

Patient Information Leaflet

SCHEDULING STATUS:

S4

JASUPA Film-coated Tablets

Dolutegravir 50 mg/Rilpivirine 25 mg

Contains sugar (as lactose monohydrate 55,15 mg/tablet and D-mannitol 203,14 mg/tablet)

Read all of this leaflet carefully before you start taking JASUPA:

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

1. WHAT JASUPA IS AND WHAT IT IS USED FOR:

JASUPA contains two active ingredients that are used to treat HIV infection: dolutegravir plus rilpivirine. Dolutegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors* (INIs). Rilpivirine belongs to a group of anti-retroviral medicines called *non-nucleoside analogue reverse transcriptase inhibitors (NNRTIs)*.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE JASUPA:

Do not take JASUPA:

- if you are hypersensitive (allergic) to dolutegravir or rilpivirine or to any of the other ingredients of JASUPA (listed in section 6)
- if you are taking any of the following medicines:
 - dofetilide or pilsicainide (to treat heart conditions) carbamazepine, oxcarbazepine, phenobarbitone or phenytoin (also known as anticonvulsants used to treat epilepsy and prevent seizures)
 - fampridine (also known as dalfampridine; used in multiple sclerosis)
 - rifampicin or rifapentine (to treat some bacterial infections such as tuberculosis)
 - omeprazole, esomeprazole, lansoprazole, pantoprazole or rabeprazole (proton pump inhibitors that are medicines to prevent and treat stomach ulcers, heartburn, or acid reflux disease)
 - dexamethasone (a corticosteroid used in a variety of conditions such as inflammation and allergic reactions)
 - products that contain St John's wort (*Hypericum perforatum*) (a herbal product used to treat depression).

Do not take JASUPA with any of these medicines. Tell your doctor immediately.

- if you have severe liver disease
- if you want to fall pregnant and, in the time, just before/during/after conception (peri and post-conception) and are in the first trimester of your pregnancy
- if you are breastfeeding.

Warnings and precautions:

Take special care with JASUPA:

If you develop a rash you must contact your doctor immediately.

If any of the following occur, you must tell your doctor as soon as possible:

- if you get any symptoms of infection while you are taking JASUPA. See 'Conditions you need to look out for' in section 4 Old infections may flare up
- if you have ever had liver disease, including hepatitis B or C
- if your body shape changes. See 'Conditions you need to look out for' in section 4 Fat redistribution.

Protect other people: HIV infection is spread by unprotected sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting 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.

Keep in touch with your doctor and do not stop taking JASUPA without your doctor's advice.

Other medicines and JASUPA:

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

Do not take JASUPA with any of the medicines listed under section 'Do not take.'

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

- metformin, to treat diabetes. JASUPA may increase the way metformin works and will affect your blood sugar levels. Talk to your doctor for further advice on taking metformin with JASUPA
- medicines called antacids, to treat indigestion and heartburn. Antacids can stop JASUPA being absorbed into your body and make it less effective. JASUPA should be taken at least 4 hours before or 6 hours after you take an antacid. Talk to your doctor for further advice on taking acid-lowering (antacid) medicines with JASUPA

- calcium and iron supplements (non-antacids). Calcium and iron containing medicines can stop JASUPA from being absorbed and make it less effective. JASUPA should be taken at least 4 hours before or 12 hours after you take a calcium or iron containing supplement. However, provided you take JASUPA with a meal, you can take calcium and iron supplements at the same time as JASUPA
- famotidine, cimetidine, nizatidine, and ranitidine (H₂-receptor antagonists) to treat indigestion and heartburn. H₂-receptor antagonists (to treat indigestion and heartburn), such as famotidine, cimetidine, nizatidine, and ranitidine can stop JASUPA being absorbed into your body and make it less effective. JASUPA should be taken at least 4 hours before or 12 hours after you take a H₂-receptor antagonist
- rifabutin, to treat some bacterial infections, such as tuberculosis (TB). Rifabutin can lower the amount of rilpivirine contained in JASUPA in your body and make it less effective. If you are taking rifabutin, you must also take an additional 25-mg dose of rilpivirine at the same time as JASUPA
- clarithromycin, erythromycin, antibiotics used to treat bacterial infections. These antibiotics may increase the amount of JASUPA in your body. Talk to your doctor for further advise on taking these antibiotics with JASUPA
- methadone, a medicine used for drug withdrawal treatment. JASUPA may decrease the way methadone works and you may have to be monitored while on methadone therapy
- efavirenz, etravirine, and nevirapine (non-nucleoside reverse transcriptase inhibitors [NNRTIs]) to treat HIV infection. These medicines may decrease the way JASUPA works
- any other medicine to treat HIV infection.

Tell your doctor or pharmacist if you are taking any of these. Your doctor may decide to adjust your dose or that you need extra check-ups.

JASUPA with food and drink and alcohol:

JASUPA must be taken with food. Taking JASUPA with a meal is important to help get the right amount of medicine in your body. A protein-rich nutritional drink alone does not replace a meal.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking JASUPA.

If you are of the age of falling pregnant, you should have a negative pregnancy test before you start taking JASUPA.

While you are taking JASUPA you must use a reliable method of contraception, to prevent pregnancy.

Taking dolutegravir (one of the components of JASUPA) at the time of becoming pregnant, or during the first twelve weeks of pregnancy, may increase the risk of a type of birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

Where possible, women who are HIV-positive should not breastfeed, because HIV infection can be passed on to the baby in breast milk. You should not breastfeed your baby when you are on treatment with JASUPA.

Driving and using machines:

JASUPA can make you dizzy and have other side effects that make you less alert. Do not drive or use machines unless you are sure you are not affected.

JASUPA contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking JASUPA.

3. HOW TO TAKE JASUPA:

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

Always take JASUPA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of JASUPA is one tablet once a day **with a meal**.

Swallow the tablet with some water.

You will need regular blood tests. For as long as you are taking JASUPA, your doctor will arrange regular blood tests to check for side effects.

If you take more JASUPA than you should:

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

If you forget to take JASUPA:

If you miss a dose, take it as soon as you remember. JASUPA must be taken with a meal. If your next dose is due within 12 hours, skip the dose you missed and take the next dose at the usual time. Then continue your treatment as before. **Do not take a double dose** to make up for a missed dose.

Effects when treatment is stopped:

JASUPA helps to control your condition, but it is not a cure for HIV infection. You need to keep taking it every day to stop your illness from getting worse. Because JASUPA does not cure HIV infection, you may still develop other infections and illnesses linked to HIV infection.

- **Keep in touch with your doctor and don't stop taking JASUPA** without your doctor's advice.

4. POSSIBLE SIDE EFFECTS:

JASUPA can have side effects.

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

It is very important to talk to your doctor about any changes in your health. Some side effects may only be seen in your blood tests and may not appear immediately after you start taking JASUPA. If you get any of these effects and if they are severe, your doctor may advise you to stop taking JASUPA.

Conditions you need to look out for:

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

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to JASUPA. You may need urgent medical attention or hospitalisation. **Contact your doctor immediately.** Your doctor may decide to carry out tests on your liver, kidneys or blood.

Symptoms of infection and inflammation:

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (*opportunistic infections*). Symptoms of infection may develop, caused by old, hidden infections flaring up again as the body fights them. Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections (e.g., tuberculosis (TB), cytomegalovirus retinitis (an inflammation of the retina of the eye caused by the cytomegalovirus) and Pneumocystis pneumonia (a form of pneumonia caused by a yeast-like fungus called *Pneumocystis jirovecii*)), flaring up again as the body fights them

- the immune system attacking healthy body tissue (*auto-immune disorders* e.g., Graves' disease (overproduction of thyroid hormone), polymyositis (muscle weakness on both sides of the body) and Guillain-Barre syndrome (weakness of the feet or hands)).

The symptoms of auto-immune disorders may develop many months after you start taking medicine to treat your HIV infection.

Symptoms may include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations or tremor
- hyperactivity (excessive restlessness and movement).

If you get any symptoms of infection or if you notice any of the symptoms above, **tell your doctor immediately**. Don't take other medicines for the infection without your doctor's advice.

Fat redistribution: People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:

- fat may be lost from the legs, arms or face.
- extra fat may build up around the tummy (*abdomen*), or on the breasts or internal organs.
- fatty lumps (sometimes called buffalo hump) may appear on the back of the neck.

Tell your doctor if you notice any changes in your body shape.

Old infections may flare up: 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 caused by the body's immune system becoming stronger, so that the body starts to fight these infections. If you get symptoms of infection while you're taking JASUPA, **tell your doctor immediately**. Don't take other medicines for the infection without your doctor's advice.

Other side effects:

Frequent side effects:

- headache
- feeling sick (nausea)
- diarrhoea.
- decreased appetite
- depression
- anxiety
- difficulty sleeping or difficulty falling asleep (insomnia)
- abnormal dreams
- sleep disorders
- dizziness
- stomach pains or discomfort
- being sick (vomiting)
- wind (flatulence)
- rash
- itching (pruritus)
- lack of energy (fatigue)
- increase in liver enzymes (may be shown in blood tests).

Less frequent side effects:

- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)
- depressed mood
- inflammation of the liver (hepatitis)
- feeling drowsy.

Other side effects that may occur:

- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)
- joint pain
- muscle pain
- weight gain.

Other side effects that may show up in blood tests:

- increase in bilirubin (a substance produced by the liver) blood levels
- an increase in the blood level of enzymes produced in the muscles (creatinine phosphokinase,
- an increase in the kidney function blood test result (creatinine).

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the '6.04 Adverse Drug Reaction Reporting Form', found on-line under SAHPRA'S publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of JASUPA.

5. HOW TO STORE JASUPA:

Store at or below 30 °C.

Store in the original package to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant.

Store all medicines out of reach of children.

Return all unused medicines to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems.

6. CONTENTS OF THE PACK

What JASUPA contains:

The active substances are dolutegravir and rilpivirine.

Each film-coated tablet contains 50 mg of dolutegravir (as dolutegravir sodium) and 25 mg of rilpivirine (as rilpivirine hydrochloride).

The other ingredients are croscarmellose sodium, magnesium stearate, D-mannitol, lactose monohydrate, microcrystalline cellulose, polysorbate 20, povidone K30, povidone K29/32, sodium starch glycolate, sodium stearyl fumarate and silicified microcrystalline cellulose. The film-coat contains, polyvinyl alcohol, titanium dioxide, macrogel/PEG, talc, yellow and red iron oxide.

Contains sugar (as lactose monohydrate 55,15 mg/tablet and D-mannitol 203,14 mg/tablet).

What JASUPA looks like and contents of the pack:

Pink, film-coated, oval, biconvex tablets debossed with 'SV J3T' on one side.

A carton containing a white HDPE (high density polyethylene) bottle closed with polypropylene child-resistant closure. Each bottle contains 30 film-coated tablets and a desiccant.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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