PACKAGE LEAFLET

RIVELIME 5 mg Hard Capsules
Taken by mouth.
Cytotoxic

- ***Active substance*:** Each capsule contains 5 mg lenalidomide.
- ***Excipients:*** Lactose anhydrous (from bovine milk), microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, hard gelatin capsule (No:2): titanium dioxide, gelatin (bovine gelatin).

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. See the end of section 4 for how to report side effects.

Read all of this PACKAGE 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 or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or a **lower** dose other than recommended to you.*

In This Leaflet:

1. WHAT RIVELIME IS AND WHAT IT IS USED FOR

RIVELIME 5 mg hard capsules is supplied as white colored cap with “DEVA” print on it with black ink and white colored body with “5 mg” print on it with black ink; filled with whitish powder. Each cardboard box contains 7 or 21 capsules. RIVELIME contains an active substance called lenalidomide.

It belongs to the medicine class called immunomodulators that can change or regulate the functions of immune system.

RIVELIME works by affecting the body’s immune system and directly attacking the cancer. It works in a number of different ways:
- by stopping the cancer cells developing
- by stopping blood vessels growing in the cancer
- by stimulating part of the immune system to attack the cancer cells.

RIVELIME is used in adults for:

1. Multiple myeloma
2. Myelodysplastic syndromes
3. Mantle cell lymphoma
4. Follicular lymphoma

Multiple myeloma
Multiple myeloma is a type of cancer, which affects a certain kind of white blood cell, called the plasma cell. These cells collect in the bone marrow and divide, becoming out of control. This can damage the bones and kidneys.

Multiple myeloma generally cannot be cured. However, the signs and symptoms can be greatly reduced or disappear for a period. This is called a 'response'.

Newly diagnosed multiple myeloma – in patients who have had a bone marrow transplant
RIVELIME is used on its own as a maintenance therapy after patients have recovered enough following a bone marrow transplant.

Newly diagnosed multiple myeloma – in patients who cannot have a bone marrow transplant
RIVELIME is taken with other medicines. These may include:
• a chemotherapy medicine called 'bortezomib'
• an anti-inflammatory medicine called 'dexamethasone'
• a chemotherapy medicine called 'melphalan' and
• an immunosuppressant medicine called 'prednisone'.
.
You will take these other medicines at the start of treatment and then continue to take RIVELIME on its own.

If you are aged 75 years or older or have moderate to severe kidney problems - your doctor will check you carefully before starting treatment.

Multiple myeloma – in patients who have had treatment before
RIVELIME is taken together with an anti-inflammatory medicine called 'dexamethasone'.
RIVELIME can stop the signs and symptoms of multiple myeloma getting worse. It has also been shown to delay multiple myeloma from coming back following treatment.

Myelodysplastic syndromes
Myelodysplastic syndromes (MDS) are a collection of many different blood and bone marrow diseases. The blood cells become abnormal and do not function properly. Patients can experience a variety of signs and symptoms including a low red blood cell count (anemia), the need for a blood transfusion, and be at risk of infection.

RIVELIME is used alone to treat adult patients who have been diagnosed with MDS, when all of the following apply:
1. you need regular blood transfusions to treat low levels of red blood cells ('transfusion-dependent anemia')
2. you have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic abnormality'. This means your body does not make enough healthy blood cells
3. other treatments have been used before, are not suitable or do not work well enough.

RIVELIME can increase the number of healthy red blood cells that the body produces by reducing the number of abnormal cells:
This can reduce the number of blood transfusions needed. It is possible that no transfusions will be needed.

Mantle cell lymphoma (MCL)
MCL is a cancer of part of the immune system (the lymph tissue). It affects a type of white blood cell called 'B-lymphocytes' or B-cells. MCL is a disease where B-cells grow in an uncontrolled way and build up in the lymph tissue, bone marrow or blood.

RIVELIME is used to treat adult patients who have previously been treated with other medicines.

Follicular lymphoma (FL)
FL is a slow growing cancer that affects the B-lymphocytes. These are a type of white blood cells that help your body fight infection. When you have FL, too many of these B-lymphocytes may collect in your blood, bone marrow, lymph nodes and spleen.

RIVELIME is taken together with another medicine called 'rituximab' for the treatment of adult patients with previously treated follicular lymphoma.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RIVELIME

Carefully follow all recommendations and instructions of your doctor, even if your treatment has differences from general information given in this leaflet

You must read the package leaflet of all medicinal products to be taken in combination with RIVELIME before starting treatment with RIVELIME.

DO NOT TAKE RIVELIME,

- if you are pregnant, think you may be pregnant or are planning to become pregnant, as **RIVELIME is expected to be harmful to an unborn child** (see section 2, 'Pregnancy, breast-feeding and contraception – information for women and men').
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see section 2, 'Pregnancy, breast-feeding and contraception – information for women and men'). If you are able to become pregnant, your doctor will record with each prescription that the necessary measures have been taken and provide you with this confirmation.
- if you are allergic to lenalidomide or any of the other ingredients of RIVELIME listed in section 6. If you think you may be allergic, ask your doctor for advice.

If any of these warnings apply to you, please consult your doctor before taking RIVELIME.

TAKE SPECIAL CARE with RIVELIME

Talk to your doctor, pharmacist or nurse before taking RIVELIME
If:

- you have had blood clots in the past - you have an increased risk of developing blood clots in the veins and arteries during RIVELIME treatment

- you have any signs of an infection, such as a cough or fever
- you have or have ever had previous viral infection, particularly: hepatitis B infection, varicella zoster, HIV. If you are in doubt, talk to your doctor. Treatment with RIVELIME may cause the virus to become active again, in patients who carry the virus. This results in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection
- you have kidney problems - your doctor may adjust your dose of RIVELIME
- you have had a heart attack, have ever had a blood clot, or if you smoke, have high blood pressure or high cholesterol levels
- you have had an allergic reaction whilst taking thalidomide (another medicine used to treat multiple myeloma) such as rash, itching, swelling, dizziness or trouble breathing
- you have experienced in the past a combination of any of the following symptoms: widespread rash, red skin, high body temperature, flu-like symptoms, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes – these are signs of a severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome (see also section 4 “Possible side effects”).

If these warnings apply to you, even at any time in the past, please consult your doctor.

If;

At any time during or after your treatment:
- experience blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion. These may all be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML). If you had these symptoms prior to treatment with RIVELIME, tell your doctor about any change in these symptoms.
- experience shortness of breath, tiredness, dizziness, pain in the chest, a faster heartbeat, or swelling in the legs or ankles. These may be symptoms of a serious condition known as pulmonary hypertension (increase in lung artery pressure) (see section 4).

Test and checks

Have regular blood tests before and during treatment with RIVELIME. This is because RIVELIME may cause a fall in the blood cells that help fight infection (white blood cells) and help the blood to clot (platelets).
Your doctor will order blood tests at these times;
- before treatment
- every week for the first 8 weeks of treatment
- then at least every month after that.

You may be evaluated for signs of cardiopulmonary problems before and during the treatment with RIVELIME.

<u>For patients with MDS taking RIVELIME</u>

If you have a deficiency of blood cell production in the bone marrow (myelodysplastic syndrome) and you use RIVELIME, you may be more likely to develop a more serious disease called acute myeloid leukemia (AML), which is characterized by a sudden excessive increase in the number of white blood cells. In addition, it is not known how RIVELIME affects the chances of you getting AML. Your doctor may therefore do tests to check for signs, which may better predict the likelihood of you getting AML during your treatment with RIVELIME.

For patients with MCL taking RIVELIME
Your doctor will ask you to have a blood test:
- before treatment
- every week for the first 8 weeks (2 cycles) of treatment
- then every 2 weeks in cycles 3 and 4 (see section 3 'Treatment cycle' for more information)
- after this it will happen at the start of each cycle and
- at least every month.

For patients with FL taking RIVELIME
Your doctor will ask tests during the following periods::
- before treatment
- every week for the first 3 weeks (1 cycle) of treatment
- then every 2 weeks in cycles 2 to 4 (see Section 3 'Treatment cycle' for more information)
- after this it will happen at the start of each cycle and
- at least every month.

Your doctor may check if you have a high total amount of tumor throughout the body, including your bone marrow. This could lead to a condition where the tumors break down and cause unusual levels of chemicals in the blood which can lead to kidney failure (this condition is called 'Tumor Lysis Syndrome').

Your doctor may check you for changes to your skin such as red spots or rashes.
Your doctor may adjust your dose or stop your treatment based on the results of your blood tests and on your general condition. If you are newly diagnosed, your doctor may also assess your treatment based on your age and other conditions you already have.

Blood donation
You should not donate blood during treatment and for at least 7 days after the end of treatment.

Consult your doctor, even if these warnings were applicable to you at any time in the past.

RIVELIME with food and drink
RIVELIME capsules can be taken either with or without food (see "How to take RIVELIME")

Pregnancy, breast-feeding and contraception - information for women and men
Consult your doctor or pharmacist before using this medicine.

For women taking RIVELIME
You must not take RIVELIME if you are pregnant, as it is expected to be harmful to an unborn baby. You must not become pregnant while taking RIVELIME.

Therefore, you must use effective methods of contraception if you are a woman of childbearing potential (see 'Contraception').

If you do become pregnant during your treatment with RIVELIME, you must stop the treatment and inform your doctor immediately.

For men taking RIVELIME
If your partner becomes pregnant whilst you are taking RIVELIME, you should inform your doctor immediately. It is recommended that your partner seek medical advice (see 'Contraception').

During your treatment, if you realize that you are pregnant, consult your doctor or pharmacist immediately.

Breast-feeding
Consult your doctor or pharmacist before using this medicine.
You must not breast-feed when taking RIVELIME, as it is not known if RIVELIME passes into breast milk.

Contraception
For women taking RIVELIME
Before starting the treatment, ask your doctor if you are able to become pregnant, even if you think this is unlikely.

If you are able to become pregnant
- you will have pregnancy tests under the supervision of your doctor (before every treatment, at least every 4 weeks during treatment, and at least 4 weeks after the treatment has finished) except where it has been confirmed that the fallopian tubes have been severed and sealed, to stop eggs from reaching the uterus (tubal sterilization)
- you must use effective methods of contraception for at least 4 weeks before starting treatment, during treatment, and until at least 4 weeks after stopping treatment. Your doctor will advise you on appropriate methods of contraception.

For men taking RIVELIME
RIVELIME passes into human semen. If your female partner is pregnant or able to become pregnant, and she does not use effective methods of contraception, you must use condoms during treatment and for at least 7 days after the end of treatment, even if you have had a vasectomy. You should not donate semen or sperm during treatment and for at least 7 days after the end of treatment.

Driving and using machines
Do not drive or operate machines if you feel dizzy, tired, sleepy, have vertigo or blurred vision after taking RIVELIME.

Important information about some of the ingredients of RIVELIME

RIVELIME contains lactose anhydrous (a type of sugar). If you have been told by your doctor before that you are intolerant to some sugars, contact your doctor before taking this medicinal product.

Other medicines and RIVELIME
RIVELIME may affect the function of other medicines, causing serious side effects, or some medicines may affect the function of RIVELIME. In particular, tell your doctor or nurse if you are taking any of the following medicines:
- some medicines used to prevent pregnancy such as oral contraceptives, as they may interfere with the effect of RIVELIME
- some medicines used for heart problems – such as digoxin
- some medicines used to thin the blood – such as warfarin.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO TAKE RIVELIME
RIVELIME must be given to you by healthcare professionals with experience in treating multiple myeloma, myelodysplastic syndrome, mantle cell lymphoma and follicular lymphoma.

- When RIVELIME is used to treat multiple myeloma in patients who cannot have a bone marrow transplant or have had other treatments before, it is taken with other medicines (see section 1 'What RIVELIME is and what it is used for').
- When RIVELIME is used to treat multiple myeloma in patients who have had a bone marrow transplant or to treat patients with MDS or MCL, it is taken alone.
- When RIVELIME is used to treat follicular lymphoma, it is taken with another medicine called 'rituximab'.

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

If you are taking RIVELIME in combination with other medicines, you should refer to the Package Leaflets for these medicines for further information on their use and effects.

Instructions for proper use and dose/frequency of administration:

Treatment cycle
RIVELIME is taken on certain days over 3 weeks (21 days).
• Every 21 days is called a 'treatment cycle'.
• Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines.
• After completing every 21-day cycle, you should start a new 'cycle' over the next 21 days.

or
RIVELIME is taken on certain days over 4 weeks (28 days).
• Every 28 days is called a 'treatment cycle'.
• Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines.

• After completing every 28-day cycle, you should start a new 'cycle' over the next 28 days.

Before you start treatment, your doctor will tell you:
• how much RIVELIME you should take
• how much of the other medicines you should take in combination with RIVELIME, if any
• on what days of your treatment cycle to take each medicine.

Duration of RIVELIME treatment:
RIVELIME is used in cycles, each lasting 21 or 28 days (see "Treatment Cycle" section). Your doctor will determine how long your treatment will last. Do not discontinue your treatment early.

Method and route of administration:

- Swallow the RIVELIME capsule whole with water once a day.
- Do not break, open or chew the capsules. If the powder from a broken RIVELIME capsule comes into contact with your skin, immediately wash your skin thoroughly with soap and water.
- You can take it with food or alone.
- Healthcare professionals, caregivers and family members should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.
- You should take RIVELIME at about the same time on the scheduled days.

To remove the capsule from the blister:
- press only one end of the capsule out to push it through the foil
- do not put pressure on the center of the capsule, as this can cause it to break.

Different age groups:
Use in children:
RIVELIME should not be used in children under 18 years.

Use in the elderly:
If necessary RIVELIME can be used in elderly patients, the dosage should be adjusted by the doctor.
If you are aged 75 years or older or have moderate to severe kidney problems - your doctor will check you carefully before starting treatment.

Special conditions for use:
Kidney/liver failure:
If you have had liver and kidney function disorders in the past, tell your doctor and follow your doctor's advice. Your doctor will adjust your dose depending on your liver and kidney function disorder.

If you have an impression that the effect of RIVELIME is too strong or too weak, talk to your doctor or pharmacist.

If you take more RIVELIME than you should:
If you take more RIVELIME than was prescribed, tell your doctor immediately.

If you forget to take RIVELIME:
If you forget to take RIVELIME at your regular time and

- Less than 12 hours have passed: Take your capsule immediately.
- More than 12 hours have passed: Do not take your capsule. Take your next capsule at the usual time the next day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
Do not take a double dose to make up for a forgotten dose.

If you stop taking RIVELIME
RIVELIME does not cause any side effects after stopping the treatment.

4. POSSIBLE SIDE EFFECTS
Like all medicines, RIVELIME can cause side effects, although not everybody gets them.

Side effects are defined according frequency:
Very common : affects at least 1 in 10 patients
Common : may be seen less than one in 10 patients, but more than one in 100 patients.
Uncommon : may be seen less than one in 100 patients, but more than one in 1000 patients.
Rare : may be seen less than one in 1000 patients, but more than one in 10000 patients.
Very rare : may be seen less than one in 10000 patients.
Unknown : cannot be estimated from the available data.

Stop taking RIVELIME and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Hives, rashes, swelling of eyes, mouth or face, difficulty breathing, or itching, which may be symptoms of serious types of allergic reactions called angioedema and anaphylactic reaction.
- A serious allergic reaction that may begin as a rash in one area but spread with extensive loss of skin over the whole body (Stevens-Johnson syndrome and/or toxic epidermal necrolysis).
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). (See section "TAKE SPECIAL CARE with RIVELIME").

Tell your doctor straight away if you notice any of the following serious side effects:

- Fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection including within the bloodstream (sepsis)
- Bleeding or bruising without an injury or injury, bleeding after any intervention,
- Chest pain or leg pain
- Shortness of breath

- Bone pain, muscle weakness, confusion or tiredness that might be due to high level of calcium in the blood.

RIVELIME may reduce the number of white blood cells that fight infection and also the blood cells which help the blood to clot (platelets) which may lead to bleeding disorders such as nosebleeds and bruising. RIVELIME may also cause blood clots in the veins (thrombosis).

It should be noted that a small number of patients may develop additional cancer types, and it is possible that this risk will increase with treatment with RIVELIME. Therefore, your doctor should carefully consider the benefits and risks when prescribing RIVELIME to you.

Very common
- A fall in the number of red blood cells which may cause anemia leading to tiredness and weakness
- Rashes, itching
- Muscle cramps, muscle weakness, muscle pain, muscle aches, bone pain, joint pain, back pain, pain in the extremities
- Generalized swelling including swelling of your arms and legs
- Weakness, tiredness
- Fever and flu like symptoms including fever, muscle ache, headache, earache, cough and chills
- Numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor
- Increase in pain, tumor size or redness around the tumor
- Weight loss
- Constipation, diarrhea, nausea, stomach pain, heartburn
- Low levels of potassium or calcium and/or sodium in the blood
- Thyroid functioning less than it should be
- Leg pain (which could be a symptom of thrombosis), chest pain or shortness of breath (which may be a symptom of blood clots in the lungs, called pulmonary embolism)
- Infections of all types (including infection of the sinuses that surround the nose, infection of the lung and the upper respiratory tract)
- Shortness of breath
- Blurred vision
- Clouding of your eye (cataract)
- Kidney problems (which include kidneys not working properly or not being able to maintain normal function)
- Abnormal liver test results
- Increase in liver test results
- Changes to a protein in the blood that can cause swelling of the arteries (vasculitis)
- Increases in your blood sugar levels (diabetes)
- Decreases in your blood sugar levels
- Headache
- Nosebleed
- Dry skin
- Depression
- Mood change, difficulty sleeping

- Cough
- A fall in blood pressure
- A vague feeling of bodily discomfort, feeling bad
- Sore inflamed mouth, dry mouth
- Dehydration

Common
- Destruction of red blood cells (hemolytic anemia)
- Certain types of skin tumor
- Bleeding of the gums, stomach, or bowels
- Increased blood pressure, slow, fast or irregular heart beat
- Increase in the amount of a substance which results from normal and abnormal breakdown of red blood cells
- Increase in a type of protein that indicates inflammation in body
- Darkening of your skin, discoloration of your skin resulting from bleeding underneath, typically caused by bruising, swelling of skin filled with blood, bruise
- Increase in uric acid in the blood
- Skin eruptions, redness of skin, cracking, flaking or peeling skin, hives
- Increased sweating, night sweats
- Difficulty swallowing, sore throat, difficulty with voice quality or voice changes
- Runny nose
- Production of much more or much less urine than usual or the inability to control when to urinate
- Passing blood in the urine
- Shortness of breath especially when lying down (which may be a symptom of heart failure)
- Difficulty getting an erection
- Stroke, fainting, vertigo (problem with inner ear which leads to feeling that everything is spinning), temporary loss of consciousness
- Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting which may be symptoms of a heart attack (myocardial infarction)
- Muscle weakness, lack of energy
- Neck pain, chest pain
- Chills
- Joint swelling
- Bile flow from liver slowed or blocked
- Low levels of phosphate or magnesium in the blood
- Difficulty speaking
- Liver injury
- Impaired balance, difficulty moving
- Deafness, ringing in the ears (tinnitus)
- Nerve pain, unpleasant abnormal sensation especially to touch
- An excess of iron in the body
- Thirst
- Confusion
- Toothache
- Fall which may result in injury

Uncommon
- Bleeding within the skull
- Circulatory problems
- Loss of vision
- Loss of sex drive (libido)
- Passing large amounts of urine with bone pain and weakness, which may be symptoms of Fanconi syndrome (a kidney disorder)
- Yellow pigmentation to the skin, mucus membrane or eyes (jaundice), pale colored stools, dark colored urine, skin itch, rash, pain or swelling of the stomach – these may be symptoms of injury to the liver (hepatic failure)
- Stomach pain, bloating, or diarrhea, which may be symptoms of inflammation in the large intestine (called colitis or cecitis)
- Damage to the cells of the kidney (called renal tubular necrosis)
- Changes to the color of your skin, sensitivity to sunlight
- Formation of some tumor types in the skin
- Tumor lysis syndrome - metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the break-down products of dying cancer cells and may include the following: changes to blood chemistry; high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heartbeat, seizures, and sometimes death.
- Increase in blood pressure within blood vessels that supply the lungs (pulmonary hypertension).

Unknown
- Sudden, or mild but worsening pain in the upper stomach and/or back, which remains for a few days, possibly accompanied by nausea, vomiting, fever and a rapid pulse – these symptoms may be due to inflammation of the pancreas.
- Wheezing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the tissue in the lungs.
- Rare cases of muscle breakdown (muscle pain, weakness or swelling) which can lead to kidney problems (rhabdomyolysis) have been observed, some of them when RIVELIME is administered with a statin (a type of cholesterol lowering medicines).
- A condition affecting the skin caused by inflammation of small blood vessels, along with pain in the joints and fever (leukocytoclastic vasculitis).
- Breakdown of the wall of the stomach or gut. This may lead to very serious infection. Tell your doctor if you have severe stomach pain, fever, nausea, vomiting, blood in your stool, or changes in bowel habits.
- Viral infections, including a disease that causes a painful skin rash with blisters (Herpes zoster- also known as ‘shingles’) and recurrence of which can cause yellowing of the skin and eyes, dark brown-colored urine, right-sided stomach pain, fever and feeling nauseous or being sick (Hepatitis B infection).
- Rejection of solid organ transplant (such as kidney, heart).

If side effects are getting serious or if you get any side effects not listed in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE RIVELIME

Keep RIVELIME out of the reach and sight of children and in its original package.
Keep at room temperature below 25°C.

Use it in accordance with the expiry date.

Do not use RIVELIME after the expiry date, which is stated on the package.
If you notice any damage on the product and/or package, do not use RIVELIME.

Empty boxes of used cytotoxic or cytostatic medicinal products are **HAZARDOUS WASTE MATERIALS**. Waste material should be disposed of in accordance with local requirements.

Please return unused RIVELIME capsules to your pharmacist.

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

Marketing Authorization Holder:
DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing Site:
DEVA Holding A.Ş.
Kapaklı – TEKİRDAĞ / TÜRKİYE

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