

PACKAGE LEAFLET: Information for the patient

RIVANOL

Solution for local use – 0.1%

(Ethacridine lactate monohydrate)

Read this leaflet carefully before you start using this medicine.

- 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet:

1. What Rivanol is and what it is used for
2. Before you use Rivanol
3. How to use Rivanol
4. Possible side effects
5. How to store Rivanol
6. Other information

1. WHAT RIVANOL IS AND WHAT IT IS USED FOR

Rivanol is a medicine that is applied locally as a disinfectant and antiseptic.

2. BEFORE YOU USE RIVANOL

Do not use Rivanol if you are hypersensitive to ethacridine lactate or to any other acridine derivative.

Rivanol should not be applied in the eye area.

Take special care with Rivanol

It is not required any special care during the local application of Rivanol solution.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Rivanol. Please contact your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Rivanol if you have been given any other medicine during the treatment.

Rivanol should not be mixed with other solutions, because it may form flakes.

Pregnancy and breastfeeding

Rivanol should not be used during pregnancy, since there are no experiences on its use.

Rivanol should not be applied during breastfeeding, since it is not known whether it is excreted with breast milk.

Driving and using machinery

There are no data to indicate if Rivanol may affect the ability to drive or use machinery.

3. HOW TO USE RIVANOL

Always use this drug exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Rivanol is applied locally on the skin twice daily as a non-diluted solution and it is allowed to react for at least 30 minutes.

It is advised not to use it for more than 7 days without the advice of the doctor.

Please contact your doctor or pharmacist if you feel that the effect of Rivanol is too weak or too strong.

Important instructions on use

Rivanol solution 0.1 % colors the skin, clothes and other items into yellow. The contact of the solution with materials that can be coloured (e.g. clothes, carpets, linoleums, etc.) should be avoided.

If you use more Rivanol than you should

If you use more Rivanol than you should, you can continue the treatment according to the recommended dose. There are no signs or specific symptoms associated with the exceeded use of Rivanol.

If you forget to use Rivanol

If you forget a dose (or more doses), use the following dose when it is time to use it usually. Do not use a double dose (or higher) to make up for a forgotten dose.

If you stop the treatment with Rivanol

If you stop the use of Rivanol, you may risk the success of the treatment.

Ask your doctor if you want to stop the treatment with Rivanol.

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Ethacridine solution can cause side effects, although not everybody manifests them.

Rarely and especially under the effect of the sunlight, ethacridine can cause allergic skin reactions, which rapidly disappear when treatment is interrupted.

In some cases swelling of the face, urticaria, headache and spasms are observed.

Occasionally inflammation of the skin may appear.

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

5. HOW TO STORE RIVANOL

Keep out of the reach and sight of children.

Do not use it after the expiry date, which is stated on the carton box.

Do not store in a temperature above 25°C.

Keep in the original packaging.

6. OTHER INFORMATION

What Rivanol 0.1% solution for local use contains

The active substance is ethacridine lactate monohydrate.

1 ml solution contains 1.05 mg ethacridine lactate monohydrate.

The excipient is: purified water.

Contents of the pack:

Carton box with one glass bottle 100 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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