

Package leaflet: Information for the user

Ictastan 200 mg/245 mg film-coated tablets

Emtricitabine/tenofovir disoproxil

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 Ictastan is and what it is used for
2. What you need to know before you take Ictastan
3. How to take Ictastan
4. Possible side effects
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1. What Ictastan is and what it is used for

Ictastan is a treatment for Human Immunodeficiency Virus (HIV) infection in adults aged 18 years and over.

Ictastan contains two active substances, *emtricitabine* and *tenofovir disoproxil succinate*. Both of these active substances are *antiretroviral* medicines which are used to treat HIV infection. Emtricitabine is a *nucleoside reverse transcriptase inhibitor* and tenofovir is a *nucleotide reverse transcriptase inhibitor*. However, both are generally known as NRTIs and they work by interfering with the normal working of an enzyme (reverse transcriptase) that is essential for the virus to reproduce itself. Ictastan should always be used combined with other medicines to treat HIV infection. Ictastan can be administered in place of emtricitabine and tenofovir disoproxil used separately at the same doses.

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

2. What you need to know before you take Ictastan

Do not take Ictastan

- **If you are allergic** to emtricitabine, tenofovir, tenofovir disoproxil succinate, 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.** Ictastan may affect your kidneys. Before starting treatment, your doctor may order blood tests to assess kidney function. Your doctor may also order blood tests during treatment to monitor your kidneys and may advise you to take the tablets less often. Ictastan is not recommended if you have severe kidney disease or are receiving haemodialysis.

Ictastan is not usually taken with other medicines that can damage your kidneys (see *Other medicines and Ictastan*). If this is unavoidable, your doctor will monitor your kidney function once a week.

- **Talk to your doctor if you are over 65.** Ictastan has not been studied in patients over 65 years of age. If you are older than this and are prescribed Ictastan, 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. Both active substances in Ictastan show some activity against hepatitis B virus although emtricitabine is not approved for the treatment of hepatitis B infection. 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.

Other precautions

Look out for infections. If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with Ictastan is started. These symptoms may indicate that your body's improved immune system is fighting infection. Look out for signs of inflammation or infection soon after you start taking Ictastan. If you notice signs of inflammation or infection, **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 inform your doctor.

Bone problems (sometimes resulting in fractures) may also occur due to damage to kidney tubule cells (see section 4, *Possible side effects*).

Children and adolescents

Ictastan is not for use in children and adolescents under 18 years of age.

Other medicines and Ictastan

You should not take Ictastan if you are already taking other medicines that contain the components of Ictastan, emtricitabine and tenofovir disoproxil, or any other antiviral medicines that contain lamivudine or adefovir dipivoxil.

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

- **It is especially important to tell your doctor if you are taking other medicines which may damage your kidneys.**

These include:

- aminoglycosides (for bacterial infection)

- amphotericin B (for fungal infection)
- foscarnet (for viral infection)
- ganciclovir (for viral infection)
- pentamidine (for infections)
- vancomycin (for bacterial infection)
- interleukin-2 (to treat cancer)
- cidofovir (for viral infection)
- non-steroidal anti-inflammatory drugs (NSAIDs, to relieve bone or muscle pains)
- **Other medicines containing didanosine (for HIV infection):** Taking Ictastan with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood and may reduce CD4 cell counts. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes causes death, have been reported when medicines containing tenofovir disoproxil and didanosine were taken together. Your doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.
- **It is also important to tell your doctor** if you are taking ledipasvir/sofosbuvir to treat hepatitis C infection.

Do not stop your treatment without contacting your doctor.

Ictastan with food and drink

Ictastan should be taken with food.

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 Ictastan during pregnancy** unless specifically discussed with your doctor. Although there are limited clinical data on the use of Ictastan in pregnant women, it is not usually used unless absolutely necessary.
- If you are a woman who could get pregnant during treatment with Ictastan, you must use an effective method of contraception to avoid becoming pregnant.
- If you become pregnant, or plan to become pregnant, ask your doctor about the potential benefits and risks of therapy with Ictastan to you and your child.

If you have taken Ictastan 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 during treatment with Ictastan.** This is because the active substances in this medicine pass into human breast milk.
- If you are a woman with HIV it is recommended that you do not breast-feed, to avoid passing the virus to the baby in breast milk.

Driving and using machines

Ictastan can cause dizziness. If you feel dizzy while taking Ictastan, **do not drive** and do not use any tools or machines.

Ictastan contains lactose

Tell your doctor if you are lactose-intolerant or intolerant to other sugars. Ictastan contains lactose monohydrate. If you know you are lactose-intolerant, or if you have been told that you have an intolerance to any other sugars, talk to your doctor before taking this medicine.

3. How to take Ictastan

- **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 tablet each day with food.**

If you have difficulty swallowing, you can use the tip of a spoon to crush the tablet. Then mix the powder with about 100 ml (half a glass) of water, orange juice or grape juice, and drink immediately.

- **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 Ictastan less frequently.
- **If your doctor decides to stop** one of the components of Ictastan or change the dose of Ictastan, you may be given emtricitabine and/or tenofovir separately instead of the combined medicine or other medicines for the treatment of HIV infection.
- **Your doctor will prescribe Ictastan with other antiretroviral medicines.** Please refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

If you take more Ictastan than you should

If you accidentally take more than the recommended dose of Ictastan, contact your doctor or nearest emergency department for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take Ictastan

It is important not to miss a dose of Ictastan.

If you do miss a dose of Ictastan 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 tablet.

If you throw up less than 1 hour after taking Ictastan, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking Ictastan.

If you stop taking Ictastan

- **Stopping treatment** with Ictastan may reduce the effectiveness of the anti-HIV therapy recommended by your doctor. Speak with your doctor before you stop taking Ictastan for any reason, particularly if you are experiencing any side effects or you have another illness. Contact your doctor before you restart taking Ictastan tablets.
- **If you have HIV infection and hepatitis B,** it is especially important not to stop your Ictastan treatment without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping Emtricitabine/Tenofovir disoproxil. 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 your 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 lifestyle, 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:

Possible serious side effects: tell a doctor immediately

The following side effect is **rare** (this can affect up to 1 in every 1,000 patients):

- **Lactic acidosis (excess lactic acid in the blood)** is a serious side effect that can be life threatening. The following side effects may be signs of lactic acidosis:
 - deep rapid breathing
 - drowsiness
 - feeling sick (nausea), being sick (vomiting) and stomach pain

If you think you may have lactic acidosis, contact your doctor immediately.

Other possible serious side effects

The following side effects are **uncommon** (these can affect up to 1 in every 100 patients):

- pain in the abdomen (tummy) caused by inflammation of the pancreas
- swelling of the face, lips, tongue or throat
- damage to kidney tubule cells

The following side effects are **rare** (these can affect up to 1 in every 1,000 patients):

- fatty liver
- yellow skin or eyes, itching, or pain in the abdomen (tummy) caused by inflammation of the liver
- inflammation of the kidney, passing a lot of urine and feeling thirsty, kidney failure. Your doctor may do blood tests to see if your kidneys are working properly.
- softening of the bones (with bone pain and sometimes resulting in fractures)

Damage to kidney tubule cells may be associated with breakdown of muscle, softening of the bones (with bone pain and sometimes resulting in fractures), muscle pain, muscle weakness and decreases in potassium or phosphate in the blood.

If you think that you may have any of these serious side effects, talk to your doctor.

Most frequent side effects

The following side effects are **very common** (these can affect at least 10 in every 100 patients):

- diarrhoea, being sick (vomiting), feeling sick (nausea), dizziness, headache, rash
- feeling weak

Tests may also show:

- decreases in phosphate in the blood
- increased creatine kinase

Other possible side effects

The following side effects are **common** (these can affect up to 10 in every 100 patients):

- pain, stomach pain
- difficulty sleeping, abnormal dreams
- problems with digestion resulting in discomfort after meals, feeling bloated, flatulence
- 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
- other allergic reactions, such as wheezing, swelling or feeling light-headed

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)
- breakdown of muscle, muscle pain or weakness which may occur due to damage to the kidney tubule cells

Tests may also show:

- decreases in potassium in the blood
- increased creatinine in your blood
- changes to your urine

The following side effects are **rare** (these can affect up to 1 in every 1,000 patients):

- back pain caused by kidney problems

Other possible effects

Children who were administered emtricitabine, one of the components of Ictastan, also experienced anaemia (low red blood cell count), commonly and changes in skin colour including darkening of the skin in patches, very 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ictastan

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 the original package in order to protect from moisture.

Keep the container tightly closed.

Use within 30 days after first opening; store under 25 °C.

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 Ictastan contains

- **The active substances are** *emtricitabine* and *tenofovir*.
Each Ictastan film-coated tablet contains 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (equivalent to 300.6 mg of tenofovir disoproxil succinate).
- **The other ingredients are** lactose monohydrate, microcrystalline cellulose (E460), starch pregelatinised maize, croscarmellose sodium, magnesium stearate (E470b), poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 4000 (E1521), talc (E553b), indigo carmine aluminium lake (E132).

What Ictastan looks like and contents of the pack

Ictastan 200mg and 245 mg film-coated tablets are blue coloured, capsule shaped film-coated tablets, plain on both sides. The dimensions of the tablet are 19.3 mm x 8.8 mm \pm 5%.

Ictastan 200mg and 245 mg film-coated tables are supplied in HDPE bottles of 30 tablets. Each bottle contains a silica gel desiccant that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate canister and should not be swallowed.

30 (1 x 30) film-coated tablets

90 (3 x 30) film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Actavis Group PTC ehf.
Reykjavíkurvegi 76-78,
220 Hafnarfjörður,
Iceland

Manufacturer

Remedica Ltd
Aharnon Street, Limassol Industrial Estate
Limassol
3056 Cyprus

This medicinal product is authorised in the Member States of the EEA under the following names:

NL	Ictastan 200 mg/245 mg filmomhulde tabletten
AT	Ictastan 200 mg/245 mg Filmtabletten
CY	Ictastan
CZ	Ictastan 200 mg/245 mg
DK	Ictastan
EE	Ictastan
EL	Ictastan
FI	Ictastan
HU	Ictastan 200 mg/245 mg filmtabletta
IE	Ictastan 200mg/245mg Film-coated Tablets
IS	Ictastan
MT	Ictastan
NO	Ictastan
PL	Ictastan
SE	Ictastan
UK	Ictastan 200mg/245mg Film-coated Tablets

This leaflet was last revised in April 2017.