CONSUMER INFORMATION
Product Monograph Part III

EMTRIVA™

emtricitabine
emtricitabine capsules

Gilead Sciences Inc.

Submission Control No. 094127

The Consumer Information Section (Part III) of the Product Monograph for EMTRIVA has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on November 21, 2005 and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Emtriva™

(Emtricitabine Capsules)

This leaflet is part III of a three-part "Product Monograph" published when EMTRIVA was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about EMTRIVA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- EMTRIVA is a type of medicine called an HIV (human immunodeficiency virus) nucleotide analog reverse transcriptase inhibitor (NRTI).
- EMTRIVA is always used in combination with other anti-HIV medicines to treat people with HIV infection.
- EMTRIVA is for adults age 18 and older. EMTRIVA has not been studied fully in children under age 18 or adults over age 65.

What it does:

- EMTRIVA helps to block HIV reverse transcriptase (enzyme) that is needed for HIV to multiply. EMTRIVA lowers the amount of HIV in the blood (viral load).
- EMTRIVA does not cure HIV infection or AIDS. The long-term effects of EMTRIVA are not known at this time. People taking EMTRIVA may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak.
- EMTRIVA may also help increase the number of T cells called CD4 cells which are important to your immune system.
- **EMTRIVA does not lower your chance of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood**. For your health and the health of others it is important to always practice safer sex by using a latex or polyurethane condom or other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

When it should not be used:

- Do not take EMTRIVA if you are allergic to EMTRIVA or any of its ingredients **(See: What the important nonmedicinal ingredients are)**.

What the medicinal ingredient is:

Emtricitabine

What the important nonmedicinal ingredients are:

Crospovidone, magnesium stearate, microcrystalline cellulose and povidone.

What dosage forms it comes in:

EMTRIVA is available as capsules. Each capsule contains 200 mg of emtricitabine and inactive ingredients. EMTRIVA capsules have a blue cap and white body, printed with "200 mg" in black on the cap and "GILEAD" and the corporate logo in black on the body.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Some people who have taken nucleoside analog medications like EMTRIVA have developed a serious condition called lactic acidosis (build up of acid in the blood) and a condition called hepatoxicity (serious liver problems), with hepatomegaly (liver enlargement) and steatosis (fat in the liver). Fatal cases have been reported. Lactic acidosis is a medical emergency and must be treated in the hospital.

If you have hepatitis B virus infection (inflammation of the liver), you may have a "flare-up" of hepatitis B, in which the disease suddenly returns in a worse way than before if you stop taking EMTRIVA.

BEFORE you use EMTRIVA talk to your doctor or pharmacist if:

- ***You are pregnant, planning to become pregnant or breast-feeding****:* Pregnant or breast- feeding mothers should not take EMTRIVA unless specifically directed by the doctor. It is recommended that HIV-infected women do not breast feed their infants under any circumstances in order to avoid

transmission of HIV. It is therefore recommended that mothers do not breast feed their babies while receiving treatment with EMTRIVA.

- ***You have other medical conditions****:* Let your doctor know if you have other medical conditions, especially hepatitis (inflammation of the liver), and kidney problems.
- ***You are taking other medicines****:* Some medicines can interact when taken together, including prescription and non-prescription medicines and dietary supplements.

INTERACTIONS WITH THIS MEDICATION

Let your doctor know if you are taking any other medications.

PROPER USE OF THIS MEDICATION

Stay under a doctor's care when taking EMTRIVA. Do not change your treatment or stop treatment without first talking with your doctor.

Carefully follow the directions and dosing schedule prescribed by your doctor.

When your EMTRIVA supply starts to run low, see your doctor or pharmacist for a refill. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to EMTRIVA and become harder to treat.

Only take medicine that has been prescribed specifically for you. Do not give EMTRIVA to others or take medicine prescribed for someone else.

Usual Dose

- The usual dose of EMTRIVA is one 200 mg capsule orally (by mouth) once a day, in combination with other anti-HIV medicines.
- EMTRIVA may be taken with or without food.

Overdosage

- If you suspect that you took more than the prescribed dose of EMTRIVA, contact your local poison control center or emergency room right away.

Missed Dose

- If you miss a dose of EMTRIVA, take it as soon as possible and then take your next scheduled dose at its regular time.
- Do not double the next dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of EMTRIVA are Headache, Diarrhea, Nausea, Rash, Vomiting, Sleeplessness and Cough. Other side effects include Skin discoloration.

Changes in body fat have been seen in patients taking antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck ('buffalo hump"), breast, and around the trunk. Loss of fat from the legs, arms and face may also happen.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	Symptoms / Effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare	**Effect: Lactic acidosis** **Symptoms** • Feeling very weak or tired • Unusual muscle pain • Stomach pain with nausea and vomiting • Feeling cold especially in arms and legs • Feeling dizzy or lightheaded • Fast or irregular heartbeat		✓ ✓ ✓ ✓ ✓ ✓	
Very Rare	**Effect: Hepatotoxicity (severe liver problems) with hepatomegaly (liver enlargement) and steatosis (fat in the liver)** **Symptoms** • Jaundice (skin or the white part of eyes turn yellow) • Urine turns dark • Bowel movements (stools) turn light in color • Loss of appetite for several days or longer • Feeling sick to your stomach (nausea) • Lower stomach pain		✓ ✓ ✓ ✓ ✓ ✓	
Very Rare	**Effect: Flare-ups of hepatitis B virus infection following drug discontinuation** **Symptoms** • Jaundice (skin or the white part of eyes turn yellow) • Urine turns dark • Bowel movements (stools) turn light in color • Loss of appetite for several days or longer • Feeling sick to your stomach (nausea) • Lower stomach pain		✓ ✓ ✓ ✓ ✓ ✓	

This is not a complete list of side effects. For any unexpected effects while taking EMTRIVA, contact your doctor or pharmacist.

HOW TO STORE IT

- Keep EMTRIVA and all other medications out of reach of children.
- EMTRIVA should be stored at 15–30 °C.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

Toll-free Telephone: 866–234–2345
Toll-free Fax: 866–678–6789
By email: cadrmp@hc-sc.gc.ca

By regular mail:
National AR Centre
Marketed Health Products Safety and Effectiveness Information Division
Marketed Health Products Directorate
Tunney's Pasture, AL 0701C
Ottawa, ON K1A 0K9

NOTE: ***Before contacting Health Canada, you should contact your physician or pharmacist.***

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at:

www.gilead.ca

or requested by contacting the sponsor, Gilead Sciences, Inc., at:

1–800–GILEAD5 (1–800–445–3235)

This leaflet was prepared by Gilead Sciences, Inc.

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Gilead Sciences, Inc.
Foster City, CA 94404
USA

Gilead Sciences Canada, Inc.
Mississauga L5N 2W3
Canada

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