RIBAVAN®

Rivaroxaban
2.5 mg, 10 mg, 15 mg and 20 mg film coated tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What you need to know before you take RIBAVAN®

RIBAVAN® may cause serious side effects, including:
- **Increased risk of blood clots if you stop taking RIBAVAN®.** People with atrial fibrillation (a type of irregular heart beat) that is not caused by a heart valve problem (non-valvular) are at an increased risk of forming a blood clot in the heart, which can travel to the brain, causing a stroke, or to other parts of the body. RIBAVAN® lowers your chance of having a stroke by helping to prevent clots from forming. If you stop taking RIBAVAN®, you may have increased risk of forming a clot in your blood.

Do not stop taking RIBAVAN® without talking to the doctor who prescribes it for you. Stopping RIBAVAN® increases your risk of having a stroke.
If you have to stop taking RIBAVAN®, your doctor may prescribe another blood thinner medicine to prevent a blood clot from forming.

- **Increased risk of bleeding**. RIBAVAN® can cause bleeding which can be serious, and may lead to death. This is because RIBAVAN® is a blood thinner medicine (anticoagulant) that lowers blood clotting. During treatment with RIBAVAN® you are likely to bruise more easily and it may take longer for bleeding to stop.

You may have a higher risk of bleeding if you take RIBAVAN® and take other medicines that increase your risk of bleeding, including:
- Aspirin or aspirin containing products
- Long-term (chronic) use of non-steroidal anti-inflammatory drugs (NSAIDS)
- Warfarin sodium
- Any medicine that contains heparin
- Clopidogrel
- Selective serotonin reuptake inhibitors (SSRIS) or serotonin norepinephrine reuptake inhibitors (SNRIS)
- Other medicines to prevent or treat blood clots

Tell your doctor if you take any of these medicines. Ask your doctor or pharmacist if you are not sure if your medicine is one listed above.

Call your doctor or get medical help right away if you develop any of these signs or symptoms of bleeding:
- Unexpected bleeding or bleeding that lasts a long time, such as:
  - Nose bleeds that happen often
  - Unusual bleeding from the gums
  - Menstrual bleeding that is heavier than normal or vaginal bleeding
- Bleeding that is severe or you cannot control
- Red, pink or brown urine
- Bright red or black stools (looks like tar)
- Cough up blood or blood clots
- Vomit blood or your vomit looks like "coffee grounds"
- Headaches, feeling dizzy or weak
- Pain, swelling, or new drainage at wound sites
- **Spinal or epidural blood clots (hematoma)**.

People who take a blood thinner medicine (anticoagulant) like RIBAVAN®, and have medicine injected into their spinal and epidural area, or have a spinal puncture have a risk of forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis). Your risk of developing a spinal or epidural blood clot is higher if:
- A thin tube called an epidural catheter is placed in your back to give you certain medicine
- You take NSAIDS or a medicine to prevent blood from clotting
- You have a history of difficult or repeated epidural or spinal punctures
- You have a history of problems with your spine or have had surgery on your spine

If you take RIBAVAN® and receive spinal anesthesia or have a spinal puncture, your doctor should watch you closely for symptoms of spinal or epidural blood clots. Tell your doctor right away if you have back pain, tingling, numbness, muscle weakness (especially in your legs and feet), loss of control of the bowels or bladder (incontinence).
- RIBAVAN® is not for use in people with artificial heart valves.

2. What RIBAVAN® is and what it is used for

RIBAVAN® is a prescription medicine used to:
- Reduce the risk of stroke and blood clots in people who have a medical condition called atrial fibrillation that is not caused by a heart valve problem. With atrial fibrillation, part of the heart does not beat the way it should. This can lead to the formation of blood clots, which can travel to the brain, causing a stroke, or to other parts of the body.
- Treat blood clots in the veins of your legs (deep vein thrombosis or DVT) or lungs (pulmonary embolism or PE)
- Reduce the risk of blood clots happening again in people who continue to be at risk for DVT or PE after receiving treatment for blood clots for at least 6 months.
- Help prevent a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery

RIBAVAN®, is used with low dose aspirin to:
- Reduce the risk of serious heart problems, heart attack and stroke in patients with coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) or peripheral artery disease (a condition where the blood flow to the legs is reduced).

It is not known if RIBAVAN® is safe and effective in children.

Do not take RIBAVAN® if you:
- Currently have certain types of abnormal bleeding. Talk to your doctor before taking RIBAVAN® if you currently have unusual bleeding.
- Are allergic to rivaroxaban or any of the ingredients in RIBAVAN®. See the end of this medication guide for a complete list of ingredients in RIBAVAN®.

Before taking RIBAVAN®, tell your doctor about all of your medical conditions, including if you:
- Have ever had bleeding problems
- Have liver or kidney problems
- Are pregnant or plan to become pregnant. It is not known if RIBAVAN®, will harm your unborn baby.
  - Tell your doctor right away if you become pregnant during treatment with RIBAVAN®. Taking RIBAVAN®, while you are pregnant may increase the risk of bleeding in you or in your unborn baby.
  - If you take RIBAVAN® during pregnancy tell your doctor right away if you have any signs or symptoms of bleeding or blood loss. **See "What you need to know before you take RIBAVAN®"** For signs and symptoms of bleeding.
- Are breastfeeding or plan to breastfeed RIBAVAN®, can pass into your breast milk. Talk to your doctor about the best way to feed your baby during treatment with RIBAVAN®.

Tell all of your doctors and dentists that you are taking RIBAVAN®. They should talk to the doctor who prescribed RIBAVAN®, for you before you have any surgery, medical or dental procedure.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Some of your other medicines may affect the way RIBAVAN®, works, causing side effects. Certain medicines may increase your risk of bleeding. **See "What you need to know before you take RIBAVAN®"**

Especially tell your doctor if you take:
- Ketoconazole
- Ritonavir
- Erythromycin
- Carbamazepine
- Phenytoin
- Rifampin
- St. John's wort

RIBAVAN® contains lactose
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

3. How to take RIBAVAN®

Take RIBAVAN® exactly as prescribed by your doctor.
Do not change your dose or stop taking RIBAVAN® unless your doctor tells you to.
Your doctor may change your dose if needed.

If you take RIBAVAN® for:
Atrial fibrillation that is not caused by a heart valve problem:
Take RIBAVAN® 1 time a day with your evening meal.
If you miss a dose of RIBAVAN®, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.

Blood clots in the veins of your legs or lungs:
Take RIBAVAN® **1 or 2 times a day** as prescribed by your doctor.
For the **15 mg** and **20 mg** doses, RIBAVAN® **should be taken with food**.
For the **10 mg** dose, RIBAVAN® may be taken with or without food.

Take your RIBAVAN® doses at the same time each day.

If you miss a dose:
- If you take the **15 mg** dose of RIBAVAN® 2 times a day (a total of 30 mg of RIBAVAN® in 1 day): take RIBAVAN® as soon as you remember on the same day. You may take 2 doses at the same time to make up for the missed dose. Take your next dose at your regularly scheduled time.
- If you take RIBAVAN® 1 time a day: take RIBAVAN® as soon as you remember on the same day. Take your next dose at your regularly scheduled time.

Hip or knee replacement surgery:
Take RIBAVAN® 1 time a day with or without food.
If you miss a dose of RIBAVAN®, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.

Reducing the risk of serious heart problems, heart attack and stroke in coronary artery disease or peripheral artery disease:
Take RIBAVAN® 2.5mg twice daily with or without food in addition to 75-100mg of aspirin once daily.
If you miss a dose of RIBAVAN®, take your next dose at your regularly scheduled time.

If you have difficulty swallowing the RIBAVAN® tablet whole, talk to your doctor about other ways to take RIBAVAN®.

Your doctor will decide how long you should take RIBAVAN®.

RIBAVAN® may need to be stopped, if possible for one or more days before any surgery or medical or dental procedure. If you need to stop taking RIBAVAN® for any reason, talk to the doctor who prescribed RIBAVAN to you to find out when you should stop taking it. **Do not stop taking RIBAVAN® without first talking to the doctor who prescribes it to you.** Your doctor will tell you when to start taking RIBAVAN® again after your surgery or procedure.
Do not run out of RIBAVAN®. Refill your prescription of RIBAVAN® before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will have RIBAVAN® available to avoid missing any doses.

If you take too much RIBAVAN®, go to the nearest hospital emergency room or call your doctor right away.

4. Possible side effects

The most common side effect of RIBAVAN® was bleeding.
See "What you need to know before you take RIBAVAN®".
Call your doctor for medical advice about side effects.

5. How to store RIBAVAN®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister. The expiry date refers to the last day of that month.

Store in the original package.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask yo ur pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

General information about the safe and effective use of RIBAVAN®.
Medicines are sometimes prescribed for purposes other than those listed in a medication guide. Do not use RIBAVAN® for a condition for which it was not prescribed. Do not give RIBAVAN® to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about RIBAVAN® that is written for health professionals.

6. Contents of the pack and other information

RIBAVAN® tablets contain:
Active ingredient: Rivaroxaban
Inactive ingredients: Croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate.
- The proprietary film coating mixture for RIBAVAN® 2.5 mg tablets is Opadry® yellow and contains: iron oxide yellow, hypromellose 2910, macrogol 400 and titanium dioxide.
- The proprietary film coating mixture for RIBAVAN® 10 mg tablets is Opadry® pink and contains: iron oxide red, hypromellose 2910, macrogol 3350 and titanium dioxide.
- The proprietary film coating mixture for RIBAVAN® 15 mg tablets is Opadry® red and contains: iron oxide red, hypromellose 2910, macrogol 3350 and titanium dioxide.
- The proprietary film coating mixture for RIBAVAN® 20 mg tablets is Opadry® ii dark red and contains: iron oxide red, hypromellose 2910, macrogol 3350 and titanium dioxide.

What RIBAVAN® looks like and contents of the pack
RIBAVAN® 2.5 mg: The film coated tablets are yellow, round, biconvex, engraved with "2.5" on one side and plain on other side.
RIBAVAN® 10 mg: The film coated tablets are pink, round, biconvex, engraved with "10" on one side and plain on other side.
RIBAVAN® 15 mg: The film coated tablets are red, round, biconvex, engraved with "15" on one side and plain on other side.
RIBAVAN® 20 mg: The film coated tablets are dark red, round, biconvex, engraved with "20" on one side and plain on other side.

For more information about this medicinal product, please contact:
Algorithm SAL
Tel: +961-9-222050

To report adverse events, please contact:
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Email: pharmacovigilance@algorithm-lb.com
Phone: +961-9-222050 ext. 347
Fax: +961-9-222604
Website: www.algorithm-lb.com
Also contact the relevant competent authority.

This is a medicament
- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicines, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Marketing Authorization Holder and Final Batch Releaser:
ALGORITHM S.A.L. Zouk Mosbeh, Lebanon
® Registered Trademark

Manufacturers:

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