

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ASPEN DOLUTEGRAVIR 50 mg film-coated tablets

Dolutegravir

Contains sugar: Mannitol (E421) 134,28 mg

Read all of this leaflet carefully before you start taking ASPEN DOLUTEGRAVIR

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

1. What ASPEN DOLUTEGRAVIR is and what it is used for

ASPEN DOLUTEGRAVIR contains the active substance dolutegravir (as dolutegravir sodium).

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

ASPEN DOLUTEGRAVIR is used to treat HIV infection in combination with antiretroviral medicines in adults aged 18 years and older.

ASPEN DOLUTEGRAVIR does not cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level. As a result of that, it also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection. ASPEN DOLUTEGRAVIR is always used in combination with other anti-retroviral medicines (combination therapy).

2. What you need to know before you take ASPEN DOLUTEGRAVIR

Do not take ASPEN DOLUTEGRAVIR:

- if you are hypersensitive (allergic) to dolutegravir or any of the other ingredients of ASPEN DOLUTEGRAVIR (listed in section 6).
- if you are taking another medicine called dofetilide or pilsicainide (to treat heart conditions).
- if you have moderate or severe liver problems.
- If you are pregnant (in your first trimester) or breastfeeding your baby.
- If you are a woman of child-bearing age not using effective contraception.

ASPEN DOLUTEGRAVIR could seriously harm your unborn child if you fall pregnant while on treatment or if you start taking ASPEN DOLUTEGRAVIR in the first few weeks of your pregnancy (see Pregnancy and breastfeeding).

Tell your doctor if you are taking metformin to treat diabetes. You must not take metformin and ASPEN DOLUTEGRAVIR together.

Warnings and precautions

Take special care with ASPEN DOLUTEGRAVIR:

Tell your doctor if:

- You are pregnant or suspect that you might be pregnant, you should **immediately** tell your doctor. Taking ASPEN DOLUTEGRAVIR when conception takes place may cause serious birth defects in your baby. If you want to become pregnant, while on ASPEN DOLUTEGRAVIR treatment, consult your healthcare provider before trying to conceive a baby. You might need to be switched to another type of medicine (see Do not take ASPEN DOLUTEGRAVIR and Pregnancy and breastfeeding,
- You develop a rash, stop taking ASPEN DOLUTEGRAVIR and tell your doctor immediately. Some people taking ASPEN DOLUTEGRAVIR have had allergic reactions,
- You get any symptoms of infection or inflammation while you are taking ASPEN DOLUTEGRAVIR. 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 (such as tuberculosis) flare up, causing signs and symptoms of inflammation,
- Your body shape changes, because of changes in fat distribution. People taking combination therapy for HIV may find that their body shape changes, and that they have higher blood sugar and blood lipid (fat in the blood) levels,
- You experience joint pain, joint stiffness or difficulty in movement, you should see your doctor immediately,

- You do not see your doctor regularly. Keep in touch with your doctor, and do not stop taking ASPEN DOLUTEGRAVIR without your doctor's advice. You might still develop infections. For as long as you are taking ASPEN DOLUTEGRAVIR, your doctor will arrange regular blood tests to check for side effects,
- You have regular sexual contact with someone or if there has been transfer of your blood to another person by sharing needles. 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). ASPEN DOLUTEGRAVIR 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 and do not risk blood transfer (for example, don't share needles). HIV can still be transmitted despite taking ASPEN DOLUTEGRAVIR. ASPEN DOLUTEGRAVIR does not cure HIV infection; it reduces the amount of virus in your body,
- You have liver problems or if you have an infection in your liver called hepatitis B or C,
- You are taking any other medicine you need to tell your doctor about it. This includes herbal or traditional medicines and medicines that you are taking that do not need a prescription (see Other medicines and ASPEN DOLUTEGRAVIR).

Keep in touch with your doctor, and do not stop taking ASPEN DOLUTEGRAVIR without your doctor's advice. You might still develop infections. For as long as you are taking ASPEN DOLUTEGRAVIR your doctor may arrange for blood tests.

Children and adolescents

There is no experience with ASPEN DOLUTEGRAVIR in children and adolescents younger than 18 years.

Other medicines and ASPEN DOLUTEGRAVIR

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

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

- Antidysrhythmics (e.g. dofetilide, pilsicainide): medicine used to treat heart conditions (see Do not take ASPEN DOLUTEGRAVIR).
- Antidiabetics (e.g. metformin): medicine used to treat diabetes (see Do not take ASPEN DOLUTEGRAVIR).
- Antacids: medicines used to treat indigestion and heartburn. Do not take an antacid during the 2 hours before you take ASPEN DOLUTEGRAVIR, or for at least 6 hours after you have taken ASPEN DOLUTEGRAVIR.
- Supplements (e.g. calcium supplements, iron supplements, multivitamins): Do not take a calcium or iron supplement during the 2 hours before you have taken ASPEN DOLUTEGRAVIR, or for at least 6 hours after you take ASPEN DOLUTEGRAVIR.
- Antivirals (e.g. etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir): medicines used to treat HIV infection.
- Antimycobacterials (e.g. rifampicin): medicine used to treat tuberculosis.
- Anticonvulsants (e.g. phenytoin, phenobarbitone, oxcarbazine, carbamazepine): medicines used to treat epilepsy.
- Herbal medicines e.g. St. John's wort - *Hypericum perforatum*: a herbal remedy used for depression.
- Antifungals (e.g. ketoconazole, fluconazole, itraconazole): medicines used to treat fungal infections.
- Corticosteroids (e.g. prednisone): medicine used to treat swelling (inflammation).
- Oral contraceptives: medicines used to prevent pregnancy or regulate your menstrual cycle.

- Analgesics (e.g. methadone): medicines used to treat pain.

ASPEN DOLUTEGRAVIR with food and drink

ASPEN DOLUTEGRAVIR may be taken at any time of the day, with or without food.

Pregnancy and breastfeeding

Pregnancy

You should not take ASPEN DOLUTEGRAVIR if you are planning to become pregnant (see Do not take ASPEN DOLUTEGRAVIR).

You should not take ASPEN DOLUTEGRAVIR if you are pregnant (in your first trimester) or breastfeeding your baby (see Do not take ASPEN DOLUTEGRAVIR).

You should not take ASPEN DOLUTEGRAVIR if you are a woman of child-bearing age and you are not using effective contraception.

If you are a woman of child-bearing age you could get pregnant while taking ASPEN DOLUTEGRAVIR, you need to use a reliable method of barrier contraception (for example, a condom) with other methods of contraception including oral (pill) or other hormonal contraceptives (for example, implants, injection), to prevent pregnancy.

Your doctor will check with a pregnancy test that you are not pregnant before you start taking ASPEN DOLUTEGRAVIR. Your doctor will repeat the pregnancy test during your treatment with ASPEN DOLUTEGRAVIR, to ensure you have not become pregnant while you are taking ASPEN DOLUTEGRAVIR.

ASPEN DOLUTEGRAVIR can harm your baby if you become pregnant or are in the early stages of pregnancy. You should not take ASPEN DOLUTEGRAVIR if you have become pregnant, as there is potential risk of neural tube defects that will affect your unborn baby. Tell your doctor immediately.

Breastfeeding

You should not breastfeed your baby while you are taking ASPEN DOLUTEGRAVIR.

If you are pregnant or breastfeeding your baby, 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 ASPEN DOLUTEGRAVIR.

Driving and using machines

Adverse reactions such as dizziness have been reported in patients taking ASPEN DOLUTEGRAVIR. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that ASPEN DOLUTEGRAVIR does not adversely affect your ability to do so safely (see section 4).

ASPEN DOLUTEGRAVIR contains Sunset yellow FCF (E110)

Sunset yellow FCF (E110) may cause allergic reactions.

ASPEN DOLUTEGRAVIR contains mannitol and may cause diarrhoea.

3. How to take ASPEN DOLUTEGRAVIR

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

Always take ASPEN DOLUTEGRAVIR exactly as your doctor has told you. Check with your doctor if you are not sure.

The usual dose of ASPEN DOLUTEGRAVIR is one 50 mg tablet once a day.

Your doctor will decide on the correct dose of ASPEN DOLUTEGRAVIR for you. Swallow the tablet with some liquid.

ASPEN DOLUTEGRAVIR can be taken with or without food.

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

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

If you take more ASPEN DOLUTEGRAVIR than you should

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

If you forget to take ASPEN DOLUTEGRAVIR

If you have missed a dose of ASPEN DOLUTEGRAVIR, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for forgotten individual doses. If you have forgotten to take several doses contact your doctor without delay.

4. Possible side effects

ASPEN DOLUTEGRAVIR can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and 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 ASPEN DOLUTEGRAVIR. 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:

- an inflammatory condition which may develop as your immune system becomes stronger (immune reconstitution syndrome or 'IRIS'). Symptoms can include fever, headache, stomach pain, difficulty breathing, changes in the way your heart beats, restlessness and weakness,
- suicidal thoughts or an attempt to take one's own life (particularly if you have a history of mental illness),
- yellowing of the skin and the whites of the eyes (jaundice), unusually dark urine, loss of appetite, sudden nausea and vomiting, abnormally tired, pain in the stomach area.

These may be signs of liver inflammation (hepatitis) or liver failure.

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

- difficulty in sleeping (insomnia),
- feelings of deep sadness and unworthiness (depression), anxiety,

- headache, dizziness, abnormal dreams,
- nausea, loose stools (diarrhoea), vomiting, passing wind (flatulence), stomach pain,
- itching (pruritus),
- lack of energy (fatigue),
- increase in the level of liver enzymes when your blood is tested.

Less frequent side effects:

- stomach pain, stomach discomfort,
- pain in the joints (arthralgia), pain in the muscles (myalgia).

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to:

SAHPRA: <https://www.sahpra.org.za/health-products-vigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store ASPEN DOLUTEGRAVIR

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 ASPEN DOLUTEGRAVIR contains

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

The other ingredients are mannitol (E421), microcrystalline cellulose, povidone, sodium starch glycolate, sodium stearyl fumarate.

Tablet coating: Macrogol, Sunset yellow FCF (E110), polyvinyl alcohol, talc, titanium dioxide (E171).

What ASPEN DOLUTEGRAVIR looks like and contents of the pack

ASPEN DOLUTEGRAVIR is a round, orange, bevelled edged, biconvex, film-coated tablet, marked F33 on one side and plain on the other side.

28 or 30 tablets are packed in a white, high density polyethylene bottle with white polypropylene cap with heat seal liner. The bottle may be packed in an outer cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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