PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NOVALUTE 50 mg film-coated tablets

Dolutegravir

NOVALUTE contains 145,4 mg mannitol per tablet

Read all of this leaflet carefully before you start taking NOVALUTE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- NOVALUTE 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 NOVALUTE is and what it is used for

- NOVALUTE contains the active ingredient dolutegravir.
- Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs).
- NOVALUTE is used to treat HIV (human immunodeficiency virus) infection in adults aged 18 years and older.
- It is used in combination with other antiretroviral medicines.

2. What you need to know before you take NOVALUTE

Do not take NOVALUTE:

- if you are hypersensitive (allergic) to dolutegravir or any of the other ingredients of NOVALUTE
- if you are taking other medicines called dofetilide or pilsicainide (to treat heart conditions)
- if you have moderate or severe liver disease
- if you are taking a medicine called metformin (to treat diabetes)
- if you are planning to become pregnant, are pregnant or breastfeeding your baby
- if you are of childbearing age and not on effective contraception.

Warnings and precautions

Take special care with NOVALUTE

Some people taking medicines for HIV infection such as NOVALUTE develop other conditions, which can be serious. These include:

Allergic/hypersensitivity reactions

You may experience:

- swelling, sometimes of the lips, tongue or throat (angioedema), causing difficulty in breathing,
- severe rash accompanied by raised liver enzymes,
- fever,
- general feeling of weakness, tiredness,
- muscle or joint aches,
- blisters, mouth sores,
- pink eyes, facial swelling, higher than normal level of a certain type of white blood cell,
- severe swelling beneath the skin.

Lipodystrophy and metabolic abnormalities

Accumulation of body fat, central obesity, buffalo hump, peripheral and/or facial wasting, breast enlargement and elevation of serum lipid and glucose levels. The latter which will be demonstrated by blood tests.

Immune Reconstitution Inflammatory Syndrome

An exaggerated inflammatory reaction to a disease-causing microorganism that sometimes occurs when the immune system begins to recover.

In some cases of AIDS or immunosuppression, in which the immune system begins to recover, but then responds to a previously acquired opportunistic infection with an overwhelming inflammatory response that paradoxically makes the symptoms of infection worse.

Osteonecrosis

You can develop a condition called osteonecrosis. Symptoms may include joint aches and pain (especially in the hip, knee or shoulder), stiffness and difficulty moving. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. You may be more likely to get this condition:

- if you have been taking combination therapy for a long time
- if you are also taking anti-inflammatory medicines called corticosteroids
- if you drink alcohol
- if your immune system is very weak
- if you are overweight

Serious infections

- If you are taking NOVALUTE you should remember that NOVALUTE or any other antiretroviral therapy does not cure HIV infection.
- You may continue to develop serious infections and other complications of HIV infection because of your weakened immunity.
- You will need to check your CD4 levels regularly, if so instructed by your doctor.

Protect other people

- HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles).
- NOVALUTE will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:
  - Use a condom when you have oral or penetrative sex.
  - Do not risk blood transfer - for example, don’t share needles.

HIV can still be transmitted despite taking NOVALUTE. NOVALUTE does not cure HIV infection; it reduces the amount of virus in your body.

Children and adolescents

NOVALUTE is indicated in adults aged 18 years and older.

Other medicines and NOVALUTE

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

Do not take NOVALUTE with the following medicines:

- dofetilide or pilsicainide (used to treat heart conditions)
- metformin, to treat diabetes

Some medicines can affect how NOVALUTE works or make it more likely that you will have side effects. NOVALUTE can also affect how some other medicines work.

Tell your doctor if you are taking any of the following medicines as your dose may need to be changed or you may need to have regular tests performed:

- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, (these are all medicines used to treat HIV infection)
- phenytoin and phenobarbitone, to treat epilepsy
- oxcarbamazepine and carbamazepine, to treat epilepsy and bipolar disorder
- St. John's wort (*Hypericum perforatum*), a herbal remedy used for depression
- rifampicin, to treat tuberculosis and other bacterial infections
- medicines called antacids, to treat indigestion and heartburn. Do not take an antacid during the 2 hours before you take NOVALUTE, or for at least 6 hours after you take it
- calcium and iron supplements or multivitamins. Do not take a calcium supplement, iron supplement or multivitamin during the 2 hours before you take NOVALUTE, or for at least 6 hours after you take it.

Taking NOVALUTE with food and drink

NOVALUTE can be taken with or without food.

Your doctor will be able to tell you if you have integrase class resistance. If you do, NOVALUTE should preferably be taken with food.

NOVALUTE should be taken with food if taken concomitantly with calcium or iron supplements.

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 healthcare provider for advice before taking NOVALUTE.

Women of childbearing age should use contraception during treatment.

NOVALUTE should not be used during the first trimester of pregnancy.

Safe use during the second and third trimester of pregnancy has not been established.

Women who are HIV-positive must not breastfeed because HIV infection can be passed on to the baby in breast milk.

Mothers on treatment with NOVALUTE should not breastfeed their babies.

Driving and using machinery

NOVALUTE may influence your ability to drive and use machines.

NOVALUTE can make you dizzy and have other side effects that make you less alert.

It is not always possible to predict to what extent NOVALUTE may interfere with your daily activities. You should ensure that you do not engage in driving or using machinery until you are aware of the measure to which NOVALUTE affects you.

NOVALUTE contains sodium

Each NOVALUTE 50 mg tablet contains 4 mg sodium.

3. HOW TO TAKE NOVALUTE

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

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

The usual dose of NOVALUTE is one 50 mg tablet, **once a day**.

For people with HIV infection that are resistant to other medicines similar to NOVALUTE, the usual dose of NOVALUTE is one 50 mg tablet, twice a day.

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

Swallow the tablet with some liquid. NOVALUTE can be taken with or without food.
If you have HIV infection that is resistant to other medicines similar to NOVALUTE, the NOVALUTE dose should be taken with food.
Certain medicines, such as antacids, calcium supplements, iron supplements or multivitamins can stop NOVALUTE being absorbed into your body and make it less effective. Do not take these medicines during the 2 hours before you take NOVALUTE, or for at least 6 hours after you take it. See also 'Other medicines and NOVALUTE'.

Your doctor will tell you how long your treatment with NOVALUTE will last. Do not stop treatment unless your doctor advises you to.

If you have the impression that the effect of NOVALUTE is too strong or too weak, tell your doctor or pharmacist.

If you take more NOVALUTE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.
If possible, show them the NOVALUTE pack.

If you forget to take a dose of NOVALUTE

If you miss a dose, take it as soon as you remember. But if your next dose is due within 4 hours, skip the dose you missed and take the next one at the usual time.

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

If you stop taking NOVALUTE

Take NOVALUTE for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

NOVALUTE can have side effects.

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

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

- skin rash or itching
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- blisters or sores in mouth
- a high temperature (*fever*)
- lack of energy (*fatigue*)
- muscle or joint aches.

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

Your doctor may decide to carry out tests on your liver, kidneys or blood and may tell you to stop taking NOVALUTE.

Tell your doctor if you notice any of the following:

Frequent side effects

- difficulty in sleeping (*insomnia*)
- abnormal dreams
- depression
- feeling anxious
- headache
- dizziness
- diarrhoea
- feeling sick (*nausea*)
- being sick (*vomiting*)
- wind (*flatulence*).
- stomach pain (*upper abdominal pain*)
- stomach (*abdominal*) pain/discomfort.
- itching (*pruritis*)
- rash
- lack of energy (*fatigue*)

Less frequent side effects:

- allergic reaction (*hypersensitivity*)
- having suicidal thoughts or suicide attempt (particularly in patients with a pre-existing history of depression or psychiatric illness)
- an inflammatory condition which may develop as the immune system becomes stronger (*immune reconstitution syndrome*)
- inflammation of the liver (*hepatitis*)
- liver failure
- pain in joints
- muscle pain

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 NOVALUTE.

5. How to store NOVALUTE

Store at or below 30 °C.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the label and carton

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 NOVALUTE contains

The active substance is dolutegravir. Each tablet contains dolutegravir sodium equivalent to 50 mg dolutegravir.

The other ingredients are mannitol, microcrystalline cellulose, povidone (K29/32), sodium starch glycolate, sodium stearyl fumarate, polyvinyl alcohol-part hydrolysed, macrogol/polyethylene glycol 3350, titanium dioxide, talc, iron oxide red.

What NOVALUTE looks like and contents of the pack

Reddish brown coloured, round, biconvex, film-coated tablets debossed with 'T over 50' on one side and plain on the other side.

NOVALUTE tablets are packed in opaque, white round high density polyethylene (HDPE) bottles with white opaque polypropylene child-resistant closure with wad having induction seal liner. The HDPE bottle is packed into an outer carton.

Pack size: 30 tablets.

Holder of Certificate of Registration

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