PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start to take your medicine, even if you have just refilled your prescription or used this medicine before. Some of the information in the previous leaflet may have changed. Remember that your doctor has prescribed this medicine only for you.
Never give it to anyone else.

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:
ADCO-NEVIRAPINE TABLETS

WHAT ADCO-NEVIRAPINE TABLETS CONTAIN:
Each tablet contains 200 mg nevirapine as an active ingredient.
The other ingredients in the tablet are: polyvinylpyrrolidone K30, lactose monohydrate, pregelatinized starch, microcrystalline cellulose pH 101, microcrystalline cellulose pH 102, sodium starch glycolate, aerosil 200, magnesium stearate, purified water and permitted colourants.

WHAT ADCO-NEVIRAPINE TAB LETS ARE USED FOR:
Nevi rapine is an anti-virus medicine used in the treatment of the infection caused by the Human Immunodeficiency Virus (HIV). HIV grows and multiplies through DNA chain formation. Nevirapine helps control HIV infection by blocking an enzyme that HIV needs to multiply. This helps keep HIV from reproducing.
This medicine is used in combination with other antiviral medicines in the treatment of HIV infection in adults and children. **ADCO-NEVIRAPINE TABLETS** are suitable for adults and children (50 kg or more in weight) who can swallow tablets easily.

BEFORE TAKING ADCO-NEVIRAPINE TABLETS:

If you are taking medicines on a regular basis, using the medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.
If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

PATIENT INFORMATION LEAFLET

ADCO-NEVIRAPINE TABLETS is not a cure for HIV infection or AIDS. People taking this medicine may still develop infections or other illnesses associated with HIV disease and AIDS. It is therefore important that you remain under the supervision of your doctor while taking this medicine. **ADCO-NEVIRAPINE TABLETS** does not reduce the risk of passing HIV to others through sexual contact or blood contamination. You should use appropriate precautions.

Do not take this medicine:

- If you or your child have ever had an allergic reaction to nevi rapine or any of the other ingredients in this tablet.
- If you have severe liver or kidney disease.
- If you or your child previously experienced severe skin rash, hepatitis (inflammation of the liver) or other liver injury while taking **ADCO-NEVIRAPINE TABLE**

Take special care with this medicine:

- During the first 18 weeks of using it. This is an important period, which requires careful monitoring to discover the appearance of severe and life-threatening skin reactions and serious liver effects. During this time, especially the first 14 days of treatment (the 'lead-in period'), the dosage must be strictly adhered to (see more information under 'HOW TO TAKE THIS MEDICINE' below).

Stop taking ADCO-NEVIRAPINE TABLETS and tell your doctor immediately if you or your child experiences a rash. This rash may be accompanied by other side-effects such as fever, blistering, mouth sores, eye inflammation, facial swelling, muscle or joint pain, or a general feeling of illness.
If you or your child experience rash and any of the other side-effects of a hypersensitivity (allergic) reaction, notify your doctor immediately. Treatment with ADCO-NEVIRAPINE TABLETS should be stopped. If your doctor has stopped treatment with ADCO-NEVIRAPINE TABLETS, NEVER TAKE THIS MEDICINE AGAIN.

- Notify your doctor if you or your child are suffering with, or have ever suffered from liver disease. ADCO-NEVIRAPINE TABLETS can cause LIFE-THREATENING LIVER TOXICITY.

If you are unwell or notice any symptoms (loss of appetite, nausea, vomiting, yellow discolouration of skin and eyes), notify your doctor immediately. Because of the effects of ADCO-NEVIRAPINE TABLETS on the liver, your doctor will do blood tests before starting treatment and during treatment to monitor your liver function. Depending on the results, your

doctor may decide to discontinue treatment. If treatment has been stopped due to liver disease, you should never take ADCO-NEVIRAPINE TABLETS again.

Pregnancy: Consult your doctor or pharmacist before using any medicine Avoid falling pregnant while using ADCO-NEVIRAPINE TABLETS.

Breast-feeding: Continue breast-feeding if you are taking **ADCO-NEVIRAPINE TABLETS.** If you are not taking this medicine and you have the HIV infection, it is recommended that you stop breast-feeding to reduce the chances of passing the infection to your baby.

Driving and using machinery: This medicine has been reported to cause sleepiness. Take care if you are driving or operating machinery. If you feel sleepy, stop driving or operating machines.

Taking other medicines with ADCO-NEVIRAPINE TABLETS: If you are using any other medicines, including over-the-counter medicines, please tell your doctor or pharmacist.
ADCO-NEVIRAPINE TABLETS may decrease the blood levels of the anti-HIV medications saquinavir and indinavir. Your doctor will decide if any dosage adjustments are needed. It has no effect on the following antiviral medicines: zidovudine, didanosine, zalcitabine, stavudine, nelfinavir and ritonavir.

Medicines containing ketoconazole should not be taken together with **ADCO-NEVIRAPINE TABLETS,** as it results in decreased levels of ketoconazole and increased levels of nevirapine.

Fluconazole causes increased blood levels of nevirapine. Your doctor will monitor co-administration of these two medicines. If you are taking medication containing warfarin at the same time as **ADCO-NEVIRAPINE TABLETS,** the prothrombin time should be more frequently monitored.

The antibiotics rifampicin and rifabutin have been shown to decrease the blood concentration of nevirapine, whilst cimetidine and macrolide antibiotics have been shown to increase the blood concentration of nevirapine Your doctor will monitor and consider dosage adjustments if necessary.

St. John's Wort and medicines containing it may decrease the amount of nevirapine in the body.

It is possible that **ADCO-NEVIRAPINE TABLETS** can affect oral contraceptives, and therefore, barrier means of contraception (e.g. condoms) should be used.

ADCO-NEVIRAPINE TABLETS may affect the blood concentrations of methadone. If you are undergoing methadone treatment, your doctor will consider what dosage adjustments are necessary, if any.

HOW TO TAKE ADCO-NEVIRAPINE TABLETS:

Do not share medicines prescribed for you with other persons.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the hospital or poison control center. It is important that you take this medicine exactly as directed by your doctor. Even if you feel better, do not stop taking **ADCO-NEVIRAPINE TABLETS** without talking to your doctor. Using **ADCO-NEVIRAPINE TABLETS** as directed should give you the best chance to delay the development of drug resistance. Do not take more than prescribed by your doctor; to do so may increase the chance of side-effects.

For adults and children (50 kg or more in weight) who can swallow tablets easily.

Lead-in period: the recommended dose is 1 tablet (200 mg of nevirapine) once daily for the first 14 days.

Thereafter: one tablet (200 mg of nevirapine) twice daily. This gives a daily maximum of 400 mg.

It is essential to observe the once-a-day lead-in period before increasing to the twice-daily dosage. The total daily dose should not exceed 400 mg.

The lead-in period for the tablets has been shown to decrease the incidence of rash.

ADCO-NEVIRAPINE TABLETS should always be taken in combination with other antiretroviral medicines.

SIDE-EFFECTS:

ADCO-NEVIRAPINE TABLETS can have side-effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Check with your doctor if any of the following side-effects occur:
More common allergic reaction, headache, nausea, inflammation of the liver (symptoms include loss of appetite, nausea, vomiting, yellow discolouration of skin and eyes), rash.
Less common: vomiting, stomach pain, jaundice, Stevens-Johnson syndrome, muscle pain, fatigue, fever.
Rare: blood disorders including anaemia (symptoms include unusual weakness or tiredness), severe allergic reaction resulting in shock, diarrhoea, liver failure, joint pain, and severe skin reactions.

Notify your doctor immediately if you notice any rash symptoms. If the symptoms are severe, **stop taking ADCO-NEVIRAPINE TABLETS and see your doctor immediately.**
The allergic reactions may appear in the form of a rash and be accompanied by other side-effects such as fever, blistering, mouth sores, eye inflammation, facial swelling, muscle or joint aches and general feeling of illness. If you experience this, be sure to tell your doctor immediately as it could be life-threatening.
Liver problems do occur which can potentially be life-threatening. Notify your doctor immediately if you have suffered or are suffering with liver disease.

STORAGE AND DISPOSAL INFORMATION:
KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
Store at or below 25 °C. Store in the original package or container. Keep the container tightly closed.
Protect from light and moisture. Do not store in the bathroom.
Do not remove the blister from the carton until required for use.
Do not use after the expiry date on the label/carton/bottle.
Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems.

PRESENTATION:
Amber glass bottles:
60 tablets are packed in 100 ml amber glass bottles with a silica gel, fitted with a white EXPE screw generic closure.
Blisters:
60 tablets are packed in blister strips composed of white PVC/PE/PVDC and aluminium foil blisters or white PVC/PVDC and aluminium foil blister. Blister strips are packed in an outer cardboard carton.

PATIENT INFORMATION LEAFLET

Securitainers:

56 and 60 tablets are packed in a white, plain polypropylene securitainer fitted with a low density polyethylene securitainer closure or white round high density polyethylene (HOPE) bottle fitted with white polypropylene child resistant closure. A white polypropylene capsule containing silica gel desiccant is included in the container.

IDENTIFICATION:

Pale yellow, round, double convex tablet with a break-line on one side.

REFERENCE NUMBER:

410235

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685
Private Bag X69
Bryanston, 2021
www.adcock.com
Tel: (011) 709 9300

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

02 February 2007

adcock ingram