

Handbook for Dovato[®] Combination Tablets

Guidance of the medication

 **Dovato**



Clinic/Hospital:

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Introduction

This **Handbook for Dovato Combination Tablets** will tell you, especially as a user of Dovato Combination Tablets, about what Dovato Combination Tablets is, how it should be taken, points that you need to know regarding Dovato Combination Tablets, and other relevant information.

In the treatment of HIV infection, it is important to discover the infection at an early stage and start treatment before the immune system is weakened due to the effect of the virus, thereby minimizing the level of HIV in the body.

HIV infection is a lifelong disease, but advancements in treatment methods have enabled patients with HIV to live to a similar age as those without it (Europe)¹⁾.

In order to achieve this, it is important to continue taking medication appropriately for a prolonged period of time. If you notice a change in your health or any other symptoms that cause concern on taking Dovato Combination Tablets, you should consult your doctor rather than depending on your own judgment to stop taking Dovato Combination Tablets or reduce your dose.

If you have any questions regarding Dovato Combination Tablets, talk to your doctor, pharmacist, nurses or other healthcare providers.

HIV: Human immunodeficiency virus

1) Reference: Obel N., et al.: PLoS One 6 (7): e22698, 2011

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1. What are the characteristics of Dovato Combination Tablets?

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● Shape and color of Dovato Combination Tablets

Dovato Combination Tablets are white tablets.



Dovato Combination Tablets (actual size)

Bottle

Ingredients: This medicine contains dolutegravir sodium and lamivudine as ingredients.

● How to store Dovato Combination Tablets?

Store at room temperature (1°C to 30°C) away from direct sunlight and humidity. Keep out of reach of children.



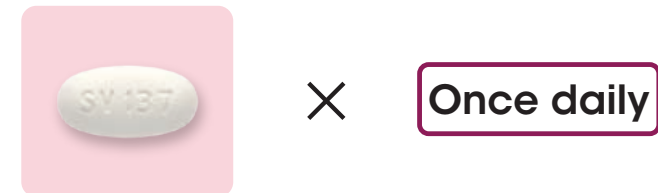
● Who should use Dovato Combination Tablets?

Dovato Combination Tablets are to be taken by **patients with HIV**.

2. How to take Dovato Combination Tablets?

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● One tablet must be taken once daily*.



Dovato Combination Tablets

* Follow the instructions of your doctor when taking this medicine.

One tablet must be taken once daily, regardless of whether you have eaten or not.



The dose should be taken at the same time every day to the extent possible to keep the dosing interval consistent.

© It is recommended that you take the medicine at regular points that match your daily routine, for example when waking up or before going to sleep.



3. What should I be careful of when taking Dovato Combination Tablets?

● Patients who must not take Dovato Combination Tablets (contraindication)

If you have a history of **hypersensitivity** to the ingredients of Dovato Combination Tablets, you must not take Dovato Combination Tablets.



● Patients who require care when taking Dovato Combination Tablets

- 1 Patients who are at risk of developing pancreatitis
- 2 Patients with chronic hepatitis B as a complication
- 3 Patients with hepatitis B or C virus infection
- 4 Patients with impaired renal function
- 5 Patients who are of childbearing age
- 6 Patients who are or who may be pregnant
- 7 Patients who are breastfeeding
- 8 Children or elderly patients

* If any of the above are applicable to you, please consult your doctor or pharmacist.



4. What Dovato Combination Tablets does?

Dovato Combination Tablets are combination tablets consisting of two types of anti-HIV drugs.

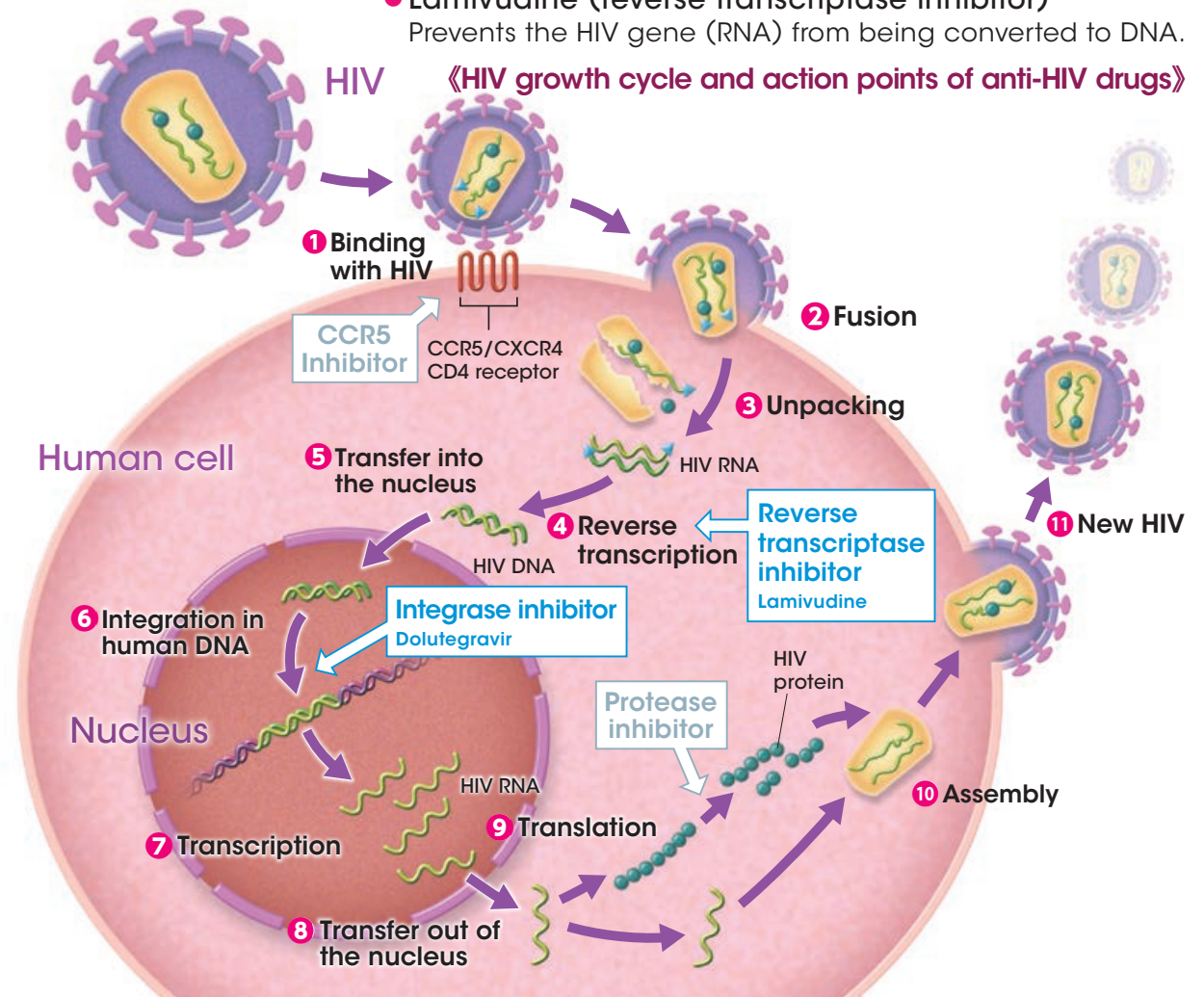
Dovato Combination Tablets combine two anti-HIV drugs with different sites of action (dolutegravir sodium and lamivudine) to suppress the process of HIV growth in the body, thereby preventing the weakening of the immune system.

Treatment of HIV infection requires lifelong treatment with medication, and it is important to minimize the patient's physical burden that is caused by prolonged exposure to anti-HIV drugs.

Previous treatment of HIV infection involved combination of three or more anti-HIV drugs. However, Dovato Combination Tablets reduced the number of anti-HIV drugs to two in order to reduce the patient's exposure, allowing treatment with reduced physical burden.

Reference: Figure prepared from Koyanagi Y., et al.:
Nihon Rinsho 68 (3): 378-381, 2010

- **Dolutegravir (integrase inhibitor)**
Prevents the HIV gene converted to DNA from entering the human DNA.
- **Lamivudine (reverse transcriptase inhibitor)**
Prevents the HIV gene (RNA) from being converted to DNA.



5. Side effects

Dovato Combination Tablets may cause side effects in some people. If you notice any changes in your health or feel different from usual, contact your doctor immediately.

● Contact your doctor immediately if you experience any of the following symptoms:

Rash, fever, fatigue, abdominal symptoms (nausea, vomiting, diarrhea, etc.), dyspnea, throat pain, cough, etc.

These symptoms may indicate hypersensitivity or allergic reaction to the drug. You must stop taking the drug immediately.

Strong abdominal pain, nausea, vomiting, abnormal results in pancreas tests

These symptoms may indicate pancreatitis.

Sluggishness, loss of appetite, decreased body weight, symptoms related to the abdomen or breathing

These symptoms may indicate lactic acidosis*.

* Conditions where there is excessive lactic acid in the blood, making the blood acidic. The onset of this condition is sudden.

Abnormality of hands and feet (weakness, swelling, numbness, pain, etc.), abnormality in urine (brown-colored urine, decreased urine volume, etc.)

These symptoms may indicate rhabdomyolysis*.

* Conditions where necrosis and dissolution of muscle cells (skeletal muscle cells) cause the components in muscle cells to flow into the bloodstream. Large inflow of myoglobin may obstruct the renal tubule, causing acute renal failure.

Numbness or pain in hands and feet, disturbance in consciousness, convulsions, heart disorders, etc.

In addition, some patients may experience the following:

- Headache
- Insomnia
- Anxiety
- Dizziness



6. Use in combination with other medicines

Please consult your doctor or pharmacist if you are using any other medicines or supplements.

● Interaction of Dovato Combination Tablets with other medicines (concomitant use)

Taking Dovato Combination Tablets with other medicines or supplements (iron preparation, drug products containing calcium), drug products containing magnesium or aluminum, or health food products (food products containing St. John's Wort) may affect the effect of the drug or lead to the onset of unexpected side effects.

For this reason, you must report all medicines and supplements you are taking to your doctor or pharmacist, including the over-the-counter drugs sold in pharmacies and drug stores, and check the combination of these products with Dovato Combination Tablets.

In some cases, the use of other drugs must be discontinued, or the dose may need to be reduced or changed.

● Main anti-HIV drugs that require care regarding concomitant use

Dovato Combination Tablets contain two types of anti-HIV drugs (dolutegravir sodium and lamivudine) as ingredients. For this reason, care must be taken to avoid taking other drugs with the same or similar effect. Care must also be taken as some anti-HIV drugs may affect the concentration of the drug in the blood.

Note: However, Tivicay Tablets (dolutegravir) may be given as additional medication 12 hours after the administration of Dovato Combination Tablets. If this is the case, this should be taken according to the instructions of the doctor.



7. Important points to keep in mind when taking Dovato Combination Tablets

● Take the medicine appropriately

In the treatment of HIV infection, it is highly important for the drug to be taken at the correct amount, correct number of doses, and at the correct interval. If the drug is not taken appropriately, the concentration of the drug in the blood becomes insufficient, which leads to growth of the virus with resistance to the drug, making the drug ineffective.

Another important point is that you should not stop taking the medicine by your own discretion even if the test results and symptoms have improved. Please continue taking the prescribed medicine appropriately according to the instructions of the doctor to maintain the therapeutic effect.

● Side effects

Please consult your doctor immediately if you experience any concerning symptoms during treatment with Dovato Combination Tablets.



● What to do if you take more Dovato Combination Tablets than you should?

Please consult your doctor or pharmacist if you experience any abnormalities.

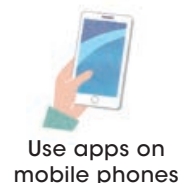
8. What to do if you forget to take Dovato Combination Tablets?

● What to do if you forget to take?

If you forget to take a dose of the medicine, you must not take a double dose under any circumstances. Take a single dose when you remember, but if your next dose is due shortly, skip the dose you missed and take the next one at the usual time.

* Before starting treatment with Dovato Combination Tablets, it is recommended that you consult with your doctor or healthcare providers (pharmacist, nurse, etc.) to reflect upon your lifestyle and discuss how to incorporate medication into your daily life in addition to the handling of missed doses and side effects.

◎ How to prevent forgetting to take (examples)



Support in medication

Changes in lifestyle, such as being busy at work, changing jobs, and moving to a new house may lead to changes in the timing of doses and dosing intervals. If you have any concerns about taking the medicine, do not hesitate to contact the doctor or healthcare providers (pharmacist, nurse, etc.).

Information on HIV infection can be accessed on the following websites:

- AIDS Clinical Center, National Center for Global Health and Medicine
<http://www.acc.go.jp/>
- AIDS Medical Center, National Hospital Organization Osaka National Hospital
<https://osaka.hosp.go.jp/khac/>
- AIDS Prevention Information Network (API-Net)
<https://api-net.jfap.or.jp/>