PATIENT INFORMATION LEAFLET

CREVAS RANGE

SCHEDULING STATUS:

S4

CREVAS 5 mg (5 mg film coated tablets)

Contains sugar (lactose monohydrate 45,72 mg)

CREVAS 10 mg (10 mg film coated tablets)

Contains sugar (lactose monohydrate 90,90 mg)

CREVAS 15 mg (15 mg film coated tablets)

Contains sugar (lactose monohydrate 137,16 mg)

CREVAS 20 mg (20 mg film coated tablets)

Contains sugar (lactose monohydrate 181,80 mg)

CREVAS 30 mg (30 mg film coated tablets)

Contains sugar (lactose monohydrate 274,372 mg)

CREVAS 40 mg (40 mg film coated tablet)

Contains sugar (lactose monohydrate 233,01 mg)

Rosuvastatin

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

- 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.
- CREVAS 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 CREVAS is and what it is used for

2. What you need to know before you take CREVAS

3. How to take CREVAS

4. Possible side effects

5. How to store CREVAS

6. Contents of the pack and other information

1. What CREVAS is and what it is used for

CREVAS contains 5 mg, 10 mg, 15 mg, 20 mg, 30 mg or 40 mg of rosuvastatin, as rosuvastatin calcium, per film coated tablet and belongs to the pharmacotherapeutic group called 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors.

CREVAS is used to reduce the risk of incidents that may cause damage to the heart muscle in patients at risk of developing heart disease as a result of build-up of fats in and on the blood vessels of the heart. CREVAS is used, together with diet, to lower high levels of fats in the blood, which are called lipids, usually when changes to diet and exercise have failed to do this. CREVAS, in addition to diet, lowers “bad” cholesterol low-density lipoprotein (LDL) and increases “good” cholesterol high-density lipoprotein (HDL) in the blood.
CREVAS is also used to reduce total cholesterol and “bad” cholesterol (LDL) in adult patients with very high cholesterol and a family history of high cholesterol, either alone or together with diet and other lipid lowering treatments.

CREVAS 40 mg should only be considered in patients with severe high cholesterol and high cardiovascular risk who do not achieve their treatment goal on 20 mg of CREVAS or alternative therapy. Specialist supervision is recommended when the 40 mg dose is initiated.
CREVAS can be used in children and adolescents (10 - 17 years of age) to reduce the total cholesterol, “bad” cholesterol (LDL) and lipids in patients with genetically inherited high cholesterol called heterozygous familial hypercholesterolaemia (HeFH).

2. What you need to know before you take CREVAS:

Do not take CREVAS:

- if you are hypersensitive (allergic) to rosuvastatin or any of the other ingredients of CREVAS (see section 6)
- if you currently have a liver disease
- if you have severe kidney problems
- if you take a medicine called ciclosporin (used, for example, after organ transplants) (see Other medicines and CREVAS)
- if you are pregnant or breastfeeding or if you are a woman of childbearing potential not using appropriate contraceptive measures (see Pregnancy, breastfeeding and fertility)
- if you have repeated or unexplained muscle aches or pains.

Patients with the following predisposing conditions for a muscle disease called myopathy must not take CREVAS 40 (the highest dose). The following conditions may increase the risk of muscle disorders:

- if you have moderate kidney problems (if in doubt, please ask your doctor)
- if you have a condition called hypothyroidism (underactive thyroid)
- if you have had any repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines
- if you regularly drink large amounts of alcohol
- if you are taking other medicines called fibrates (for high cholesterol)
- if you are of Asian descent.

Warnings and precautions

Take special care with CREVAS

Tell your doctor or healthcare professional before taking CREVAS:

- if you have problems with your kidneys
- if you have unexplained muscle aches and pains, muscle weakness, cramps and especially if you feel unwell or have a fever, tell your doctor immediately
- if your thyroid gland is not working properly (hypothyroidism)
- if you have a personal or family history of hereditary muscular disorders
- if you have a previous history of muscle problems when using cholesterol lowering medicines
- if you regularly consume large amounts of alcohol
- if you are above 70 years of age
- if you are taking fibrates (cholesterol lowering medicine) please see Other medicine and CREVAS
- if you are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection), orally or by injection. The combination of fusidic acid and CREVAS can lead to serious muscle problems (rhabdomyolysis), please see Other medicine and CREVAS
- if you are taking other HMG-CoA reductase inhibitors together with fibric acid derivatives including gemfibrozil, ciclosporin, nicotinic acid, azole antifungals, protease inhibitors (such as lopinavir/ritonavir – medicines used to treat human immunodeficiency virus (HIV) infection) and macrolide antibiotics (see Other medicine and CREVAS).

CREVAS may cause interstitial lung disease, especially with long-term treatment. Tell your doctor if you experience difficulty breathing, develop a non-productive cough and/or deterioration in general health (e.g. fatigue, weight loss and fever) while taking CREVAS.

Serious skin reactions including Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with CREVAS treatment. Stop taking CREVAS and seek medical attention immediately if you notice any of the following symptoms: reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes preceded by fever and flu-like symptoms, widespread rash, high body temperature and enlarged lymph nodes.

Should you develop a serious reaction such as SJS or DRESS during CREVAS therapy, treatment must not be restarted at any time.

In a small number of people, CREVAS can affect the liver. This is identified by a test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will usually carry out this blood test (liver function test) before treatment starts with CREVAS, and if needed thereafter.

CREVAS may cause myasthenia gravis and ocular myasthenia, which are conditions that cause muscle weakness, impaired speech, difficulty swallowing and drooping of one or both eyelids or double vision. Tell your doctor if you experience any of these symptoms while taking CREVAS.

In patients whose high cholesterol is caused by another disease, such as thyroid or kidney problems, the underlying disease should be treated prior to initiating therapy with CREVAS.

While you are on CREVAS your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. CREVAS should be used with care in patients with type 2 diabetes and in patients at risk.

Children and adolescents

The same special warnings and special precautions for use in adults also apply to children and adolescents.

Other medicines and CREVAS:

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

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

Contraindicated combinations

CREVAS should not be used together with ciclosporin (used for example, after organ transplants).

The 40 mg dose is contraindicated with concomitant use of a fibrate.

There may be a higher than usual chance of other side effects

- fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe) as these medicines may increase the effect of CREVAS and the risk of developing serious muscle problems (see Do not take CREVAS above)
- fusidic acid (an antibiotic) may increase the risk of developing serious muscle problems (see Take special care with CREVAS above). If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using CREVAS. Your doctor will tell you when it is safe to restart CREVAS. Taking CREVAS with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis)
- darolutamide (used to treat cancer) may increase the effect of CREVAS
- medicines used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Take special care with CREVAS above), as these medicines may increase the effect of CREVAS and may lead to an increase in the possible side effects of CREVAS: ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir, darunavir, tipranavir, simeprevir.

Effect of CREVAS may be increased when taken with the following:

- warfarin or clopidogrel (or any other medicine used for thinning the blood) as CREVAS may affect the way this medicine works; clopidogrel may increase the effect of CREVAS

- ticagrelor (used for the prevention of stroke, heart attack) as taking CREVAS at the same time may cause unwanted side effects
- regorafenib (used to treat cancer) as this may increase the effect of CREVAS
- eltrombopag (used to treat low blood platelet counts caused by an autoimmune disorder) as this may increase the effect of CREVAS
- dronedarone (used to treat abnormal heart rhythm) as this may increase the effect of CREVAS
- itraconazole (used to treat fungal infections) as this may increase the effect of CREVAS
- niacin and nicotinic acid (used for example, to lower the fat in your blood).

Effect of CREVAS may be decreased if taken with the following:

- indigestion remedies, such as antacids (used to neutralise acid in your stomach) as these medicines may decrease the effect of CREVAS
- erythromycin (an antibiotic) as this may decrease the effect of CREVAS.

CREVAS may increase the effect of other medicines including the following:

- oral contraceptives (the pill) as CREVAS may increase the effect of contraceptives
- hormone replacement therapy as CREVAS may increase the effect of these medicines.

CREVAS with food and alcohol

You can take CREVAS with or without food.

If you regularly drink large amounts of alcohol, it may increase your risk of muscle disorders.

Pregnancy, breastfeeding and fertility

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 taking CREVAS.

You should use appropriate contraceptive measures, if you are a woman of child bearing potential.

You should not take CREVAS if you are pregnant or breastfeeding your baby.

Driving and using machines

CREVAS is unlikely to affect this ability. CREVAS may cause dizziness, therefore you should not drive or use machines until you know how CREVAS affects you.

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

CREVAS contains colourants

CREVAS 5 mg, 15 mg and 30 mg contains quinoline yellow aluminium lake (E104).

CREVAS 10 mg contains alura red aluminium lake (E129).

CREVAS 40 mg contains sunset yellow aluminium lake (E110) and ponceau aluminium lake (E124).

The above colourants may cause allergic reactions.

CREVAS contains lactose monohydrate

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

3. How to take CREVAS:

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

Always take CREVAS exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Before starting treatment, your doctor should place you on a standard cholesterol-lowering diet that should continue during treatment.

The dosage range for CREVAS is 5 - 40 mg orally once a day. The recommended start dose is 5 mg once a day.

Your dosage will be individualised according to your cholesterol levels, your risk factors and your response to CREVAS-therapy. The majority of patients are controlled at the 10 mg dose. However, if necessary, your doctor will adjust your dose at 2 – 4 week intervals.

A 5 mg starting dose is recommended for patients of Asian ancestry and for patients requiring a smaller reduction in “bad” cholesterol (LDL-C) to achieve treatment target.

For patients with severely high cholesterol (including genetically inherited high cholesterol,), a start dose of 20 mg may be considered.

For patients with genetically inherited high cholesterol, a start dose of 20 mg once a day is recommended.

Children and adolescents 10 - 17 years of age

In children and adolescents with genetically inherited high cholesterol, the usual dose range is 5 – 20 mg orally once daily.

Special populations

Your doctor will prescribe a suitable dosage if you are elderly, if you have a kidney or liver disorder.

Your doctor will tell you how long your treatment with CREVAS will last. It may take weeks or months of treatment for you to see any improvement in your symptoms and your symptoms might even worsen when CREVAS is started. Do not stop treatment early.

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

If you take more CREVAS 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 you forget to take CREVAS

If you forget to take CREVAS, take a dose as soon as you remember, then continue to take CREVAS at the usual times. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking CREVAS

Talk to your doctor if you want to stop taking CREVAS. Your cholesterol levels might increase again if you stop taking this medicine.

4. Possible side effects

CREVAS can have side effects.

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

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

- 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 allergic reaction to CREVAS. 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:

- severe itching of the skin (with raised lumps), blistering of the skin, mouth and eyes (Stevens-Johnson syndrome)

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)
- jaundice (yellowing of the skin and eyes)
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)
- any unusual aches and pains in your muscles which go on for longer than you might expect, especially if you develop a fever or feel unwell. Unpleasant muscle effects may become a potentially life-threatening muscle damage known as rhabdomyolysis. Muscle symptoms are more frequent in children and adolescents than in adults
- tendon disorders sometimes complicated by rupture
- serious muscle damage presenting as unexplained muscle aches and pains, feeling unwell and a fever (immune-mediated necrotising myopathy)
- a severe stomach pain (inflamed pancreas)
- increase in liver enzymes in the blood
- hepatitis (an inflamed liver).

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:

- increased glucose levels, diabetes
- headache, dizziness
- constipation, nausea, stomach pain
- muscle pain
- feeling weak or a lack of energy.

Less frequent side effects:

- abnormal bleeding or bruising
- memory loss

- numbness, tingling, loss of sensation in the arms and legs, burning feeling in the hands or feet (polyneuropathy)
- rash, itching or other skin reactions
- oedema (swelling under the skin)
- muscle rupture, inflammation of the muscle
- joint pain
- traces of blood in your urine
- breast enlargement in men (gynaecomastia).

The following side effects have been reported but the frequency for them to occur is not known*:*

- depression
- sleep disturbances including insomnia and nightmares
- diarrhoea
- an increase in the amount of protein in the urine
- numbness and tingling in hands or feet (peripheral neuropathy)
- muscle weakness, impaired speech, difficulty swallowing and drooping of one or both eyelids or double vision (myasthenia gravis and ocular myasthenia)
- cough, shortness of breath, difficulty breathing.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CREVAS. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store CREVAS

Store all medicines out of reach of children.

Store at or below 30 °C in a cool, dry place.

Protect from light.

Keep the tablets in the outer carton until required for use.

Do not use after the expiry date stated on the 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 CREVAS contains:

The active substance is rosuvastatin.

Each film coated tablet contains rosuvastatin calcium equivalent to either rosuvastatin 5, 10,15, 20, 30 or 40 mg.

The other ingredients are:

Tablet cores

Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

Opadry-coating/Film coating

Allura red aluminium lake (E29)[2], carmine (E120)[3], hypromellose (E464), lactose monohydrate, ponceau aluminium lake (E124)[4], quinolone yellow aluminium lake (E104)[1], sunset yellow aluminium lake (E110)[4], titanium dioxide (E171), triacetin (E1518).

[1] Applicable to 5 mg, 15 mg and 30 mg strengths only

[2] Applicable to 10 mg strength only

[3] Applicable to 20 mg strength only

[4] Applicable to 40 mg strength only

What CREVAS looks like and contents of the pack

CREVAS 5 mg: Round, biconvex, yellowish film coated tablets, 6 mm in diameter, debossed with "5" on one side.

CREVAS 10 mg: Round, biconvex, light pink film coated tablets, 7 mm in diameter, debossed with "10" on one side.

CREVAS 15 mg: Round, biconvex, yellow film coated tablets, 8 mm in diameter, debossed with "15" on one side and "15" on the other side.

CREVAS 20 mg: Round, biconvex, dark pink film coated tablets, 9 mm in diameter, debossed with "20" on one side

CREVAS 30 mg: Round, biconvex, yellow film coated tablets, 10 mm in diameter, debossed with "30" on one side.

CREVAS 40 mg: Round, biconvex, red film coated tablets, 10 mm in diameter, debossed with "40" on one side

CREVAS is available in polyamide/aluminium/PVC/

aluminium foil blister strips, packed in an outer carton, in packs of 7, 14, 28, 30, 56 or 98 film coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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CREVAS 5 mg: A46/7.5/0313

CREVAS 10 mg: A46/7.5/0314

CREVAS 15 mg: A55/7.5/0453*

CREVAS 20 mg A46/7.5/0315

CREVAS 30 mg: A55/7.5/0454*

CREVAS 40 mg: A46/7.5/0316*

NAMIBIA

CREVAS 5 mg: NAM NS2 21/7.5/0057

CREVAS 10 mg: NAM NS2 21/7.5/0058

CREVAS 20 mg: NAM NS2 21/7.5/0059

CREVAS 40 mg: NAM NS2 21/7.5/0060

MOZAMBIQUE*

CREVAS 5 mg: C6912

CREVAS 10 mg: C6913

CREVAS 20 mg: C6914

*CREVAS 15 mg, CREVAS 30 mg and CREVAS 40 mg are not marketed in Mozambique.