PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ADCO EFAVIRENZ 50 mg capsule

ADCO EFAVIRENZ 100 mg capsule

ADCO EFAVIRENZ 200 mg capsule

ADCO EFAVIRENZ 600 mg film coated tablet

Read all of this leaflet carefully before you start taking ADCO EFAVIRENZ.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ADCO EFAVIRENZ** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ADCO EFAVIRENZ CONTAINS

ADCO EFAVIRENZ 50 mg: Each capsule contains 50 mg efavirenz.

ADCO EFAVIRENZ 100 mg: Each capsule contains 100 mg efavirenz.

ADCO EFAVIRENZ 200 mg: Each capsule contains 200 mg efavirenz.

ADCO EFAVIRENZ 600 mg: Each film coated tablet contains
600 mg efavirenz.

The other ingredients are Hydroxypropylcellulose, lactose monohydrate, magnesium stearate, sodium lauryl sulphate.

ADCO EFAVIRENZ 50 mg, 100 mg and **200 mg** also contains gelatine, sodium starch glycolate, Opacode Black (containing iron oxide black (colourant), isopropyl alcohol, methylated spirit (industrial), N-Butyl alcohol, propylene glycol, purified water, shellac glaze).

ADCO EFAVIRENZ 600 mg also contains croscarmellose sodium, microcrystalline cellulose, Opadry II white (containing macrogol, polyvinyl alcohol-part hydrolysed, talc, titanium dioxide).

Contains sugar (lactose monohydrate).

DATE OF APPROVAL: 16 MAY 2017

2. WHAT ADCO EFAVIRENZ IS USED FOR

ADCO EFAVIRENZ is an antiretroviral medicine that fights human immunodeficiency virus (HIV-1) infection by reducing the amount of the virus in your blood. **ADCO EFAVIRENZ** is used by adults, adolescents and children weighing 13 kg and above, and/or 3 years and above**. ADCO EFAVIRENZ** taken in combination with other antiretroviral medicines reduces the amount of the virus in your blood. This will strengthen your immune system and reduce the risk of developing illnesses linked to HIV infection.

3. BEFORE YOU TAKE ADCO EFAVIRENZ

- Do not **take ADCO EFAVIRENZ**:
- If you are hypersensitive (allergic) to efavirenz or any of the other ingredients of **ADCO EFAVIRENZ** (see WHAT **ADCO EFAVIRENZ CONTAINS**);
- If you had a liver disorder or liver failure attributed to treatment with **ADCO EFAVIRENZ**;
- If you are taking any of the following medicine:
    - Terfenadine, astemizole (used to treat allergy symptoms);
    - Cisapride (used to treat heartburn);
    - Midazolam, triazolam (used to treat sleep problems (insomnia));
    - Ergot derivatives (used to treat acute migraine (severe headache));
- If you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**);
- **ADCO EFAVIRENZ** should not be given to children younger than 3 years of age or weighing less than 13 kg;

Take special care with ADCO EFAVIRENZ:

- **ADCO EFAVIRENZ** must be taken with other medicine that act against the HIV virus. If **ADCO EFAVIRENZ** is started because your current treatment has not prevented the virus from multiplying, another medicine you have not taken before must be started at the same time;
- If you have a history of liver disease or active chronic hepatitis. Patients with chronic hepatitis B or C and treated with combination antiretroviral medicine, including

  ADCO EFAVIRENZ, have a higher risk for severe and potentially life-threatening liver

problems. Your doctor may do blood tests in order to check how well your liver is working or may switch you to other medicine;

- A skin rash may develop while taking **ADCO EFAVIRENZ** that usually goes away with continued use. Treatment with

  ADCO EFAVIRENZ should be stop immediately if you see any signs of a severe skin rash with blistering or fever;
- Nervous system symptoms such as dizziness, difficulty sleeping, drowsiness, difficulty concentrating or abnormal dreaming may occur when starting treatment with **ADCO EFAVIRENZ**. These symptoms usually go away after taking **ADCO EFAVIRENZ** for a couple of weeks;
- If you have a history of mental illness, including depression (persistent feeling of sadness and loss of interest), or of substance or alcohol abuse. Tell your doctor immediately if you feel depressed, have suicidal thoughts or have strange thoughts while taking **ADCO EFAVIRENZ**;
- If you gain weight and have elevated cholesterol and glucose levels (determined by blood tests) while taking **ADCO EFAVIRENZ**, you should consult your doctor. Your doctor will do a thorough examination;
- If you develop any signs of inflammation or infection while taking **ADCO EFAVIRENZ**. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please consult your doctor immediately;
- In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when your immune system attacks healthy body tissue) may also occur after you start taking **ADCO EFAVIRENZ** and/or or other medicine for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations

(unusual awareness of heartbeat), tremor or hyperactivity, please consult your doctor immediately;

- If you develop symptoms such as joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. These are symptoms of osteonecrosis (death of bone tissue caused by loss of blood supply to the bone) a bone disease which may develop while taking **ADCO EFAVIRENZ**. If you experience any of these symptoms consult your doctor immediately;
- You can still pass on HIV while taking **ADCO EFAVIRENZ**, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

Taking ADCO EFAVIRENZ with food and drink:

ADCO EFAVIRENZ should be taken on an empty stomach. An empty stomach is commonly defined as 1 hour before or 2 hours after a meal.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ADCO EFAVIRENZ**.

Do not take **ADCO EFAVIRENZ** if you are pregnant or breastfeeding (see **DO NOT TAKE ADCO EFAVIRENZ**).

Driving and using machinery:

ADCO EFAVIRENZ may cause dizziness (light headedness), impaired concentration and/or drowsiness (see **POSSIBLE SIDE EFFECTS**). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how **ADCO EFAVIRENZ** affects you.

Important information about some of the ingredients of **ADCO EFAVIRENZ**:

ADCO EFAVIRENZ contains lactose. Patients with rare hereditary conditions of lactose or galactose intolerance should not take **ADCO EFAVIRENZ**.

Taking other medicines with ADCO EFAVIRENZ:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- Indinavir, ritonavir, saquinavir (used in the treatment of HIV (human immunodeficiency virus);
- Rifampicin (used to treat tuberculosis (TB));
- Clarithromycin (used to treat bacterial infections);
- Oral contraceptives such as ethinylestradiol (used to prevent pregnancy or to regulate your menstrual cycle);
- Methadone (used to reduce withdrawal symptoms in people addicted to heroin and used to relieve pain);
- St John's wort (Hypericum perforatum) (herbal supplement used to assist in the treatment of depression).

4. HOW TO TAKE ADCO EFAVIRENZ

Do not share medicines prescribed for you with any other person.

Always take **ADCO EFAVIRENZ** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults:

The usual dose is 600 mg **ADCO EFAVIRENZ**, once a day in combination with other antiretroviral medicine. **ADCO EFAVIRENZ** may be taken on an empty stomach, preferably at bedtime, in order to improve the tolerability of nervous system side effects.

Adolescents and children (17 years and younger):

If you are 17 years or younger your dose of **ADCO EFAVIRENZ** will be determined by your weight. Your doctor will work out your dose according to your weight. **ADCO EFAVIRENZ** has not been studied in paediatric patients below 3 years of age or who weigh less than 13 kg (see **DO NOT TAKE ADCO EFAVIRENZ**).

If you have the impression that the effect of **ADCO EFAVIRENZ** is too strong or too weak, tell your doctor or pharmacist.

If you take more ADCO EFAVIRENZ than you should:

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining **ADCO EFAVIRENZ** with you so the doctor will know what you have taken.

If you forget to take ADCO EFAVIRENZ:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **ADCO EFAVIRENZ** at the next regularly scheduled time. Do not take a double dose of **ADCO EFAVIRENZ** to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

ADCO EFAVIRENZ can have side effects.

Not all side effects reported for **ADCO EFAVIRENZ** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ADCO EFAVIRENZ**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **ADCO EFAVIRENZ** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching;
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ADCO EFAVIRENZ**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following*:*

Less frequent:

- Convulsions (fits);
- Loss of memory;
- Changes in the way your heart beats, if you notice it beating faster than normal for you;
- Asthma (feeling of tightness in the chest, breathlessness, wheezing);
- Yellowing of the skin and eyes, also called jaundice;
- Erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea);
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome.

Frequency unknown:

- Difficulty in breathing;
- Liver failure (clay coloured stool, dark urine, unpleasant breath odour, unusual tiredness, vomiting (being sick) of blood).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Dizziness, headache, drowsiness, inability to sleep, inability to concentrate;
- Nausea (feeling sick), vomiting (being sick), diarrhoea;
- Increased sweating;
- Tiredness.

Less frequent:

Loss of appetite;

- Feeling anxious, lack of interest, enthusiasm, or concern;
- Rapid, often exaggerated changes in your mood such as, uncontrollable laughing or crying, or heightened irritability or temper;
- Feeling intense excitement and happiness;
- Seeing, feeling or hearing things that are not there;
- Abnormal dreams;
- Feeling agitated, confused;
- Decreased feeling or sensitivity, especially in your skin;
- Tremors (involuntary trembling or shaking of hands and feet);
- Vertigo (sensation of spinning or swaying);
- Tingling or numbness of your hands and feet (pins and needles);
- Feeling of weakness or heaviness in your arms and legs, sharp stabbing pains;
- Intense pain along the course of a nerve, especially in your head or face, occurring regularly or irregularly;
- Throbbing headache, usually affecting one side of the head and often accompanied by nausea, vomiting and sensitivity to light (migraine);
- Clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech.
- Abnormal vision;
- Tinnitus (ringing in your ears);
- Stomach pain, changes in the way things taste, indigestion;
- Hair loss (temporarily);
- Clusters of small red bumps or white-headed pimples developing around your hair follicles;
- Peeling of skin over large areas of your body;
- Joint pain, pain in a muscle or group of muscles;
- Redness of your skin;
- Abnormal physical weakness or lack of energy, generally feeling unwell;
- Increased cholesterol and liver enzymes when blood tests are done.

Frequency unknown:

- Increased appetite, accumulation of body fat around your stomach area or face;
- Inability to tolerate alcohol;
- Feeling depressed;
- Upper respiratory tract infection (sneezing, coughing, runny nose, scratchy or sore throat, fever);
- Constipation (difficulty passing stool), weight loss due to absorption problems;
- Acne, skin discolouration, nail disorders, dandruff with scaly, red patches on the scalp;
- Muscle tenderness or weakness, not caused by exercise;
- Inability to get or maintain an erection;
- Increased or decreased sex drive;
- Hot flushes (sudden feeling of feverish heat);
- General pain;
- Weight loss, weight gain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ADCO EFAVIRENZ

- Keep well closed, store in a dry place and at or below 25 °C in the original packaging.
- Protect from moisture and light.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**.
- Do not use after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF ADCO EFAVIRENZ

ADCO EFAVIRENZ 50 mg: White, polypropylene or high density polyethylene securitainers in packs of 28’s and 30’s.

ADCO EFAVIRENZ 100 mg: White, polypropylene securitainers in packs of 30’s.

ADCO EFAVIRENZ 200 mg: White, polypropylene securitainers in packs of 84’s and 90’s.

ADCO EFAVIRENZ 600 mg:

Securitainers:

- 28 and 30 tablets are packed in a white polypropylene securitainer fitted with a low density polyethylene lid.
- 28 and 30 tablets are packed in a white, high density polyethylene securitainer fitted with a white polypropylene child resistant closure, with a heat induction liner.
- A white polypropylene capsule containing silica gel desiccant is included in the container.

Blister packs:

30 tablets are packed in blister strips composed of white opaque PVC/PVDC and aluminium foil. 3 blister strips containing 10 tablets each are packed in an outer cardboard carton.

Amber glass bottles:

30 tablets are packed in a 100 ml amber glass bottle with a silica gel, fitted with a white EXPE screw generic closure.

8. IDENTIFICATION OF ADCO EFAVIRENZ

ADCO EFAVIRENZ 50 mg: A hard gelatine capsule, size 4, with opaque white body and opaque white cap containing white granules. Printed, in black, on the cap: “EFV” and body “50”.

ADCO EFAVIRENZ 100 mg: A hard gelatine capsule, size 1, with opaque white body and opaque white cap containing white granules. Printed, in black, on the cap: “EFV” and body “100”.

ADCO EFAVIRENZ 200 mg: A hard gelatine capsule, size 0, with opaque white body and opaque white cap containing white granules. Printed, in black, on the cap “EFV” and body “200”.

ADCO EFAVIRENZ 600 mg: An odourless, white, double convex film coated caplet.

9. REGISTRATION NUMBERS

ADCO EFAVIRENZ 50 mg: 42/20.2.8/0979

ADCO EFAVIRENZ 100 mg: 42/20.2.8/0980

ADCO EFAVIRENZ 200 mg: 42/20.2.8/0981

ADCO EFAVIRENZ 600 mg: 41/20.2.8/0929

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

Registration date:

ADCO EFAVIRENZ 50 mg: 23 July 2010

ADCO EFAVIRENZ 100 mg: 23 July 2010

ADCO EFAVIRENZ 200 mg: 10 October 2008

ADCO EFAVIRENZ 600 mg: 16 November 2007

Date of revised patient information leaflet:

16 May 2017