

Package leaflet: Information for the user

Fortacin 150 mg/ml + 50 mg/ml
skin spray, solution
lidocaine/prilocaine

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your pharmacist.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.
- Is your complaint not getting better, or is it even getting worse? Then contact your doctor.

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1. What is Fortacin and what is it used for?

Fortacin is a combination of two medicines: lidocaine and prilocaine, which belong to the group of local anesthetics.

Fortacin is intended for the treatment of premature ejaculation (primary premature ejaculation) in adult men (18 years and older) since the first sexual intercourse. This means that you always (or almost always) ejaculate within one minute of intercourse and experience negative emotional effects as a result. Fortacin works by reducing the sensitivity of the tip of the penis (the glans) to extend the time to ejaculation.

2. When should you not use Fortacin or be extra careful with it?

When should you not use this medicine?

You or your partner are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

You or your partner have a history of allergy or sensitivity to other local anesthetics with a similar structure (known as amide-type local anesthetics).

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using Fortacin,

if you or your partner have been diagnosed with a genetic disorder or another condition affecting red blood cells (glucose-6-phosphate deficiency, anemia, or methemoglobinemia);

if you have a history of drug hypersensitivity, especially if you are unsure which drug caused the sensitivity;
if you suffer from severe liver problems.

Premature ejaculation may be the result of a condition that requires medical treatment. If this product is used as described and does not provide relief, you should consult a doctor.

Use with condoms

Fortacin should not be used with latex-free female or male condoms made of polyurethane, as degradation of this material may occur if these condoms are used in combination with Fortacin. As a result, they may not provide protection against sexually transmitted infections (STIs) or pregnancy. Fortacin can be used with contraceptives made of latex rubber, polyisoprene, nitrile, and silicone, as no degradation has been shown. Check what material your or your partner's contraceptive is made of before using this product. Not sure? Then contact your pharmacist. If you use Fortacin with condoms, you have an increased chance of not being able to get or maintain an erection. You also have a greater chance of reduced sensation in and around the penis.

Avoid unintended contact

To avoid unintended contact with ears, eyes, nose, and mouth, never aim the spray can at a face when using this medicine, especially when preparing the spray can. If you or your partner accidentally get a little medicine in the eyes, rinse the eyes immediately with cold water or saline solution and keep them closed as much as possible until the effects of the spray, such as numbness, disappear. Be aware that normal protective mechanisms, such as blinking or feeling something foreign in your eyes, may be absent as long as the numbness has not disappeared. Fortacin must not come into contact with a damaged eardrum.

Contact with other mucous membranes

Fortacin can also come into contact with other mucous membranes, such as the mouth, nose, and throat of you or your partner, causing them to feel slightly numb for a short time. This can reduce the ability to feel pain in these areas. Therefore, be extra careful not to injure yourself in these areas as long as the numbness has not disappeared.

Possible transfer to the partner, e.g., to the vagina or anus

During intercourse, a small amount of this medicine may be transferred, for example, to the vagina or anus. This may cause temporary numbness for you and your partner, and both should be careful not to injure themselves, especially during sexual activity. Refer to section 4 for more information on possible side effects in sexual partners.

If you or your partner experience a rash or skin irritation, the use of Fortacin should be discontinued. If the symptoms persist, you should consult a doctor.

Children and adolescents up to 18 years

This medicine should not be used by children and adolescents up to 18 years.

Are you taking any other medicines?

Are you taking any other medicines besides Fortacin, or have you recently done so, or is there a possibility that you will soon take other medicines? Then tell your doctor or pharmacist. This is especially important if you are taking any of the following medicines that may interact with Fortacin:

- other local anesthetics such as benzocaine and procaine
- heart medications (antiarrhythmics such as mexiletine and amiodarone)
- fluvoxamine, cimetidine, or beta-blockers, which can increase the level of lidocaine in the blood
- medicines known to lead to a higher risk of a condition that reduces the amount of oxygen in the blood (methemoglobinemia), such as the following agents:
 - benzocaine – a local anesthetic used to treat pain and itching
 - chloroquine, pamaquine, primaquine, quinine – used for treating malaria
 - metoclopramide – used for treating nausea and vomiting, including in patients with migraines
 - glyceryl trinitrate (GTN, nitroglycerin), isosorbide mononitrate, erythritol tetranitrate, pentaerythritol tetranitrate, and other nitrate- and nitrite-containing medicines – used for treating angina pectoris (chest pain caused by the heart)
 - sodium nitroprusside, isosorbide dinitrate – used for treating high blood pressure and heart failure
 - nitrofurantoin – an antibiotic used for treating urinary tract and kidney infections
 - sulfonamides (also known as “sulfa drugs”) e.g., sulfamethoxazole – an antibiotic used for treating urinary tract infections – and sulfasalazine – used for treating Crohn's disease, ulcerative colitis, and rheumatoid arthritis
 - dapsone – used for treating skin conditions such as leprosy and dermatitis and also for preventing malaria and pneumonia in patients at increased risk
 - phenobarbital, phenytoin – used for treating epilepsy
 - para-aminosalicylic acid (PAS) – used for treating tuberculosis.

The risk of methemoglobinemia can also increase with the use of certain dyes (aniline dyes) or the pesticide naphthalene. Therefore, contact your doctor if you work with dyes or chemical pesticides.

Pregnancy, breastfeeding, and fertility

Fortacin is not approved for use in women.

Consult your doctor or pharmacist before using this medicine.

Pregnancy

Fortacin should not be used when your partner is pregnant unless you use an effective male condom as indicated above in section 2 'Use with condoms' to prevent exposure to the unborn child.

Breastfeeding

This medicine may be used when your partner is breastfeeding.

Fertility

Fortacin may reduce the chance of pregnancy. Therefore, patients wishing to conceive should avoid using Fortacin or, if this medicine is necessary to achieve penetration, should wash the glans as thoroughly as possible five minutes after applying Fortacin but before intercourse.

Driving and using machines

Fortacin has no or negligible influence on the ability to drive and use machines when used in the recommended doses.

3. How to use Fortacin?

Always use this medicine exactly as described in this leaflet. Unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dosage of Fortacin is 3 sprays (3 sprays = 1 dose) on the tip of the penis (the glans) at least 5 minutes before intercourse. Within a 24-hour period, a maximum of 3 doses may be used at intervals of at least 4 hours.

The maximum recommended dosage (3 doses within 24 hours) must not be exceeded.

Instructions for use

Shake the canister briefly before first use and then prime the spray mechanism by spraying three times into the air. Never aim the canister at faces to avoid contact with eyes, nose, mouth, and ears.

Shake the canister briefly before each subsequent use and prime the spray mechanism again by spraying once into the air.

Retract the foreskin from the tip of the penis. Hold the canister upright (spray head up), apply 1 dose (3 sprays) of Fortacin to the entire tip of the penis, covering one-third of the tip with each spray.

Wait 5 minutes and then wipe off the excess spray before having intercourse. It is also important to wipe off the excess spray if you are using a condom (see also section 2 for other important information regarding use with condoms).

Have you used too much of this medicine?

Wipe away excess spray if you have applied too much.

Below is a list of complaints that may occur when you have used too much Fortacin. Contact your doctor or pharmacist if you experience any of these complaints. If you have used the medicine according to the instructions, the chance of experiencing them is small:

lightheadedness or dizziness

tingling of the skin around the mouth and numbness of the tongue

abnormal taste sensation

blurred vision

ringing in the ears

there is also a risk of a condition that reduces the amount of oxygen in the blood (methemoglobinemia). This risk is greater when you are also using certain other medications. If this condition occurs, the skin turns a bluish-gray color due to lack of oxygen.

In severe cases of overdose, you may also experience seizures, low blood pressure, slowed breathing, respiratory arrest, and altered heart rate. These effects can be life-threatening.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The following side effects of Fortacin have been reported in male patients:

Common (may affect up to 1 in 10 people)

- inability to get or maintain an erection
- reduced sensation in and around the penis
- burning sensation in and around the penis

Uncommon (may affect up to 1 in 100 people)

- headache
- local throat irritation (if inhaled)
- skin irritation
- redness on and around the penis
- absence of ejaculation during intercourse
- abnormal orgasm
- tingling in and around the penis
- pain or discomfort in and around the penis
- itching in and around the penis
- a high temperature

The following side effects of Fortacin have been reported in sexual partners:

Common (may affect up to 1 in 10 people)

- burning sensation in and around the vagina
- reduced sensation in and around the vagina

Sometimes (may occur in up to 1 in 100 people)

- headache
- local irritation of the throat (if inhaled)
- vaginal infection (Candida)
- discomfort in the anus and rectum
- loss of sensation in the mouth
- difficulty urinating or pain when urinating
- pain in the vagina
- discomfort or itching in the vulva and vagina

Reporting side effects

If you or your sexual partner experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store Fortacin?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label on the canister and on the packaging after "EXP". This refers to the last day of that month.

Store below 25 °C. Do not freeze. Dispose of the canister 12 weeks after first use. The metal canister is pressurized. Do not pierce, damage, or burn the canister, even when it seems empty. A small amount of unusable liquid remains in the canister after all doses have been administered.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. By disposing of medicines correctly, they are destroyed responsibly and do not enter the environment.

6. Contents of the pack and other information

What substances are in this medicine?

The active substances in this medicine are lidocaine and prilocaine.

Each ml of solution contains 150 mg lidocaine and 50 mg prilocaine.

Each spray delivers 50 microliters, containing 7.5 mg lidocaine and 2.5 mg prilocaine.

1 dose is equivalent to 3 activations.

The other substance in this medicine is norflurane.

The medicine contains fluorinated greenhouse gases (HFA-134a).

Each 5 ml aerosol contains 5.06 g HFA-134a. This is equivalent to 0.00724 tons CO₂ (global warming potential GWP = 1,430).

Each 6.5 ml aerosol contains 6.5 g HFA-134a. This is equivalent to 0.0093 tons CO₂ (global warming potential GWP = 1,430).

What does Fortacin look like and how much is in a package?

Fortacin is a colorless to light yellow skin spray, solution in an aluminum aerosol with a dosing spray head.

The components of the dosing spray head consist of stainless steel, POM, TPE, polypropylene, chlorobutyl rubber, and HDPE.

Each package contains one aerosol with 6.5 ml or 5 ml solution.

Each 6.5 ml aerosol contains at least 20 doses.

Each 5 ml aerosol contains at least 12 doses.

Marketing authorization holder Recordati Ireland Limited
Raheens East
Ringaskiddy Co. Cork P43
KD30 Ireland

Manufacturer Genetic S.p.A.
Via Canfora, 64
84084 Fisciano (SA)
Italy

Recordati Industria Chimica e Farmaceutica S.p.A.
Via Matteo Civitali 1
20148 Milan
Italy

For all information about this medicine, contact the local representative of the marketing authorization holder:

Belgium/Belgique/Belgien
Recordati Ireland Ltd.
Tél/Tel: + 353 21 4379400

Bulgaria
Recordati Ireland Ltd.
Тел.: + 353 21 4379400

Czech Republic
Herbacos Recordati s.r.o.
Tel: + 420 466 741 915

Denmark
Recordati Ireland Ltd.
Tlf.: + 353 21 4379400

Germany
Recordati Pharma GmbH
Tel: + 49 (0) 731 7047 0

Eesti
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Greece
Recordati Hellas Pharmaceuticals A.E.
Tel: + 30 210-6773822

Spain
Casen Recordati, S.L.
Tel: + 34 91 659 15 50

France
Laboratoires BOUCHARA-RECORDATI
Tél: + 33 1 45 19 10 00

Croatia
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Ireland
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Iceland
Recordati Ireland Ltd.
Phone: + 353 21 4379400

Italy

Lithuania
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Luxembourg/Luxemburg
Recordati Ireland Ltd.
Tél/Tel: + 353 21 4379400

Hungary
Recordati Ireland Ltd.
Tel.: + 353 21 4379400

Malta
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Netherlands
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Norge
Recordati Ireland Ltd.
Tlf: + 353 21 4379400

Austria
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Poland
RECORDATI POLSKA sp. z o.o.
Tel.: + 48 22 206 84 50

Portugal
Jaba Recordati, S.A.
Tel: + 351 21 432 95 00

Romania
Recordati Romania S.R.L.
Tel: + 40 21 667 17 41

Slovenia
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Slovakia
Republic Herbacos Recordati s.r.o.
Tel: + 420 466 741 915

Finland

Recordati Industria Chimica e Farmaceutica
S.p.A.
Tel: + 39 02 487871
Cyprus
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Recordati Ireland Ltd.
Phone/Tel: + 353 21 4379400

Sweden
Recordati Ireland Ltd.
Tel: + 353 21 4379400

Latvia
Recordati Ireland Ltd.
Tel: + 353 21 4379400

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Other sources of information

Detailed and updated information about this medicine is available by scanning the QR code below and on the outer packaging with a smartphone.

The same up-to-date information about the medicine is also available via the following URL:

www.fortacin.eu

QR-code www.fortacin.eu

More information about this medicine is available on the European Medicines Agency website: <https://www.ema.europa.eu>.