

**PROPOSED PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** **S4**

**GESAVIN 5 mg TABLETS**

**Warfarin (as warfarin sodium)**

**Contains 149,2 mg lactose monohydrate**

**0,80 mg sodium**

**Read all of this leaflet carefully before you start taking Gesavin 5 mg**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Gesavin 5 mg 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 Gesavin 5 mg is and what it is used for
2. What you need to know before you take Gesavin 5 mg
3. How to take Gesavin 5 mg
4. Possible side effects
5. How to store Gesavin 5 mg
6. Contents of the pack and other information

## **1. What Gesavin 5 mg is and what it is used for**

Warfarin belongs to a group of medicines called anticoagulants. It is used to reduce the clotting ability of the blood. (It is sometimes called a 'blood thinner').

Gesavin 5 mg is used to prevent and treat blood clots forming in the legs, lungs, brain and heart.

## **2. What you need to know before you take Gesavin 5 mg**

### **Do not take Gesavin 5 mg:**

- If you are allergic to warfarin sodium or any of the other ingredients of Gesavin 5 mg;
- If you have or have ever had any bleeding problems or recently had a stroke caused by bleeding in the brain;
- If you have a condition which causes bleeding (such as a peptic ulcer) or makes you bruise easily;
- If you have severe wounds (including surgical wounds);
- If you have a prosthetic heart valve;
- If you have had an infection of the lining of your heart or around the heart;
- If you suffer from impaired liver or kidney function;
- If you suffer from high blood pressure;
- If you have had surgery within the last 72 hours or are going to have surgery in the next 72 hours;
- If you are pregnant, breastfeeding, planning to get pregnant or gave birth within the last 48 hours;
- If you have a threatened miscarriage;
- If you suffer from painful inflammation and stiffness of your joints;
- If you take other medicines that may cause a significant risk of bleeding;
- If you suffer from a vitamin C deficiency.

### **Warnings and precautions**

Take special care with Gesavin 5 mg:

- Your doctor will monitor your blood thickness levels on a regular basis before and while you are taking Gesavin 5 mg. It is advised to carry an anticoagulant card or other proof that you are taking blood thinners;
- If you have a condition making you prone to blood clots (thrombophilia);
- You should not stop your treatment with Gesavin 5 mg abruptly. Your doctor will decrease your dose gradually over three to four weeks;
- Special care is needed during your treatment with Gesavin 5 mg if you are elderly, suffer from dietary or vitamin K deficiency, are on antibiotic treatment, suffer from thyroid disease, vascular disease, diabetes or have allergic disorders;
- If you plan to have any surgery or a dental procedure. Tell your doctor or dentists that you are taking Gesavin 5 mg. This should be done before you have any surgery or dental procedures. Your treatment with Gesavin 5 mg may need to be stopped for a short time or you may need your dose adjusted. Gesavin 5 mg can affect your anaesthetic or cause bleeding;
- Consult with your doctor on a regular basis if you have lost or gained weight, have an acute illness (e.g. diarrhoea or vomiting) or recently stopped smoking as your dose may need to be changed.

### **Children and adolescents**

Gesavin 5 mg should not be used in children and adolescents under 18 years old.

### **Other medicines and Gesavin 5 mg**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). Please inform your health care provider, before you take Gesavin 5 mg, if you are currently taking one of the following medicines:

- Any medicines used to thin your blood or dissolve blood clots;
- Any medicines to treat heart problems;
- Any medicines to treat for depression including herbal medicines;

- Any medicines used to treat pain and inflammation such as aspirin;
- Any medicines to lower cholesterol in your blood;
- Any medicines to treat bacterial or fungal infections;
- Any medicines that treat stomach ulcers or stomach acids;
- Any medicines used to treat high blood sugar;
- Any medicines used to treat gout;
- Any medicines used to treat epilepsy or fits;
- Any medicines used to treat breast or prostate cancer;
- Any medicines used to treat sleeping problems;
- Medicines used to treat alcoholism (disulfiram), oral contraceptives, anabolic steroids, corticosteroids, methylphenidate for hyperactivity or dipyridamole (to stop blood cells sticking together);
- Any medicines used to treat thyroid problems;
- Vitamin K supplements.

### **Gesavin 5 mg with food, drink and alcohol**

Gesavin 5 mg should be taken at the same time each day, preferably on an empty stomach.

Do not drink large amounts of alcohol while taking Gesavin 5 mg.

Drinking cranberry juice or taking other cranberry products (for example capsules or concentrates), might increase the effect of Gesavin 5 mg in “thinning” the blood. You should therefore avoid drinking/taking these products whilst taking Gesavin 5 mg. If you have been advised to take cranberry juice or other products for medical reasons (e.g. bladder infections), or are regularly drinking or taking cranberry products, you should contact your anticoagulant clinic or health advisor before making any changes to the amount you drink/take. Your doctor or clinic may wish to monitor you more frequently while you are taking any cranberry product.

Grapefruit juice may cause a slight increase in the time your blood takes to clot. Certain foods such as liver, broccoli, brussels sprouts and green leafy vegetables contain large amounts of vitamin K. Sudden changes in your diet can affect your bleeding time. You should seek medical advice before undertaking any major changes in your diet.

### **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 health care provider for advice before taking Gesavin 5 mg.

You should not take Gesavin 5 mg if you are pregnant, breastfeeding your baby or have had a baby within the last 48 hours.

Women of childbearing age who are taking Gesavin 5 mg should use effective contraception during treatment.

### **Driving and using machines**

It is not always possible to predict to what extent Gesavin 5 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Gesavin 5 mg affects them.

### **Gesavin 5 mg contains lactose monohydrate**

Gesavin 5 mg contains lactose monohydrate which is a sugar derived from milk. If you have been told by your doctor that you have an intolerance to sugars, contact your doctor before taking Gesavin 5 mg.

### **3. How to take Gesavin 5 mg**

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

Always take Gesavin 5 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your dose will be decided by your doctor and will depend on the results of the blood tests carried out to measure the time it takes your blood to clot.

Your doctor will tell you exactly how many tablets of Gesavin 5 mg you should take initially.

Once you have been stabilised on Gesavin 5 mg, the usual dose is between 2,5 - 10 mg once a day. Take Gesavin 5 mg at the same time each day, preferably on an empty stomach. The tablet can be divided into equal doses.

#### **Children and adolescents**

Children and adolescents under 18 years should not take Gesavin 5 mg.

If you have the impression that the effect of Gesavin 5 mg is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more Gesavin 5 mg than you should**

If you take too many tablets, or if you have unexplained bleeding, call your doctor or contact your nearest hospital immediately.

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 Gesavin 5 mg**

If you forget to take a dose, take it as soon as you remember it. 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 stop taking Gesavin 5 mg**

Your doctor will tell you how long your treatment with Gesavin 5 mg will last. Do not stop treatment early or abruptly. When your doctor tells you to stop taking Gesavin 5 mg, he/she will instruct you on how to stop taking them gradually to minimise the risk of unexpected bleeding.

#### **4. Possible side effects**

Gesavin 5 mg can have side effects.

Not all side effects reported for Gesavin 5 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Gesavin 5 mg, please consult your health care provider for advice.

If any of the following happens, stop taking Gesavin 5 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Blurred vision, slurred speech, loss of movement, numbness, dizziness, headache, confusion, feeling or being sick, fits, loss of consciousness. These could be a sign of a bleed in the brain.

- Swelling of the face, tongue, lips and throat, difficulty breathing, severe itching of your skin with raised lumps.
- A painful skin rash. On rare occasions Gesavin 5 mg can cause serious skin conditions, including one called calciphylaxis that can start with a painful skin rash but can lead to other serious complications. This adverse reaction occurs more frequently in patients with chronic kidney disease.

These are all very serious side effects. If you have them, you may have had a serious reaction to Gesavin 5 mg. 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:

- Unexplained nose bleeds.
- Black (tarry) or red stools which may be caused by internal bleeding.
- Dark red or brown urine which may be caused by problems with your kidneys or bladder.
- Coughing up blood.
- In women, unusually heavy periods or bleeding from the vagina.
- Painful, blue-purple coloured toes.
- Yellowing of the skin and white of eyes (jaundice).
- Severe pain in the upper abdomen (a sign of inflammation of the pancreas) which may cause nausea and vomiting.

Tell your doctor if you notice any of the following:

*Frequency of side effects unknown:*

- Fever;

- Allergic reactions;
- Diarrhoea;
- Vomiting;
- Hair loss;
- Purple discolouration or 'bruising' to your skin, sores or white spots in your mouth or throat.

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. 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 Gesavin 5 mg.

### **5. How to store Gesavin 5 mg**

Store all medicines out of reach of children.

Store below 25 °C (room temperature).

Store in original package.

Protect from light and moisture.

Do not store in 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).

### **6. Contents of the pack and other information**

### **What Gesavin 5 mg contains**

- The active substance is warfarin (as warfarin sodium). Each tablet contains warfarin (as warfarin sodium) 5 mg.
- The other ingredients are lactose monohydrate, maize starch, pregelatinized starch, sodium starch glycolate, purified water, magnesium stearate and erythrosine aluminium lake (E127).

### **What Gesavin 5 mg looks like**

Pink coloured mottled, round, flat, bevel-edged uncoated tablets debossed as "S" "576" divided by break line and plain on the other side.

Gesavin 5 mg is packed in PVC/PVDC/Alu-Blister Packs in pack sizes of 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120 and 500 tablets placed in an outer carton. Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

Strides Pharma SA (Pty) Ltd.

106 16<sup>th</sup> Road

Building 2

Midrand

1686

**This leaflet was last revised in**

### **Registration / Application number**

54/8.2/0680.676

**Access to the corresponding Professional Information**