B. PACKAGE LEAFLET

Package leaflet: Information for the user

Emtriva 200 mg hard capsules
Emtricitabine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Emtriva is and what it is used for

Emtriva is a treatment for Human Immunodeficiency Virus (HIV) infection in adults, children and infants aged 4 months and over. Emtriva 200 mg hard capsules are **only suitable for patients who weigh at least 33 kg.** Emtriva oral solution is available for people who have difficulty in swallowing Emtriva hard capsules.

Emtriva contains the active substance *emtricitabine.* This active substance is an *antiretroviral* medicine which is used to treat HIV infection. Emtricitabine is a *nucleoside reverse transcriptase inhibitor* (NRTI) which works by interfering with the normal working of an enzyme (reverse transcriptase) that is essential for the HIV virus to reproduce itself. Emtriva may lower the amount of HIV in the blood (viral load). It may also help to increase the number of T cells called CD4 cells. Emtriva should always be combined with other medicines to treat HIV infection.

You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

This medicine is not a cure for HIV infection. While taking Emtriva you may still develop infections or other illnesses associated with HIV infection.

2. What you need to know before you take Emtriva

Do not take Emtriva

- **If you are allergic** to emtricitabine or any of the other ingredients of this medicine (listed in section 6).

→ If this applies to you, tell your doctor immediately.

Warnings and precautions

- **Tell your doctor if you have had kidney disease,** or if tests have shown problems with your kidneys. Before starting treatment, your doctor may order blood tests to assess kidney function and may advise you to take the capsules less often or prescribe Emtriva oral solution. Your doctor may also order blood tests during treatment to monitor your kidneys.

- **Talk to your doctor if you are over 65.** Emtriva has not been studied in patients over 65 years of age. If you are older than this and are prescribed Emtriva, your doctor will monitor you carefully.

- **Talk to your doctor if you have a history of liver disease, including hepatitis.** Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you. If you have a history of liver disease or chronic hepatitis B infection your doctor may conduct blood tests in order to carefully monitor liver function.

- **Look out for infections.** If you have advanced HIV disease (AIDS) and another infection, you may develop inflammation or worsening of the symptoms of infection when you start treatment with Emtriva. These may be signs that your body's improved immune system is fighting infection. If you notice signs of inflammation or infection soon after you start taking Emtriva, **tell your doctor at once.**

  In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines 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, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

- **Bone problems.** Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

Children and adolescents

Do not give Emtriva to infants under 4 months of age.

Other medicines and Emtriva

You should not take Emtriva if you are already taking other medicines that contain emtricitabine or lamivudine, which are also used to treat HIV infection, unless otherwise directed by your doctor.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not stop your treatment without contacting your doctor.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **You must not take Emtriva during pregnancy** unless specifically directed by your doctor. Although there are limited clinical data on the use of Emtriva in pregnant women, it is not usually used unless absolutely necessary.

- **If you could get pregnant** during treatment with Emtriva, you must use an effective method of contraception to stop you getting pregnant.

- **If you become pregnant, or plan to become pregnant,** ask your doctor about the potential benefits and risks of your antiretroviral therapy to you and your child.

If you have taken Emtriva during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

- **Do not breast-feed if you are taking Emtriva.** This is because the active substance in this medicine passes into human breast milk. It is known that the virus can be passed to the baby in breast milk.

Driving and using machines

Emtriva may cause dizziness. If you experience dizziness while taking Emtriva, **do not drive** and do not use any tools or machines.

3. How to take Emtriva

- **Always take this medicine exactly as your doctor has told you.** Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- **Adults: one 200 mg hard capsule, each day with or without food.** Swallow the hard capsule with a glass of water.
- **Children and adolescents up to 18 years of age** who weigh at least 33 kg and who are able to swallow hard capsules: one 200 mg hard capsule, each day with or without food.

For infants from 4 months, children, and patients who are unable to swallow hard capsules and patients with kidney problems, Emtriva is available as a liquid (an oral solution). If you have difficulty in swallowing the capsules, tell your doctor.

- **Always take the dose recommended by your doctor.** This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.

- **If you have problems with your kidneys,** your doctor may advise you to take Emtriva less frequently.

- **Your doctor will prescribe Emtriva with other antiretroviral medicines.** Please refer to the package leaflets of the other antiretrovirals for guidance on how to take those medicines.

If you take more Emtriva than you should

If you accidentally take too many Emtriva hard capsules, contact your doctor or nearest emergency department for advice. Keep the carton with you so that you can easily describe what you have taken.

If you forget to take Emtriva

It is important not to miss a dose of Emtriva.

If you do miss a dose of Emtriva within 12 hours of when it is usually taken, take it as soon as you can, and then take your next dose at its regular time.

If it is almost time (less than 12 hours) for your next dose anyway, forget about the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten hard capsule.

If you are sick *(vomit)*
If it's less than an hour since you took Emtriva, take another capsule. You do not need to take another capsule if you were sick more than an hour after taking Emtriva.

If you stop taking Emtriva

- **Don't stop taking Emtriva without talking to your doctor.** Stopping treatment with Emtriva may reduce the effectiveness of the anti-HIV therapy recommended by your doctor. Speak with your doctor before you stop, particularly if you are experiencing any side effects or you have another illness. Contact your doctor again before you restart taking Emtriva capsules.

- **If you have both HIV infection and hepatitis B,** it is especially important not to stop your Emtriva treatment without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping Emtriva. You may require blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended as this may lead to worsening of hepatitis.

  Tell your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor about any of the following side effects:

Most frequent side effects

The following side effects are **very common** (these can affect at least 10 in every 100 patients):
- headache, diarrhoea, feeling sick (*nausea*)
- muscle pain and weakness (if creatine kinase levels in the blood are increased)

Other possible side effects

The following side effects are **common** (these can affect up to 10 in every 100 patients):
- dizziness, weakness, difficulty sleeping, abnormal dreams
- being sick (*vomiting*), problems with digestion resulting in discomfort after meals, stomach pain
- rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions, itching, changes in skin colour including darkening of the skin in patches
- pain

Tests may also show:
- low white blood cell count (a reduced white blood cell count can make you more prone to infection)
- increased triglycerides (fatty acids), bile or sugar in the blood
- liver and pancreas problems

The following side effects are **uncommon** (these can affect up to 1 in every 100 patients):
- anaemia (low red blood cell count)
- swelling of the face, lips, tongue or throat

Other possible effects

Children given emtricitabine also experienced **changes in skin colour** including darkening of the skin in patches, very commonly and **anaemia** (low red blood cell count), commonly. If the production of red blood cells is reduced, a child may have symptoms of tiredness or breathlessness.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emtriva

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle, blister pack and carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Emtriva contains

- **The active substance is** *emtricitabine.* Each Emtriva hard capsule contains 200 mg of emtricitabine.

- **The other ingredients are:**

  Capsule contents: microcrystalline cellulose (E460), crospovidone, magnesium stearate (E572), povidone (E1201)

  Capsule shell: gelatin, indigotine (E132), titanium dioxide (E171)

  Printing ink containing: black iron oxide (E172), shellac (E904)

What Emtriva looks like and contents of the pack

Emtriva hard capsules have a white opaque body with a light blue opaque cap. Each capsule is printed with "200 mg" on the cap and "GILEAD" and [Gilead logo] on the body in black ink. Emtriva comes in bottles or blister packs containing 30 capsules.

Emtriva is also available as an oral solution for use in children and infants aged 4 months and over, patients who have difficulty in swallowing and patients with kidney problems. There is a separate Package Leaflet for Emtriva 10 mg/mL oral solution.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.