concern. Almost all patients presenting with probiotic microorganism sepsis in these studies have had underlying conditions predisposing them to infection, e.g. structural heart defects in case of endocarditis, or indwelling catheters in case of sepsis. In most cases of infection, the organism appears to have originated from the patient's own microflora.[3] Several evaluations of the published literature have concluded that the risk of infection with probiotic *Lactobacilli* or *Bifidobacteria* is similar to that of infection with commensal strains, and that consumption of such products is a negligible risk to consumers, including immunocompromised hosts.[3]

A trial investigating the effects of probiotics in sepsis in preterm infants[7] and a systematic review and meta-analysis of probiotics for prevention of NEC in preterm infants is available.[8]

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3. Renew Life Canada. FloraBaby: Product information 2015. Renew Life Canada, Oakville, ON. Accessed online September 7, 2016. [Link to Website](#)
4. BC Children's Hospital Neonatal Drug Dosage Guideline: FloraBaby PRO. [BCCH Intranet Link](#)
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8. Aceti A, Gori D, Barone G et al. Probiotics for prevention of necrotizing enterocolitis in preterm infants: systematic review and meta-analysis. *Ital J Pediatr* 2015;41:89. [Full Text](#)

## **Research & Awards** **Karen Ng, BScPharm, PharmD, BCPS**



### **Research**

#### **Articles in peer-reviewed journals**

**Sih K, Goldman RD.** Nonsteroidal anti-inflammatory drug administration in children with history of wheeze. *Child Health Update* 2016;62:633-4. [Full Text](#)

**Ensom MHH.** Paving the way and passing the torch. *Can J Hosp Pharm* 2016;69:105. [Full Text](#)

**Ensom MHH, Decarie D.** Stability of extemporaneously-compounded trimethoprim in glass and plastic bottles and plastic syringes. *Can J Hosp Pharm* 2016;69:171-3. [Full Text](#)

Kiang TKL, **Ensom MHH.** Therapeutic drug monitoring of mycophenolate in adult solid organ transplant patients: an update. *Expert Opin Drug Metab Toxicol* 2016;12:545-53. DOI: 10.1517/17425255.2016.1170806. [Abstract](#)

Houlihan S, **Decarie D**, Benes C, Cleve R, Vidler M, Magee LA, **Ensom MHH**, von Dadelszen P. Magnocaine, a new take on an old drug for pre-eclampsia: physical compatibility and chemical stability of magnesium sulphate and lidocaine hydrochloride in pre-filled syringes. *J Obstet Gynaecol Can* 2016; June 29 (online first). [Full Text](#)  
DOI: 10.1016/j.jogc.2016.04.097

Cheng W, Kiang TKL, Bring P, **Ensom MHH.** Predictive performance of the Winter-Tozer and its derivative Equations for estimating free phenytoin concentrations in specific patient populations. *Can J Hosp Pharm* 2016;69:269-79. [Abstract](#)

Malcolmson C, **Ng K**, Hughes S, Kissoon N, **Schina J**, Tilley PA, Roberts A. Impact of matrix-assisted laser desorption and ionization time-of-flight and antimicrobial stewardship intervention on treatment of bloodstream infections in hospitalized children. *J Ped Infect Dis* 2016. [Full Text](#)  
DOI: 10.1093/jpids/piw033

**Dagenais R**, Barry AR, **Ensom MHH.** 'The Bus Analogy': A New Analogy to Help Pharmacy Students Conceptualize the Well-Stirred Model. 67th AFPC Annual Conference and Meetings - Canadian Pharmacy Education and Research Conference (CPERC). June 2-4, 2016. Richmond, BC. (Abstract).

### **Awards**

**Dr. Rumi McGloin** was awarded the Lower Mainland Pharmacy Services Residency Program **Veteran Preceptor of the Year** for 2015-16, recognizing her excellence in teaching, precepting, and mentoring residents.

**Dr. Vanessa Paquette** was awarded the Lower Mainland Pharmacy Services Residency Program **New Preceptor of the Year** for 2015-16, recognizing her excellence in teaching, precepting, and mentoring residents.

**Donna Leung** was awarded the Lower Mainland Pharmacy Services Residency Program **Resident of the Year** for 2015-16, recognizing excellence in all aspects of professional development in the residency program.

Erica HZ Wang, Jennifer L Bolt, **Diane Decarie**, William Semchuk, and **Mary HH Ensom** received the CSHP - BC Branch Publication Award (category: Original Research Article) at the CSHP - BC Branch Annual General Meeting in Vancouver on Nov 21, 2015: "A Study of Dabigatran Stability in 3 Clinically-Relevant Environments: Manufacturer's Blister Pack, Unit-Dose Packaging, and Community Pharmacy Blister Pack. *Can J Hosp Pharm* 2015;68:16-21." [Full Text](#)

**Kyle Collins, Mary Ensom, Dan Rainkie, and Roxane Carr** received the Canadian Society of Hospital Pharmacists Pharmacotherapy Best Practice Award for the project "Assessment of Pediatric Vancomycin Empiric Dosing" at the CSHP Professional Practice Conference in February 2016 in Toronto.

## **Pharmacy Informer Editorial Board**

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