

Applicant/HCR	:	Umsebe Healthcare	V3 (30.08.2024)
Product name, strength and dosage form	:	TERALAVID (dolutegravir 50 mg) film-coated tablets	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TERALAVID

Film-coated tablets

Dolutegravir (as Dolutegravir sodium)

Contains sugar (mannitol 134,28 mg per tablet)

Read all of this leaflet carefully before you start taking TERALAVID

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- TERALAVID has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TERALAVID is and what it is used for
2. What you need to know before you take TERALAVID
3. How to take TERALAVID
4. Possible side effects
5. How to store TERALAVID
6. Contents of the pack and other information

1. What TERALAVID is and what it is used for

TERALAVID is a type of medicine known as an anti-retroviral (ARV) and belongs to a group of medicines called integrase inhibitors (INIs).

Applicant/HCR	:	Umsebe Healthcare	V3 (30.08.2024)
Product name, strength and dosage form	:	TERALAVID (dolutegravir 50 mg) film-coated tablets	

TERALAVID is used to treat HIV (human immunodeficiency virus) infection in adults aged 18 years and older in combination with other anti-retroviral medicines (i.e., TERALAVID with other anti-retroviral medicines).

2. What you need to know before you take TERALAVID

Do not take TERALAVID:

- If you are hypersensitive (allergic) to dolutegravir or any of the other ingredients of TERALAVID (listed in section 6).
- If you are also taking medication for irregular heart beat containing dofetilide or pilsicainide.
- If you have moderate or severe liver disease.
- If you are taking metformin for the treatment of diabetes.
- If you are in your first trimester of pregnancy.

Warnings and precautions

Take special care with TERALAVID:

Tell your doctor

- If you develop changes in body fat, which may include increased fat in the upper back and neck areas ("buffalo hump"), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen.
- If you show any symptoms of infection while you are taking TERALAVID. Patients with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these patients start with the treatment, they may find that old hidden infections (such as tuberculosis, pneumonia) flare up, causing signs and symptoms of inflammation (such as localised swelling, area appears red and hot, painful). These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.
- If you experience joint aches and pain, joint stiffness or difficulty in movement or bone fractures, you may suffer from condition called osteonecrosis for which you may need treatment.

Applicant/HCR	:	Umsebe Healthcare	V3 (30.08.2024)
Product name, strength and dosage form	:	TERALAVID (dolutegravir 50 mg) film-coated tablets	

- If you have or have had problems with your liver, including hepatitis B and/or C. Your doctor may evaluate how severe your liver disease is before deciding if you can take TERALAVID and you may need regular liver function tests.

Special care should be taken with TERALAVID:

TERALAVID does not reduce the risk of passing HIV on to other people through sexual contact or blood contamination. Therefore, it is important to continue to take appropriate precautions to prevent passing HIV on to others.

Even if you are receiving treatment for HIV, you are still at risk of contracting other infections and other complications of the HIV infection. Therefore, you should remain under close observation by your doctor.

Children and adolescents

TERALAVID should not be used in children under the age of 18 years, as safety has not been established.

Other medicines and TERALAVID

Always tell your healthcare provider if you are taking any other medicine (This includes all complementary or traditional medicines).

Do not take TERALAVID with the following medicines:

- Dofetilide or pilsicainide (used to treat irregular heart beat).
- Metformin (used for the treatment of diabetes).

TERALAVID may have an effect on other medicines or other medicines may have an effect on TERALAVID thus causing you to have side effects.

Tell your doctor if you are taking any of the following medicines:

Applicant/HCR	:	Umsebe Healthcare	V3 (30.08.2024)
Product name, strength and dosage form	:	TERALAVID (dolutegravir 50 mg) film-coated tablets	

- Etravirine, efavirenz, nevirapine, tipranavir and ritonavir (these medicines are also used in the treatment of HIV infection (alone or in combination)).
- Tipranavir + ritonavir combination (this medicine combination is also used in the treatment of HIV infection).
- Phenytoin and phenobarbital (used to treat epilepsy (fits)).
- Oxcarbamazepine and carbamazepine (used to treat epilepsy (fits) and bipolar disorder).
- St. John's wort (a herbal remedy used for the treatment of depression, anxiety and sleeplessness (insomnia)).
- Medicines used to treat indigestion and heartburn called antacids should only be taken at least 2 hours before you take TERALAVID or 6 hours after taking TERALAVID.
- Calcium and iron supplements should only be taken at least 2 hours before you take TERALAVID or 6 hours after taking TERALAVID.
- Rifampicin and isoniazid (used to treat TB (tuberculosis)).

You should tell your doctor or pharmacist if you are taking any of these medicines. Your doctor will then decide to adjust your dose if required.

TERALAVID with food, drink and alcohol

TERALAVID can be taken with or without food.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

If you are able to fall pregnant, your healthcare provider will perform a pregnancy test before you start your treatment with TERALAVID.

You should ensure that you always use effective contraception while you are taking TERALAVID. If you are thinking about having a baby, do not stop using TERALAVID and contraception before you have

Applicant/HCR	:	Umsebe Healthcare	V3 (30.08.2024)
Product name, strength and dosage form	:	TERALAVID (dolutegravir 50 mg) film-coated tablets	

talked to your healthcare professional. If you think you are pregnant go to your healthcare professional to get a pregnancy test and to be advised on your future HIV treatment and on a pregnancy management plan.

It is not recommended to breastfeed your baby if you are HIV positive, as HIV infection may be transmitted through the breast milk. TERALAVID passes into breastmilk, but the effect on the baby is not known.

Driving and using machines

It is not always possible to predict to what extent TERALAVID may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TERALAVID affects them.

TERALAVID can cause side effects (including headache, dizziness, fatigue), which may affect your ability to drive or operate machinery.

TERALAVID contains sodium

TERALAVID contains approximately 4,08 mg sodium (found in table salt) per tablet and may be regarded as essentially sodium free. If you are following a low salt (sodium) diet and have any questions, please ask your doctor or pharmacist.

3. HOW TO TAKE TERALAVID

Do not share medicines prescribed for you with any other person.

Always TERALAVID exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of TERALAVID is one 50 mg film-coated tablet, taken orally, once a day, with or without food. Film-coated tablets must be swallowed whole with water and must not be crushed or chewed.

Applicant/HCR	:	Umsebe Healthcare	V3 (30.08.2024)
Product name, strength and dosage form	:	TERALAVID (dolutegravir 50 mg) film-coated tablets	

For HIV that is resistant to other medicines similar to TERALAVID, the usual dose is 50 mg, twice a day.

TERALAVID should only be used by adults and should not be taken by patients younger than 18 years of age.

Your doctor will decide on the correct dose of TERALAVID for you.

If you take more TERALAVID than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TERALAVID

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking TERALAVID

Your doctor will tell you how long your treatment with TERALAVID will last. Do not stop treatment early because this may worsen your condition and make your body resistant to the medicine.

4. Possible side effects

TERALAVID can have side effects.

Not all side effects reported for TERALAVID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TERALAVID, please consult your health care provider for advice.

If any of the following happens, stop taking TERALAVID and tell your doctor immediately or go to the casualty department at your nearest hospital:

Applicant/HCR	:	Umsebe Healthcare	V3 (30.08.2024)
Product name, strength and dosage form	:	TERALAVID (dolutegravir 50 mg) film-coated tablets	

- Swelling of the hands, feet ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TERALAVID. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- IRS (Immune reconstitution syndrome):
 - People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections. 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.
- Swelling (inflammation) of the liver (hepatitis), that may include the following symptoms:
 - Fatigue (tiredness).
 - Nausea and vomiting.
 - Stomach pain or discomfort, especially in the area of your liver on your right side beneath your lower ribs.
 - Clay-coloured bowel movements.

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Product name, strength and dosage form	:	TERALAVID (dolutegravir 50 mg) film-coated tablets	

- Loss of appetite.
- Fever.
- Dark urine.
- Joint pain.
- Yellowing of the skin and eyes (jaundice).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Insomnia (difficulty in sleeping).
- Headache.
- Dizziness.
- Abnormal dreams.
- Nausea and vomiting.
- Diarrhoea.
- Flatulence (excessive gas/ wind).
- Upper abdominal pain.
- Fatigue (feeling tired).

Less frequent side effects

- Abdominal pain or discomfort.

The following side effects have also been reported (frequency not known)

- Anxiety.
- Damage to the liver or liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine).
- Muscle pain.
- Inflammation and sore joints.

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Product name, strength and dosage form	:	TERALAVID (dolutegravir 50 mg) film-coated tablets	

- Increase in weight.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of TERALAVID.

5. How to store TERALAVID

Store at or below 30 °C in the original container.

Keep the container tightly closed.

After first opening, store at or below 25 °C in the original container and use within 30 days (28’s and 30’s tablets) or 90 days (84’s and 90’s tablets) after first opening.

STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TERALAVID contains

The active substance in TERALAVID is dolutegravir.

The other ingredients are mannitol, microcrystalline cellulose, povidone K 30, sodium starch glycolate and sodium stearyl fumarate. The tablets are film-coated with a coating material containing FD&C YELLOW #6, polyethylene glycol 3350, polyvinyl alcohol, talc and titanium dioxide.

What TERALAVID looks like and contents of the pack

TERALAVID are light orange coloured, round shaped, biconvex film coated tablets debossed with “LA54” on one side and plain on the other side.

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Containers of 28's: TERALAVID is packed in white 60 cc HDPE bottles with 33 mm child resistant screw caps containing 28 tablets.

Containers of 30's: TERALAVID is packed in white 60 cc HDPE bottles with 33 mm child resistant screw caps containing 30 tablets.

Containers of 84's: TERALAVID is packed in white 85 cc HDPE bottles with 33 mm child resistant screw caps containing 84 tablets.

Containers of 90's: TERALAVID is packed in white 85 CC HDPE bottle with 33 mm child resistant cap containing 90 tablets.

Holder of Certificate of Registration

Umsebe Healthcare

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21 Dreyer Street, Claremont

Cape Town

7708

South Africa

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58/20.2.8/0005

Access to the corresponding Professional Information

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