

PACKAGE LEAFLET: INFORMATION FOR THE USER

Efavirenz/ Lamivudine/ Tenofovir Disoproxil Fumerate Tablet 400mg/300mg/300mg

{Efavirenz/ Lamivudine/ Tenofovir Disoproxil Fumerate}

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Efavirenz/Lamivudine/Tenofovir Disoproxil Fumerate 400mg/300mg/300mg Tablets is and what it is used for
2. What you need to know before you take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumerate 400mg /300mg/300mg Tablet
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1. WHAT EFAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMERATE 400mg /300mg/300mg TABLETS IS AND WHAT IT IS USED FOR

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets is a treatment for Human Immunodeficiency Virus (HIV) infection in adults and adolescents over 12 years of age.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets contains the active substances efavirenz, lamivudine and tenofovir disoproxil fumarate.. All of these are antiviral medicines. Efavirenz is a non-nucleoside reverse transcriptase inhibitor.Lamivudine is a nucleoside reverse transcriptase inhibitor. Tenofovir is a nucleotide reverse transcriptase inhibitor. All active substances interfere with enzymes used by HIV for making copies of itself and, by doing so, block the reproduction of the virus. Antiviral medicines used for HIV infection are known as antiretrovirals.

This medicine is not a cure for HIV infection. While taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg /300mg/300mg Tablets you may still develop infections or other illnesses associated with HIV infection.

2. BEFORE YOU TAKE EFAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE 400mg/300mg/300mg TABLETS

Do not take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets:

- if you are allergic to efavirenz, lamivudine, tenofovir disoproxil fumarate or any of the other ingredients of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets listed at the end of this leaflet. If this applies to you, tell your doctor immediately and don't take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets
- if you are currently taking St. John's wort (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety) or voriconazole (a drug used against fungal infections).

Take special care with Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets:

Tell your doctor if you have had kidney disease or if tests have shown problems with your kidneys. If so, the doses of tenofovir and lamivudine may need to be reduced. In such cases other formulations of efavirenz, lamivudine and tenofovir than Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets should be used.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets may affect your kidneys. Before starting this medicine you may need blood tests to check how well your kidneys are working. Blood tests may also be required during treatment to check the health of your kidneys.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets is not usually taken with other medicines that can damage your kidneys. If this is unavoidable, you may need regular tests to check how well your kidneys are working.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets should not be used by children under the age of 12 or weighing less than 40 kg.

Before using this medicine, you should have told your doctor or health care provider about past or present medical problems including allergies, seizures, mental illness, or substance or alcohol abuse.

A mild-to-moderate skin rash commonly develops in the first two weeks after starting with Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets. This usually resolves within 4 weeks of the beginning of treatment; in case of a progression to a severe rash you need to tell your doctor or health care provider immediately and Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets may have to be discontinued.

Following the start of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets, central nervous system side effects are very common, usually starting in the first week of treatment. These may include dizziness, confusion, difficulty sleeping, sleepiness, impaired concentration and abnormal dreaming. Other side effects are amnesia, hallucinations, euphoria,

depression, suicidal ideation or psychosis. These usually resolve within four weeks of the start of treatment.

Talk to your doctor or health care provider if you have a history of liver disease, including hepatitis. HIV-infected 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 are infected with HIV and hepatitis B virus your doctor will carefully consider the best treatment for you. If you have a history of liver disease or chronic hepatitis B infection your doctor may conduct blood tests to monitor your liver function.

Look out for possible signs of lactic acidosis (excess of lactic acid in your blood) once you start taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets. Possible signs of lactic acidosis are:

- deep, rapid breathing
- drowsiness
- nausea, vomiting and stomach pain

This rare but serious side effect can cause enlargement of the liver and has occasionally been fatal. Lactic acidosis occurs more often in women and in patients that are very overweight. If you have liver disease you may also be more at risk of getting this condition. While you are being treated with Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets, your doctor will monitor you closely for any signs that you may be developing lactic acidosis. If you think you may have lactic acidosis, contact your doctor immediately.

Take care not to infect other people. Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets does not eliminate the risk of passing on HIV to others through sexual contact or contamination with blood. You must continue to take precautions to avoid this.

Look out for infections. If you have advanced HIV infection (AIDS) and have a so-called opportunistic infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of this infection once treatment with Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets 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 Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets. If you notice signs of inflammation or infection, tell your doctor or health care provider at once.

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 duration of antiretroviral therapy, use of a corticosteroid such as dexamethasone or prednisolone, alcohol consumption, severe immunosuppression, and being overweight 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, tell your doctor.

Bone problems (sometimes resulting in fractures) may also occur due to damage to the kidney cells. The growth of bone could be affected when adolescents that are not fully grown use Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets. Therefore, if you or the person in your care is an adolescent, the doctor or health care provider will carefully consider whether the benefit of taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets exceeds this risk.

You will need to take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets every day. This medicine helps to control your condition, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease. You should keep in regular contact with your doctor or health care provider. Do not stop taking your medicine without first talking to your doctor or health care provider.

Taking other medicines:

Tell your doctor, pharmacist or health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets must not be taken with herbal preparations containing St John's wort (*Hypericum perforatum* – used against anxiety and depression) or voriconazole (used against fungal infections).

Furthermore Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets should not be used in combination with:

- astemizole or terfenadine (used to treat hay fever or other allergies)
- bepridil (used to treat heart disease)
- cisapride (used to treat heartburn)
- ergot alkaloids (for example, ergotamine, dihydroergotamine, ergonovine, and methylergonovine) (used to treat migraines and cluster headaches)
- pimozide (used to treat certain mental conditions)

Do not take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets if you are already taking other medicines containing emtricitabine, lamivudine or tenofovir disoproxil fumarate. Do not take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets and adefovir dipivoxil at the same time.

It is very important to tell your doctor or health care provider if you are taking other medicines that may damage your kidneys. These include:

- aminoglycosides or vancomycin (for bacterial infection)
- amphotericin B or pentamidine (for fungal infection)
- foscarnet, ganciclovir, or cidofovir (for viral infection)
- adefovir dipivoxil (for hepatitis B virus infection)
- tacrolimus (for suppression of the immune system)
- interleukin-2 (used to treat renal cancer)

- Other medicines containing didanosine (for HIV infection): Taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets with medicines that contain didanosine can raise the levels of didanosine in your blood. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes caused death, has been reported when medicines containing tenofovir disoproxil fumarate and didanosine were taken together. Combining tenofovir with didanosine can also reduce the effects of antiretroviral therapy.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets may also interact with the following medicines and may make any side effects worse or may impact on the either agent's efficacy:

- amprenavir, atazanavir, darunavir, indinavir, lopinavir, maraviroc, nelfinavir, ritonavir, saquinavir and tipranavir (antiviral agents).
- methadone, buprenorphine (used to treat severe pain or opioid dependency)
- clarithromycin, rifabutin or rifampicin (antibacterials/antituberculosics)
- atorvastatin, pravastatin, or simvastatin (lipid-lowering medicines, also called statins)
- hormonal contraceptives such as birth control pills, an injected contraceptive or a contraceptive implant. Therefore, you should employ an alternative contraceptive method such as barrier contraception (e.g. condoms), if you are taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets
- itraconazole, posaconazole (antifungals)
- amodiaquine /artesunate, quinine, lumefantrine, halofantrine, artemisinines (antimalarials)
- carbamazepine, phenytoin (anticonvulsants)
- diltiazem, verapamil, felodipine, nifedipine, nifedipine, nicardipine (calcium channel blocker)
- tacrolimus, cyclosporine, sirolimus (immunosuppressants)
- midazolam or triazolam (used to help you sleep)
- warfarin (medicine for prophylaxis of blood clots)

Pregnancy & Breast-feeding

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets should not be taken during the first trimester of pregnancy. Inform your doctor immediately if you are pregnant or intend to become pregnant. If you are pregnant, you should take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets only if you and your doctor decide it is clearly needed.

Malformations have been seen in foetuses from animals and in newborns of women treated with efavirenz during pregnancy; therefore, pregnancy should be avoided in women receiving Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets.

If you are a woman receiving Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets, a reliable form of barrier contraception (for example a condom)

should always be used, with other methods of contraception including oral (pill) or other hormonal contraceptives (for example implant, injection). Efavirenz, one of the active components of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets, may remain in your blood for a time after therapy is stopped. Therefore, you should continue to use contraceptive measures, as above, for 12 weeks after you stop taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets.

If you are interested in breastfeeding your baby, you should discuss the risks and benefits with your doctor or healthcare provider.

Driving and using machines:

Dizziness, impaired concentration, and drowsiness have been reported during treatment with Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets. If you experience these symptoms you should avoid potentially hazardous tasks such as driving or operating machinery.

**Important information about some of the ingredients of
EFAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMERATE 400mg /300mg/300mg
TABLETS**

Not Applicable

**3. HOW TO TAKE EFAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMERATE 400mg
/300mg/300mg TABLETS**

Always take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets exactly as your doctor or health care provider has told you. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. You should check with your doctor, pharmacist or health care provider if you are not sure. Always take the dose recommended by your doctor or health care provider. Do not change the dose unless your doctor tells you to.

The usual dose is one tablet each day. Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets should be taken on an empty stomach (commonly defined as 1 hour before or 2 hours after a meal). Swallow Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets whole with water.

It can help to take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets at bedtime. This may make some side effects (for example, dizziness, drowsiness) less troublesome.

This product is not for use by children (under 12 years of age or weighing less than 40 kg).

If your doctor decides to stop one of the components of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets or change the dose of either component of

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets you may be given efavirenz, lamivudine and/or tenofovir separately instead of the combined medicine or other medicines for the treatment of HIV infection.

If you take more Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets than you should

If you accidentally take too many tablets of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets, contact your doctor or nearest emergency department for advice. Take the tablet container with you so that you can easily describe what you have taken.

If you forget to take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets

Try not to miss a dose. If you do miss a dose, take the next dose as soon as possible. However, when the next regular dose is due within 12 hours, then simply take your normal next dose at its due time.

If you throw up the tablet (just after taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets) you should take another tablet. Do not wait until your next dose is due.

If you stop taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets

Don't stop taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets without talking to your doctor. Stopping Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets can seriously affect your response to future treatment. If Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets is stopped, speak to your doctor before you restart taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets. Your doctor may consider giving you the components of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets separately if you are having problems or need your dose adjusted.

When your supply of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The virus may then become harder to treat.

If you have both HIV infection and hepatitis B, it is especially important not to stop your treatment with Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping lamivudine or tenofovir disoproxil fumarate (two of the three components of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets).

If Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets is stopped your doctor may recommend that you resume hepatitis B treatment. You may require blood tests to check how your liver is working for 4 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, which may be life-threatening.

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 product, ask your doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets can cause side effects, although not everybody gets them.

Tell your doctor about any of the following side effects:

Very common side effects

(These can affect more than 1 user in 10)

- Dizziness,
- Diarrhoea, feeling sick (nausea), being sick (vomiting)
- Skin rash
- Changes in fat metabolism as shown by increase in lipid levels in the blood.

Tests may also show:

- abnormally low levels of phosphate in the blood

Common side effects

(These can affect 1 to 10 users in 100)

- Stomach pain, flatulence
- Cough, nasal symptoms
- Headache
- Abnormal dreams, difficulties sleeping, sleepiness, anxiety, depression, disturbance in attention
- Hair loss
- Itching
- Feeling weak, fever
- Pain in muscles and joints
- Disturbed liver function as detected by elevation of liver enzymes in blood

Uncommon side effects

(These can affect 1 to 10 users in 1,000)

- Anaemia (low red blood cell count, which can make you tired and out of breath), low white blood cell count (which could make you more prone to infection), low platelet count (which could make you more prone to bleeding).
- angry behaviour, mood being affected, abnormal thoughts, nervousness, euphoric mood, mania (condition characterised by episodes of overactivity, elation or irritability), delusion (paranoia), forgetfulness, problems with coordination, confusion, suicidal thoughts and attempt, seeing or hearing things that are not really there (hallucinations)
- seizures (convulsions)
- giddiness, lightheadedness (vertigo)
- Blurred vision
- Inflammation of the liver with yellow skin or eyes, itching, or pain in the abdomen (stomach) (acute hepatitis)
- Inflammation of the pancreas with pain in the abdomen (acute pancreatitis)
- Breast enlargements in males (gynaecomastia)
- Severe skin rash (erythema multiforme, Stevens-Johnson-syndrome).

Rare side effects

(These can affect 1 to 10 users in 10,000)

- excess lactic acid in the blood (lactic acidosis, a serious side effect that can be fatal). The following side effects may be signs of lactic acidosis:
 - o deep rapid breathing
- drowsiness
- feeling sick (nausea), being sick (vomiting) and stomach pain
- kidney problems, including kidney failure. Symptoms may include nausea and fatigue, but also passing a lot of urine and feeling thirsty. This may also lead to softening of the bones (with bone pain and sometimes resulting in fractures).

Very rare side effects

(These can affect less than 1 users in 10,000)

- shortness of breath
- nerve injury causing weakness and sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy)
- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia).
- damage to kidney tubule cells (acute tubular necrosis)

Other possible side effects:

- Breakdown of muscle tissue
- Disorders of bone (e.g., softening of the bones (with bone pain and sometimes resulting in fractures).
- Low levels of potassium in blood

- changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen and internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump').
- appearance of symptoms of infection as part of the 'immune reactivation
- liver failure, fatty liver
- inflammation of the kidney (nephritis), passing a lot of urine and feeling thirsty (nephrogenic diabetes insipidus)
- whistling, ringing or other persistent noise in the ears (tinnitus)
- tremor (shaking)
- neurosis, completed suicide
- itchy rash caused by a reaction to sunlight (photoallergic dermatitis)
- sudden reddening of the face (flushing)

When Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets is given to adolescents, bone growth may be reduced.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or health care provider.

5. HOW TO STORE EFAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMERATE 400mg /300mg/300mg TABLETS

Keep out of the reach and sight of children.

Store below 30°C, in dry place and protected from light.

Do not use Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets contains

The active ingredient is Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate

The other ingredients are:

Lactose Monohydrate, Croscarmellose sodium, Poloxamer, Hydroxypropyl Cellulose, Sodium lauryl sulfate, magnesium stearate, Microcrystalline cellulose, pregelatinized starch, hypromellose, titanium dioxide, triacetin, ferric oxide.

What Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets looks like and contents of the pack

Pink colored, capsule shaped, biconvex film coated tablets debossed with "F 31" on one side and plain on other side.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 400mg/300mg/300mg Tablets will be packed in,

180's HDPE Container

180 Tablets packed in HDPE container and continuous thread closure with 3 X 3gm silica sachets.

90's HDPE Container

90 Tablets packed in HDPE container and child resistant closure with 2 X 3gm silica sachets.

30's HDPE Container

30 Tablets packed in HDPE container and child resistant closure with 2 X 3gm silica sachets.

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This leaflet was last approved on {MM/YYYY}.