

MOTHER TO CHILD TRANSMISSION OF HIV (MTCT-HIV) PREVENTION KIT DRUG INFORMATION FOR HEALTH CARE PROVIDERS

DRUG NAME: Zidovudine (ZDV, AZT)
BRAND NAME: Retrovir®

BENEFITS OF ZIDOVUDINE:

- Zidovudine, (also called azidothymidine or AZT), an antiviral drug that slows the growth of the HIV virus, has been shown in a large randomized, multicentre study to decrease the rate of perinatal transmission of HIV when it is taken by the mother during pregnancy and delivery, and by the baby for 6 weeks after birth.
- The use of ZDV has greatly reduces the risk of the baby being infected, however it does not prevent all infections.

DOSE AND ADMINISTRATION:

There are two zidovudine preparations in this MTCT-HIV Prevention Kit, 10 parenteral vials (10mg/ml) and 240 ml oral liquid (10 mg/ml):

Mother:

- During labour and delivery, ZDV is given intravenously (IV) to the mother as a loading dose of 2 mg/kg over one hour followed by an infusion of 1 mg/kg/hour until the cord is clamped (see IV ZDV Administration Protocol for details on mixing and administration).

Baby:

- ZDV 2 mg/kg by mouth every six hours for *six weeks*. The first dose of ZDV should be given within 6 to 8 hours after birth if the mother received ZDV during delivery. If IV ZDV was not administered to the mother, oral liquid for the baby should start as soon as possible.
- ZDV liquid is a 10 mg/ml syrup. Each dose for a baby is usually less than 1 ml. ZDV syrup may be kept at room temperature.
- ZDV can be given with food or on an empty stomach. Gently slip the oral syringe in the baby's mouth just inside the cheek, and with 4 or 5 gentle pushes on the plunger of the syringe, administer the dose.
- If the infant vomits within 15 minutes of the dose, give another dose if possible. If it is more than 15 minutes, do NOT give another dose, just give the next dose when scheduled.

ENSURE THAT THE ENTIRE BOTTLE OF ZDV ORAL LIQUID IS SENT HOME WITH THE BABY- IT IS MORE THAN ENOUGH TO COMPLETE THE SIX WEEKS OF THERAPY

ADVERSE EFFECTS:

- Parenteral zidovudine is generally well tolerated. Initial adverse effects may include weakness, headache, dizziness, insomnia, anorexia, vomiting, malaise and myalgia. These symptoms seldom require lowering dosage or stopping the drug.
- Mild anemia and neutropenia have been noted in some infants receiving ZDV- reductions in hemoglobin or neutrophils may occur as early as 2-4 weeks. These conditions are usually mild and resolve when the dose is reduced or the drug is discontinued.
- Follow-up blood work should be done at 2 and 4 weeks after birth to check for these side effects.

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DRUG INFORMATION FOR HEALTH CARE PROVIDERS

DRUG NAME: Nevirapine
BRAND NAME: Viramune®

BENEFITS OF NEVIRAPINE:

- Nevirapine, an antiviral drug that slows the growth of the HIV virus, has been shown to decrease the risk of a mother passing the HIV virus to her baby when nevirapine is taken by the mother as a single oral dose at delivery, followed by a single oral dose to the baby within 48 to 72 hours of birth
- The use of nevirapine can reduce the risk of the baby being infected, however it does not prevent all infections

DOSE AND ADMINISTRATION:

There are two nevirapine preparations in this MTCT-HIV Prevention Kit, oral tablets (two tablets of 200mg each) and oral liquid (5 ml of 10mg/ml liquid)

Mother:

- Nevirapine 200mg orally should be administered as soon as possible after arrival at the hospital to the pregnant HIV positive woman who is in labour **if she** :
 - has **not** received **any** antiretroviral therapy during pregnancy
 - has received antiretroviral therapy but is known or suspected to have a **detectable viral load** at or near delivery
 - is thought to be at high risk of HIV infection, but her HIV status is not known
- If the nevirapine tablet is vomited within 15 minutes of administration it should be re-administered.
- mother should also receive zidovudine (ZDV) intravenously 2 mg/kg loading dose over 1 hour followed by 1 mg/kg/hour until delivery

Baby:

- Nevirapine 2 mg/kg is given by mouth as a single dose within 48 to 72 hours after birth if mother received oral nevirapine, or as soon as possible after delivery if the mother received no treatment at all
- Nevirapine oral suspension contains 10 mg/ml- the infant dose is usually less than 1 ml.
- Gently slip the oral syringe in the baby's mouth just inside the cheek and with 4 or 5 gentle pushes on the plunger of the syringe, administer the medicine
- the baby should **also** receive zidovudine (ZDV) 2 mg/kg orally every six hours for the first six weeks of life.

ADVERSE EFFECTS:

- Nevirapine given as a single dose is very well tolerated- only mild adverse effects on mother and baby were seen during the research trials for prevention of mother to child transmission
 - these included mild skin rash and mild anemia
 - no other adverse effects have been noted in long-term follow-up of the babies to date
- An allergic reaction (shortness of breath, closing of the throat, swelling of lips, tongue or face) is extremely rare after a single dose, and requires immediate medical attention
- Adverse effects seen with long-term use of nevirapine include rash, altered liver function, nausea, vomiting, diarrhea, abdominal pain, headache, numbness, tingling or muscle pain, but these have not been reported following a single dose.