



IMPAACT 2007

PHARMACY CONSIDERATIONS

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STUDY PRODUCT SUPPLIES FROM THE CRPMC

- Maraviroc 20mg/ml oral solution
- 250ml ready to use bottle
- Press in Bottle Adaptor (PIBA)
- Comar 5ml and 1ml oral syringes (consisting of a polypropylene barrel & HDPE Plunger)
- Syringe caps

MARAVIROC ORAL SOLUTION STORAGE

- Store at room temperature – 15 to 30°C (59 to 86°F).
- Store upright
- Any issues with the product must be immediately communicated with the CRPMC

STUDY PRODUCT PREPARATION

- Prepare the bottle by inserting the PIBA and label with the date and time of opening (60 days expiration date). You may use this bottle for dispensing additional doses as long as the product is stored at appropriate temperature and is within use date.

Figure 8-1: Press in Bottle Adaptor (PIBA)



- Open bottle, set cap aside. Retain the cap.
- The PIBA has three fins plus the top lip that acts as the stop (see Figure 8-1). Place the PIBA into the bottle opening, with the top lip or 'stop' uppermost.

- Using gentle pressure, push the PIBA down into the neck of the bottle (so that all three fins are completely inserted into the bottle) leaving only the single top lip (stop) of the PIBA outside of the bottle.

Figure 8-2: Insertion of PIBA



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- The stop should be flush with the top of the bottle.
 - Once inserted, the PIBA should not be removed.
 - Securely close the bottle utilizing the original cap.



SYRINGE PREPARATION

- Draw up appropriate dose in a correct size syringe, place a cap on the syringe, and label the syringe (refer to the study Manual of Procedures (MOP)).
- Maraviroc oral solution held within a Comar oral dosing syringe is stable for 24 hours at 15 to 30°C.
- From Appendix II, Table D-Dose of 8 mg/kg

Weight Band (kg)	8 mg/kg	Volume (mL)
	Dose in (mg)	Volume to Administer
2.0-2.5	20 mg	1 mL
2.6-3.1	25 mg	1.25 mL (1/4 tsp)
3.2-3.8	30 mg	1.5 mL
3.9-5.0	40 mg	2 mL
5.1-6.0	50 mg	2.5 mL (1/2 tsp)



STUDY DRUG REGIMENS

Cohort I (Stratum IA or Stratum IB)

First single dose:

Maraviroc 8mg/kg oral solution as a single dose within 3 days of birth.

Second single dose:

Maraviroc 8mg/kg oral solution as a single dose at Week 1 (Day 7-14) of life.

- Pharmacists will prepare the dose in the appropriate size COMAR oral syringe.
- The COMAR oral syringe will be dispensed to study staff for administration.

STUDY DRUG REGIMENS

Cohort 2 (Stratum 2A and 2B)

- Maraviroc oral solution at the dose and frequency determined from Stratum 1A and Stratum 1B will be administered within 3 days of birth and continued for up to 42 (35 to 42 days) of life.
- Appendix II has a range of doses for the protocol team to chose from and the chosen dose (determined from Cohort 1) will be communicated to sites via a Clarification Memorandum which must go to pharmacist and by prescription.

COHORT 2: HOME ADMINISTRATION

- Parent or caregiver should be given adequate oral dosing syringes of the correct size.
- A clean dry syringe should be used for each dose
- Completely depress the plunger on the dosing syringe. Remove the cap from the bottle and insert the dosing syringe tip into the PIBA.
- Invert the bottle and syringe.
- Pull back on the plunger of the oral dosing syringe to the appropriate graduation mark on the oral dosing syringe barrel, being careful not to remove the syringe from the PIBA

COHORT 2: HOME ADMINISTRATION (CONTINUED)

- When pulling back, check for air bubbles in the syringe. If an air bubble is present, depress the plunger to expel the air and continue to pull back to obtain the full dose.
- Recap bottle and cap syringe if not used immediately
- After each use do the following:
 - Clean the syringe(s) by removing the plunger and rinsing the barrel and plunger with water.
 - Allow the barrel and plunger to air dry or use a clean paper towel or clean cloth to dry.
 - When dry, push the plunger back into the syringe barrel



Questions?