PATIENT INFORMATION LEAFLET FOR STORWIN

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

STORWIN® 10 mg film-coated tablets

STORWIN® 20 mg film-coated tablets

STORWIN® 40 mg film-coated tablets

Read this leaflet carefully before you start taking STORWIN:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- STORWIN 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 STORWIN CONTAINS:

The active substance is rosuvastatin.

STORWIN 10 mg: Each film-coated tablet contains 10 mg of rosuvastatin as rosuvastatin calcium.

STORWIN 20 mg: Each film-coated tablet contains 20 mg of rosuvastatin as rosuvastatin calcium.

STORWIN 40 mg: Each film-coated tablet contains 40 mg of rosuvastatin as rosuvastatin calcium.

The other ingredients are: colloidal anhydrous silica, croscarmellose sodium, hypromellose 2910/5, iron oxide red, lactose monohydrate, macrogol 6 000, magnesium stearate, microcrystalline cellulose, talc and titanium dioxide.

Contains sugar:

STORWIN 10 mg: 60 mg lactose monohydrate per film-coated tablet.

STORWIN 20 mg: 120 mg lactose monohydrate per film-coated tablet.

STORWIN 40 mg: 240 mg lactose monohydrate per film-coated tablet.

WHAT STORWIN IS USED FOR:

STORWIN belongs to a group of medicines called statins.

You have been prescribed STORWIN because changing your diet and increased exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking STORWIN.

BEFORE YOU TAKE STORWIN:

Do not take STORWIN if:

- You have ever had an allergic reaction to STORWIN, or to any of its ingredients, or similar medicines.
- You are pregnant or breastfeeding (see Pregnancy and breastfeeding).
- You currently have liver disease.
- You have severe kidney problems.
- You have repeated or unexplained muscle aches or pains, or any disease of the muscles.
- You take a medicine called ciclosporin (used for example, after organ transplants).

Safety and efficacy have not been demonstrated in children.

If any of the above applies to you (or you are in doubt), **please go back and see your doctor**.

In addition, do not take STORWIN 40 mg (the highest dose) if:

- You have moderate kidney problems (if in doubt, please ask your doctor).
- Your thyroid gland is not working properly.
- You have had 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.

- You drink large amounts of alcohol.
- You are of Asian descent.
- You take other medicines called fibrates to lower your cholesterol.

If any of the above applies to you (or you are in doubt), **please go back and see your doctor**.

Take special care with STORWIN if:

- You have problems with your kidneys.
- You have problems with your liver.
- You have had 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. Tell your doctor immediately if you have unexplained muscle aches or pains, especially if you feel unwell or have a fever.
- You regularly drink large amounts of alcohol.
- Your thyroid gland is not working properly.
- You take other medicines, called fibrates, to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
- You take medicines to fight HIV infection e.g. lopinavir/ritonavir (see Taking other medicines with STORWIN).
- You are below 18 years of age: STORWIN is not suitable for use in children and adolescents below 18 years of age.
- You are over 70 years old (your doctor needs to choose the right starting dose of STORWIN to suit you).
- You have severe respiratory failure.
- You are of Asian descent. Your doctor needs to choose the right starting dose of STORWIN to suit you.

If any of the above applies to you (or if you are not sure), **do not take STORWIN and check with**

your doctor or pharmacist before you actually start taking any dose of STORWIN.

STORWIN may affect the liver. This is identified by a simple 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 and during treatment with STORWIN. In addition, you should notify your doctor right away if you have any of the following symptoms: unusual fatigue or weakness; loss of appetite; stomach pain; dark-coloured urine; or yellowing of the skin or the whites of the eyes.

STORWIN may cause an increase in blood sugar levels. If you are diabetic or are at risk of developing diabetes, you should monitor your blood sugar level and contact your doctor for advice. 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.

Taking STORWIN with food and drink:

You may take STORWIN with or without food.

Pregnancy and breastfeeding:

Do not take STORWIN if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking STORWIN.

Women should avoid becoming pregnant while taking STORWIN by using suitable contraception.

Driving and using machinery:

Most people can drive a car and operate machinery while taking STORWIN - it will not affect their ability. However, some people feel dizzy during treatment with STORWIN. If you feel

dizzy, consult your doctor before attempting to drive a vehicle or use machines.

Important information about some of the ingredients of STORWIN:

STORWIN contains lactose monohydrate (a type of sugar), which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking STORWIN.

Taking other medicines with STORWIN:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines). Concomitant use of these medicines with STORWIN may cause undesirable interactions.

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

- ciclosporin (used for example, after organ transplants)
- warfarin or clopidogrel (used for thinning the blood)
- eltrombopag (used to prevent bleeding in people with bleeding conditions)
- fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe)
- indigestion remedies (used to neutralise acid in your stomach)
- erythromycin (an antibiotic)
- baicalin (used in traditional Chinese medicine to treat inflammation, high blood pressure or heart diseases)
- an oral contraceptive (the pill)
- hormone replacement therapy
- fucidic acid (an antibiotic) (see Take special care with STORWIN)
- anti-viral medications such as ritonavir with lopinavir and/or atazanavir, simeprevir,

darunavir, tipranavir (used to treat infections, including HIV or hepatitis C infection (see Take special care with STORWIN)).

- dronedarone is used to treat heart rhythm disorders
- itraconazole (used to treat fungal infections).

The effects of these medicines could be changed by STORWIN or they could change the effects of STORWIN.

HOW TO TAKE STORWIN:

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

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

Usual doses in adults:

If you are taking STORWIN for high cholesterol:

Your doctor will determine the dose according to the severity of your condition and other factors affecting the dose.

Starting dose:

Your treatment with STORWIN usually starts with the 5 mg (halve a 10 mg tablet with a break-line) dose**,** even if you have taken a higher dose of a different statin before.

Your dose will depend upon:

- your cholesterol level.
- the level of risk you have of experiencing a heart attack or stroke.
- whether there are factors that may make you more sensitive to possible side effects.

The following patients should start with the lowest dose (5 mg – halve a 10 mg tablet with a break-line):

- patients of Asian descent
- patients who are over 70 years of age
- patients with moderate kidney problems
- patients at risk of muscle aches and pains (myopathy).

Increasing the dose and maximum daily dose:

Your doctor may decide to increase your dose. This is so that you are taking the amount of STORWIN that is right for you.

If you started with a 5 mg dose (halve a 10 mg tablet with a break-line), your doctor may decide to double this to 10 mg, then 20 mg and then 40 mg if necessary.

There should be a gap of four weeks between every dose adjustment.

The maximum daily dose of STORWIN is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg, without the risk factors mentioned above.

If you are taking STORWIN to reduce your risk of having a heart attack, stroke or related health problems:

The recommended dose is 20 mg daily. However, your doctor may decide to use a lower dose if you have any of the factors mentioned above.

Your doctor will tell you how long your treatment with STORWIN will last.

If you have the impression that the effect of STORWIN is too strong or too weak, tell your doctor or pharmacist. Do not stop taking your tablets even if you are feeling well unless your

doctor tells you to, or you become pregnant.

Taking your tablets:

Swallow each tablet whole with a little water.

Take STORWIN once a day, every day, at about the same time each day. You can take it at any time of the day. Taking your tablets at the same time each day will help you remember when to take the tablets.

Regular cholesterol checks:

It is important to go back to your doctor for regular cholesterol checks, to make sure your cholesterol has reached and is staying at the correct level. Your doctor may decide to increase your dose so that you are taking the amount of STORWIN that is right for you.

If you take more STORWIN 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 go into hospital or receive treatment for another condition, tell the medical staff that you are taking STORWIN.

If you forget to take STORWIN:

If you forget to take your dose of STORWIN, just take your next scheduled dose at the correct time. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with STORWIN is stopped:

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

POSSIBLE SIDE EFFECTS:

STORWIN can have side effects.

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

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

- difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat.
- swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.
- severe itching of the skin (with raised lumps).

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

- you have any unusual aches or pains in your muscles which go on for longer than you might expect. A very small number of people have experienced unpleasant muscle effects and these have, not frequently, gone on to become potentially life-threatening muscle damage known as *rhabdomyolysis.*
- you have severe stomach pain (due to an inflamed pancreas).
- you have an increase in liver enzymes in the blood, jaundice (yellowing of the skin and whites of the eyes), or hepatitis (an inflamed liver).

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

Possible side effects frequently encountered in patients:

- headache
- stomach pain
- constipation
- feeling sick
- muscle pain
- feeling weak
- dizziness
- lack of energy
- an increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your STORWIN tablets (only STORWIN 40 mg)
- diabetes, mostly in those with blood sugar at the upper end of "normal".

Possible side effects less frequently encountered in patients:

- rash, itching or other skin reactions
- an increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your STORWIN tablets (only STORWIN 5 mg (halve a 10 mg tablet with a break-line), 10 mg and 20 mg)
- bleeding or bruising more easily than normal due to low level of blood platelets
- traces of blood in your urine
- damage to the nerves of your legs and arms (such as numbness)
- joint pain
- memory loss
- diarrhoea (loose stools)
- Stevens-Johnson syndrome (serious blistering condition of the skin, mouth, eyes and genitals)
- cough

- oedema (swelling)
- sleep disturbances, including sleeplessness and nightmares
- sexual difficulties
- depression
- breathing problems, including persistent cough and/or shortness of breath or fever
- breast enlargement in men (gynaecomastia).

Possible side effects encountered in patients, with an unknown frequency:

- peripheral neuropathy (characterized by numbness, prickling or tingling in your hands and feet), sleep disturbances (including insomnia and nightmares)
- coughing
- muscle weakness, tendon disorders (sometimes complicated by rupture).

If any of the side effects become troublesome, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF STORWIN:

Store all medicines out of the reach of children.

Store at or below 25 °C.

Store in the original container.

Protect from light and moisture.

Do not remove from outer carton until required for use.

Do not store in a bathroom.

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).

PRESENTATION OF STORWIN:

STORWIN 10 mg: The packs consist of 30 tablets each, packed in blister strips, 10 or 15 film-coated tablets in each blister, enclosed in a cardboard carton, inclusive of a professional information leaflet.

STORWIN 20 mg: The packs consist of 30 tablets each, packed in blister strips, 10 film-coated tablets in each blister, enclosed in a cardboard carton, inclusive of a professional information leaflet.

STORWIN 40 mg: The packs consist of 30 tablets each, packed in blister strips, 10 film-coated tablets in each blister, enclosed in a cardboard carton, inclusive of a professional information leaflet.

The blister strips are composed of triple laminated forming material and aluminium lidding material and are silver in colour.

IDENTIFICATION OF STORWIN:

STORWIN 10 mg: light pink, film-coated, oval, biconvex tablet with halving score.

STORWIN 20 mg: pink, film-coated, oval, biconvex tablet.

STORWIN 40 mg: dark pink, film-coated, oval, biconvex tablet.

REGISTRATION NUMBERS:

STORWIN 10 mg: 45/7.5/0502

STORWIN 20 mg: 45/7.5/0503

STORWIN 40 mg: 45/7.5/0504

NAME AND ADDRESS OF REGISTRATION HOLDER:

Zentiva South Africa (Pty) Ltd

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