

GUIDELINES FOR THE ADMINISTRATION OF VIRAMUNE® 200mg TABLETS and 50mg/5ml ORAL SUSPENSION FOR USE IN THE PREVENTION OF MOTHER TO CHILD TRANSMISSION (pMTCT) OF HIV-1 (WHERE SINGLE DOSE PROPHYLAXIS WITH VIRAMUNE IS INDICATED)

The use of VIRAMUNE in programs for the prevention of mother to child transmission of HIV should be considered, amongst other things, in the context of local health policies and 2006 WHO recommendations for the use of nevirapine, the active ingredient of VIRAMUNE.

Where other antiretroviral medicines are accessible, the single dose VIRAMUNE should be combined with additional effective antiretroviral medicines as recommended in the latest WHO guidelines for pMTCT.

Medication:

- VIRAMUNE® 200mg tablets
- VIRAMUNE® Oral Suspension 50 mg/5 ml (10 mg/ml):

Dosage regimen

Maternal Dosing: A single 200 mg dose as soon as possible after the onset of labour.

Neonatal Dosing: A single dose of 2 mg/kg orally within 72 hours after birth. If the mother received her VIRAMUNE® dose less than two hours prior to delivery, the infant should be administered the single 2mg/kg dose of VIRAMUNE® immediately after birth and the second 2mg/kg dose within 24-72 hours after the first dose.

In circumstances where it is not feasible to administer a dose based on weight, a fixed 0.6 ml dose can be administered as this approximates the appropriate dose to a newborn of average weight.

Storage of suspension

The bottle should be recapped and tightly sealed immediately following each use.

The bottle should be stored at 15°C-30°C (59°F-86°F), this applies also to the suspension filled dispenser.

The bottle should be labeled with the date on which it was opened. Based on results from in-use stability studies, after opening, the bottle should be used within 6 months.

The content of the bottle should be used in any event prior to the date of expiry printed on the label.

Bottles should be discarded after expiry.

Preparing the dose of suspension in a health care institution

Gently shake the VIRAMUNE suspension by inverting the bottle several times. The bottle should not be shaken vigorously.

In some instances, several infants will receive medication from the same bottle of VIRAMUNE. The suspension should be measured by pouring a small amount into a cup. The suspension should then be drawn into an oral syringe and administered orally. The remainder of the VIRAMUNE in the cup should not be returned to the bottle and should be discarded. **To avoid contamination of the VIRAMUNE bottle, the oral syringe should not be placed directly into the bottle.**

Ideally, a new oral syringe should be used for each infant to avoid the spread of infection. If a new oral syringe is not available, the used one should be cleaned and disinfected according to local procedures prior to each use.

The dose should be administered using a calibrated oral syringe. A hypodermic syringe may also be used for oral administration if the needle has been removed.

The oral syringe used should be able to ensure the accurate delivery of 0.6ml of VIRAMUNE suspension.

Based on results from in-use stability studies with the Baxa oral syringe, the suspension filled in the oral syringe and stored in a pouch (supplied on request) should be used within 2 months. The filling date or date of expiry should be documented on a pouch.

VIRAMUNE suspension does contain preservative to minimize the possibility of harmful microbial growth in the open bottle.

NB: This document is for general guidance only; it does not replace locally-binding labeling in specific countries.