

GUIDELINES FOR THE ADMINISTRATION OF VIRAMUNE® SUSPENSION FOR USE IN THE PREVENTION OF MOTHER TO CHILD TRANSMISSION (MTCT) OF HIV -1

Medication

Viramune® (nevirapine) Oral Suspension 50 mg/5 ml (10 mg/ml):

Dosing of Viramune® Suspension for the Prevention of MTCT

The infant should be given a single dose of 2 mg/kg by mouth within 72 hours after birth. If possible, this dose should be given after 24 hours of birth.

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.

If the mother received her Viramune® dose less than two hours prior to delivery, then the infant should receive the single 2 mg/kg dose of Viramune® immediately after birth and a second 2 mg/kg dose within 24 – 72 hours after the first dose.

If the newborn vomits within one hour of Viramune® administration, the dose should be repeated.

Dose Preparation

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

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 syringe should hold a maximum total volume of 3 ml or less to ensure accuracy.

Ideally, a new syringe should be used for each patient. Used syringes should be discarded to avoid contamination of the Viramune® multiple dose bottle and the spread of infections between patients.

If a new syringe is not available, the used syringe should be cleaned and disinfected according to local procedures prior to each use.

Since multiple patients 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 the 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, the syringe should not be placed directly into the bottle.

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

Storage

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).

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.