Package leaflet: Information for the user

Emtriva 10 mg/mL oral solution
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 oral solution is particularly suitable 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.

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 a reduced dose of the oral solution or prescribe Emtriva hard capsules. 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.

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.

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

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.

Emtriva oral solution contains:

Sunset yellow (E110) may cause allergic reactions. The methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed). This medicine contains 38 mg of sodium (main component of cooking/table salt) per 24 mL dose.This is equivalent to 1.8% of the recommended maximum daily dietary intake of sodium for an adult.
This medicine also contains 480 mg propylene glycol per 24 mL (maximum single dose) which is equivalent to a maximum of 12 mg/kg/day.

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:** Your doctor will advise the correct amount of Emtriva oral solution to be taken. Emtriva oral solution can be taken with or without food.

- **Infants, children and adolescents weighing 40 kg or less:** the dose of Emtriva 10 mg/mL oral solution is calculated according to your body weight. Examples of body weight and the corresponding doses and volumes of the oral solution to be taken each day are given in the table below:

	Per day	
Body weight (kg)	**Emtricitabine dose (mg)**	**How much 10 mg/mL solution to take (mL)**
5 kg	30 mg	3 mL
10 kg	60 mg	6 mL
15 kg	90 mg	9 mL
20 kg	120 mg	12 mL
25 kg	150 mg	15 mL
30 kg	180 mg	18 mL
35 kg	210 mg	21 mL
40 kg	240 mg	24 mL

Make sure that you understand how to measure and give the right amount of oral solution according to the weight of the person being treated. Use the measuring cup provided in the carton to measure the correct dose. The cup has lines to indicate each mL of solution.

If you are unsure how much Emtriva you should take ask your doctor or pharmacist.

- **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 leaflet of the other antiretrovirals for guidance on how to take those medicines.

Emtriva is also available as hard capsules. These are only suitable for patients who weigh at least 33 kg and can swallow hard capsules. The blood levels obtained after taking one Emtriva 200 mg hard capsule are similar to those obtained after taking 24 mL of the oral solution. If you would like to switch from taking Emtriva oral solution to Emtriva hard capsules, please talk to your doctor.

If you take more Emtriva than you should

If you accidentally take too much Emtriva oral solution, contact your doctor or nearest emergency department for advice. Keep the oral solution bottle 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 dose.

If you are sick *(vomit)*
If it's less than an hour since you took Emtriva, take another dose. You do not need to take another dose 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 oral solution.

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

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 and carton after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C) until opened.

After opening the bottle, do not store above 25°C. The content of the bottle should be used up within 45 days of opening. It is advised to write the date of removal from the refrigerator on the package.

If there is any solution left in the bottle after 45 days, this should be disposed of in accordance with local requirements or returned to the pharmacy.

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.* One mL of Emtriva oral solution contains 10 mg of emtricitabine (10 mg/mL).

- **The other ingredients are:** cotton candy flavouring, disodium edetate, hydrochloric acid, methyl parahydroxybenzoate (E218), propylene glycol, propyl parahydroxybenzoate (E216), sodium hydroxide, sodium phosphate monobasic hydrate, sunset yellow (E110), purified water, xylitol (E967).

What Emtriva looks like and contents of the pack

Emtriva oral solution is a clear, orange to dark orange solution that comes in bottles containing 170 mL with a measuring cup.

Emtriva is also available as hard capsules. These are only suitable for patients who weigh at least 33 kg and can swallow hard capsules. There is a separate Package Leaflet for Emtriva 200 mg hard capsules.

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