SCHEDULING STATUS: S3

DIPSAR 5/160 (5 mg amlodipine and 160 mg valsartan), film-coated tablets

DIPSAR 10/160 (10 mg amlodipine and 160 mg valsartan), film-coated tablets

Sugar free

Read all of this leaflet carefully before you start taking DIPSAR

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

DIPSAR tablets contain two substances called amlodipine and valsartan. Both of these substances help to control high blood pressure.

Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

Valsartan belongs to a group of substances called “angiotensin-II receptor antagonists”. Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

DIPSAR is used to treat high blood pressure in adults whose blood pressure is not controlled enough with either amlodipine or valsartan on its own.

2. What you need to know before you take DIPSAR

Do not take DIPSAR:

- if you are hypersensitive (allergic) to amlodipine or any other calcium channel blockers, valsartan or to any of the other ingredients of DIPSAR (listed in section 6);
- if you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking DIPSAR and contact your doctor straight away. You should never take DIPSAR again;
- if you have recurrent episodes of severe swelling;
- if your doctor has diagnosed that you are suffering from a narrowing of valves in your heart (called aortic or mitral stenosis), or abnormally increased thickness of your heart muscle with narrowing (called obstructive hypertrophic cardiomyopathy);
- if you have received a kidney transplant or if you had been diagnosed to suffer from a narrowing of your kidney artery or if you are suffering from severe kidney problems;
- if you are taking other medicine or substances, which increase the potassium levels in your blood (such as certain types of diuretics, potassium supplements, etc.);
- if you have porphyria;

- if you are taking a medicine called lithium;
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren;
- if you have severe liver impairment;
- if you have severe low blood pressure (hypotension);
- if you have cardiogenic shock (a condition where your heart is unable to supply enough blood to the body);
- if you suffer from heart failure after a heart attack;
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with DIPSAR:

- if you are taking aliskiren (see "Do not take");
- if you have been sick (vomiting or diarrhoea);
- if you have had a kidney transplant or if you had been told that you have a narrowing of your kidney arteries;
- if you have liver or kidney problems;
- if you have a condition affecting the renal glands called "primary hyperaldosteronism";
- if you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking DIPSAR and contact your doctor straight away. You should never take DIPSAR again;
- if you have had heart failure or have experienced a heart attack. Follow your doctor's instructions for the starting dose carefully. Your doctor may also check your kidney function;

Contact your doctor to re-evaluate your treatment if you are treated with ACE Inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Children and adolescents

The use of DIPSAR in children and adolescents is not recommended (aged below 18 years old).

Other medicines and DIPSAR

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

Tell your doctor if you are taking:

- ACE inhibitors or aliskiren (medicines used to treat high blood pressure) (see also information under the headings "Do not take DIPSAR");
- diuretics (a type of medicine also called "water tablets" which increases the amount of urine you produce);
- potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and other substances that may increase potassium levels;
- nitroglycerin and other nitrates, or other substances called "vasodilators";
- medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir);
- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole);
- clarithromycin (for infections caused by bacteria);
- verapamil, diltiazem (heart medicines);
- medicines used to treat bacterial infections (such as rifampicin, erythromycin, telithromycin);
- anticonvulsant medicines (e.g. carbamazepine, phenobarbitone, phenytoin, fosphenytoin, primidone);
- St. John's wort;
- simvastatin (a medicine used to control high cholesterol levels);
- dantrolene (infusion for severe body temperature abnormalities);
- tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ);
- medicines used to protect against transplant rejection (ciclosporin);

- lithium (a medicine used to treat some types of depression) (see also information under the headings “Do not take DIPSAR”);
- certain types of painkillers called non-steroidal anti-inflammatory medicines (NSAIDs) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may also check your kidney function.

DIPSAR with food and drink

Grapefruit and grapefruit juice should not be consumed by people who are taking DIPSAR. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of DIPSAR.

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 DIPSAR.

Safety of DIPSAR in pregnant and breastfeeding women has not been established.

You should not use DIPSAR if you are pregnant, trying to become pregnant or breastfeeding your baby.

If you are a woman of childbearing age, you should ensure that you use an effective contraception.

Driving and using machines

This medicine may make you feel dizzy. This can affect how well you can concentrate.

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

DIPSAR is sugar free.

3. How to take DIPSAR

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

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

The usual dose of DIPSAR is one tablet per day.

- It is preferable to take your medicine at the same time each day.
- Swallow the tablets with a glass of water.
- You can take DIPSAR with or without food. Do not take DIPSAR with grapefruit or grapefruit juice.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Do not exceed the prescribed dose.

DIPSAR and older people (age 65 years or over)

Your doctor should exercise caution when increasing your dose.

If you take more DIPSAR than you should

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

If you forget to take DIPSAR

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

If you stop taking DIPSAR

Stopping your treatment with DIPSAR may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

DIPSAR can have side effects.

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

If any of the following symptoms occur, stop taking the DIPSAR 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 allergic reaction to DIPSAR. 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:

- sudden wheeziness, chest pain, shortness of breath or difficulty in breathing;
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions;
- inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell;
- heart attack, abnormal heartbeat;

- upper airway swelling.

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

- influenza (flu), blocked nose, sore throat and discomfort when swallowing;
- low potassium levels;
- headache;
- asthenia (weakness);
- dizziness;
- palpitations (awareness of your heartbeat);
- stomach pain;
- feeling sick (nausea);
- tiredness;
- facial swelling;
- redness and warm feeling of the face and/or neck;
- swelling in the body caused by excess fluid. It often affects the lower body, such as the legs, feet, and ankle but it can occur anywhere.

Less frequent side effects

- loss of appetite;
- high calcium, sugar, cholesterol or uric acid levels in the blood;
- low levels of sodium in the blood;
- feeling anxious;
- dizziness, abnormal coordination;
- drowsiness, tingling or numbness of the hands or feet;

- vision disturbance and impairment;
- ringing in the ears, head spinning;
- fast heartbeat including palpitations;
- low blood pressure and light-headedness when standing up;
- cough, sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis);
- throat pain;
- constipation, change of bowel habit;
- abdominal pain;
- diarrhoea, dry mouth;
- nausea, vomiting, indigestion;
- excessive sweating;
- redness of the skin;
- skin rash all over your body;
- joint swelling;
- back pain, pain in joints, muscle spasm, muscle cramps;
- sensation of heaviness;
- passing more urine than normal or feeling more of an urge to pass urine;
- inability to get or maintain an erection;
- a low level of white blood cells in the blood;
- low blood platelet count;
- excess sugar in blood (hyperglycaemia);
- mood changes, depression, confusion;
- taste abnormalities, loss of pain sensation, abnormal sensation, typically tingling or pricking (‘pins and needles’), high level of muscle tone;
- trembling, sleeplessness, partial or total loss of sensation in a part of your body;
- an inflammation of the blood vessels that causes changes in the blood vessel walls;

- swelling of the gums;
- abdominal bloating (gastritis), increased liver enzyme increase which may have an effect on some medical tests;
- abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice);
- hair loss;
- skin discolouration;
- skin sensitivity to light, purple spots under the skin, hives;
- discomfort or enlargement of the breasts in men;
- lack of energy;
- chest pain, feeling unwell;
- pain;
- weight increase or decrease.

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 DIPSAR.

5. How to store DIPSAR

Store at or below 25 ℃.

Store in the original packaging until required for use.

6. Contents of the pack and other information

What DIPSAR contains

DIPSAR 5/160: Each film-coated tablet contains 6,94 mg amlodipine besylate (equivalent to 5 mg amlodipine base) and 160 mg valsartan.

DIPSAR 10/160: Each film-coated tablet contains 13,87 mg amlodipine besylate (equivalent to 10 mg amlodipine base) and 160 mg valsartan.

What DIPSAR looks like and contents of the pack

DIPSAR 5/160

Yellow coloured, ovaloid shaped, bevelled edge, biconvex, film-coated tablets, debossed with 'J' on one side and '37' on other side.

DIPSAR 10/160

Light yellow coloured, ovaloid shaped, bevelled edge, biconvex film-coated tablets, debossed with 'J' on one side and '38' on other side.

DIPSAR is packed in cold formable film (25-micron OPA/45-micron Aluminium foil/60-micron PVC) - Aluminium foil blister pack. DIPSAR film-coated tablets packed in above blisters will be further packed in pre-printed cartons with package leaflet according to the approved pack size.

Pack sizes: 3 x 10's (Blister)

Holder of Certificate of Registration

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This leaflet was last revised in

12 October 2021

Registration number

DIPSAR 5/160: 49/7.1.3/0009

DIPSAR 10/160: 49/7.1.3/0010