



Package leaflet: Information for the user

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

Read all of this 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 have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Fortacin is and what it is used for
2. What you need to know before you use Fortacin
3. How to use Fortacin
4. Possible side effects
5. How to store Fortacin
6. Contents of the pack and other information

1. What Fortacin is and what it is used for

Fortacin is a combination of two medicines: lidocaine and prilocaine. These belong to a group of medicines called local anaesthetics.

Fortacin is indicated for the treatment of premature ejaculation occurring in adult men (aged 18 years and over) from first sexual intercourse. This is when you always, or nearly always, have ejaculated within one minute of sexual intercourse and this causes you negative emotional effects. Fortacin works by decreasing the sensitivity of the head of the penis to increase time before ejaculation.

2. What you need to know before you use Fortacin

Do not use Fortacin

- if you or your partner are allergic to lidocaine or prilocaine or any of the other ingredients of this medicine (listed in section 6);
- if you or your partner have a history of allergy or sensitivity to other local anaesthetics with a similar structure (known as amide-type local anaesthetics).

Warnings and precautions

Talk to your doctor or pharmacist before using Fortacin

- if you, or your partner, have been diagnosed with a genetic disease or other condition affecting your red blood cells (glucose-6-phosphate deficiency, anaemia or methaemoglobinaemia);
- if you have a history of medicine sensitivities, especially if you are not certain which medicine causes sensitivity;
- if you suffer from severe liver problems.

Premature ejaculation may be due to a condition requiring medical supervision. If this product used as directed does not provide relief, consult a doctor.

Use with condoms:

- Fortacin must not be used with latex-free female and male condoms made of polyurethane as these condoms may deteriorate when used together with Fortacin and therefore may fail to protect from sexually transmitted disease or pregnancy. Fortacin can be used with contraceptive devices made of latex rubber, polyisoprene, nitrile and silicone as no deterioration has been shown. Carefully check the material that your contraceptive or your partner's contraceptive is made of before using this product. Ask your pharmacist if you are unsure.
- If you use Fortacin with condoms, you may be more likely to be unable to develop or maintain an erection. You may also be more likely to have reduced feeling in and around the penis.

Avoid accidental contact:

- When you use this medicine, particularly during priming of the container, aim the container away from the face to avoid accidental contact with ears, eyes, nose and mouth.
- If some medicine accidentally gets into your eyes or your partner's eyes, rinse them immediately with cold water or sodium chloride solution and keep them closed as much as possible until any effects, such as numbness, wear off. Be aware that normal protective mechanisms, such as blinking, or sensation of a foreign body in the eye, may not occur until the numbness has worn off.
- Fortacin should not come into contact with a damaged ear drum.

Contact with other mucous membranes:

- Fortacin may also come into contact with other

mucous membranes such as your, or your partner's, mouth, nose and throat, causing them to feel slightly numb for a short while. As this will reduce the ability to feel pain in these areas, extra care should be taken not to injure them until the numbness has worn off.

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

- During sexual intercourse, a small amount of this medicine may be transferred, e.g. to the vagina or the anus. Therefore, both you and your partner may feel slight numbness for a short while and should take care not to injure yourselves, particularly during sexual activity. For more information regarding possible side effects in sexual partners, see section 4.

If you or your partner develop a rash or irritation, discontinue use of Fortacin. If symptoms persist, consult a doctor.

Children and adolescents

This medicine should not be used in children or adolescents under 18 years of age.

Other medicines and Fortacin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is particularly important that you talk to a doctor before using Fortacin if you are taking any of the following medicines which may interact with Fortacin:

- other local anaesthetics as benzocaine and procaine
- heart medicines (anti-arrhythmic medicines as mexiletine and amiodarone)
- fluvoxamine, cimetidine or beta-blockers, which may cause an increase in the blood levels of lidocaine.
- medicines known to increase the risk of a disorder reducing the amount of oxygen in the blood (methaemoglobinaemia), such as those listed below:
 - Benzocaine – a local anaesthetic used to treat pain and itching
 - Chloroquine, pamaquine, primaquine, quinine – used to treat malaria
 - Metoclopramide – used to treat feelings of sickness (nausea) and vomiting, including in patients with migraine
 - Glyceryl trinitrate (GTN, nitroglycerin), isosorbide mononitrate, erythryl tetranitrate, pentaerythritol tetranitrate and other nitrate and nitrite medicines – used to treat angina (chest pain caused by the heart)
 - Sodium nitroprusside, isosorbide dinitrate – used to treat high blood pressure and heart failure
 - Nitrofurantoin – an antibiotic used to treat urinary and kidney infections
 - Sulphonamides (also called sulpha medicines), e.g. sulfamethoxazole – an antibiotic used to treat urinary infections, and sulfasalazine – used to treat Crohn's disease, ulcerative colitis and rheumatoid arthritis
 - Dapsone – used to treat skin conditions such as leprosy and dermatitis and also to prevent malaria and pneumonia in high risk patients
 - Phenobarbital, phenytoin – used to treat epilepsy
 - Para-aminosalicylic acid (PAS) – used to treat tuberculosis

The risk of methaemoglobinaemia can also be increased by the use of certain dyes (aniline dyes), or the pesticide naphthalene, so let your doctor know if you work with any dyes or chemical pesticides.

Pregnancy, breast-feeding and fertility

Fortacin is not approved for use by women. Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

Fortacin should not be used whilst your partner is pregnant unless you use an effective male condom, as listed above in section 2 "Use with condoms", to prevent exposure of the unborn child.

Breast-feeding


This medicine may be used while your partner is breast-feeding.

Fertility

Fortacin may reduce the possibility of pregnancy. Therefore, patients hoping to achieve conception should either avoid using Fortacin, or, if this medicine is essential to achieve penetration, should wash the penis as thoroughly as possible five minutes after Fortacin has been applied, but prior to intercourse.

Driving and using machines

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

3. How to use Fortacin	5. How to store Fortacin
<p>Always use this medicine exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.</p> <p>The recommended dose of Fortacin is 3 sprays (3 sprays = 1 dose) on the head of the penis at least 5 minutes before sexual intercourse.</p> <p>A maximum of 3 doses can be used within 24 hours with at least 4 hours between doses.</p> <p>The maximum recommended dose (3 doses within 24 hours) should not be exceeded.</p> <p>Instructions for use</p> <ul style="list-style-type: none">• Before initial use, briefly shake the spray container and then prime the pump mechanism by spraying the valve three times into the air. Aim the container away from faces to avoid contact with eyes, nose, mouth and ears.• Before each subsequent dose, briefly shake the spray container and then re-prime the pump by spraying 1 time into the air.• Retract any foreskin from the head of the penis. Holding the can upright (valve up), apply 1 dose (3 sprays) of Fortacin to the entire head of the penis, by covering one third with each spray.• Wait 5 minutes then wipe off any excess spray prior to having sexual intercourse. It is important that you wipe off any excess spray also if you use a condom (see also section 2 for other important information regarding use with condoms). <p>If you use more Fortacin than you should</p> <p>If you do apply too much, wipe it off.</p> <p>Symptoms of using too much Fortacin are listed below. Contact your doctor or pharmacist if you experience any of these. They are very unlikely to happen if it is used as instructed:</p> <ul style="list-style-type: none">• Feeling light headed or dizzy• Tingling of the skin around the mouth and numbness of the tongue• Abnormal taste• Blurred vision• Ringing in the ears• There is also a risk of a disorder reducing the amount of oxygen in the blood (methaemoglobinaemia). This is more likely when certain medicines have been taken at the same time. If this happens, the skin becomes bluish grey due to a lack of oxygen. <p>In serious cases of overdose, symptoms may include fits, low blood pressure, slowed breathing, stopped breathing and altered heart beat. These effects may be life threatening.</p> <p>If you have any further questions on the use of this medicine, ask your doctor or pharmacist.</p>	<p>Keep this medicine out of the sight and reach of children.</p> <p>Do not use this medicine after the expiry date which is stated on the spray container label and the carton after “EXP”. The expiry date refers to the last day of that month.</p> <p>Store below 25°C. Do not freeze. You must throw away the container 12 weeks after you first use it. The metal container is pressurised. Do not puncture, break or burn it even when apparently empty. A residual volume of fluid that is not usable will remain in the container after all doses have been administered.</p> <p>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 to protect the environment.</p>
4. Possible side effects	6. Contents of the pack and other information
<p>Like all medicines, this medicine can cause side effects, although not everybody gets them.</p> <p>The following side effects have been reported with Fortacin in male patients:</p> <p>Common (may affect up to 1 in 10 people)</p> <ul style="list-style-type: none">• Inability to develop or maintain an erection• reduced feeling in and around the penis• feeling of burning in and around the penis <p>Uncommon (may affect up to 1 in 100 people)</p> <ul style="list-style-type: none">• headache• local irritation of the throat (if inhaled)• irritation of the skin• redness on and around the penis• failure to ejaculate during sexual 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 <p>The following side effects have been reported with Fortacin in sexual partners:</p> <p>Common: (may affect up to 1 in 10 people)</p> <ul style="list-style-type: none">• feeling of burning in and around the vagina• reduced feeling in and around the vagina <p>Uncommon (may affect up to 1 in 100 people)</p> <ul style="list-style-type: none">• headache• local irritation of the throat (if inhaled)• vaginal thrush (<i>Candida</i>) infection• discomfort in the anus and rectum• loss of feeling in the mouth• difficulty or pain passing urine• pain in the vagina• discomfort or itching in the vulva and vagina <p>Reporting of side effects</p> <p>If you or your sexual partner get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.</p>	<p>What Fortacin contains</p> <ul style="list-style-type: none">• The active substances are lidocaine and prilocaine.• Each ml of solution contains 150 mg lidocaine and 50 mg prilocaine• Each spray delivers 50 microlitres which contains 7.5 mg lidocaine and 2.5 mg prilocaine.• 1 dose is equal to 3 actuations.• The other ingredient is norflurane• This medicine contains fluorinated greenhouse gases.• Each spray contains 5.06 g of HFA-134a corresponding to 0.00724 tonne CO2 equivalent (global warming potential GWP = 1.430).• Each spray contains 6.5 g of HFA-134a corresponding to 0.0093 tonne CO2 equivalent (global warming potential GWP = 1.430). <p>What Fortacin looks like and contents of the pack</p> <p>Fortacin is a colourless to light yellow cutaneous spray, solution in an aluminium spray container with metering valve.</p> <p>The metering valve’s components are the stainless steel, POM, TPE, polypropylene, chlorobutyl rubber and HDPE.</p> <p>Each pack contains 1 spray container with 6.5 ml or 5 ml of solution.</p> <ul style="list-style-type: none">• Each spray container of 6.5 ml delivers a minimum of 20 doses.• Each spray container of 5 ml delivers a minimum of 12 doses <p>Marketing Authorisation Holder</p> <p>Recordati Ireland Ltd. Raheens East Ringaskiddy Co. Cork Ireland</p> <p>Manufacturer</p> <p>Genetic S.p.A. Via Canfora, 64 84084 Fisciano (SA) Italy</p> <p>For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: Recordati Pharmaceuticals Ltd. Tel: + 44 (0) 1491 576 336</p> <p>This leaflet was last revised in 02/2025.</p> <p>Other sources of information</p> <p>Detailed and updated information on this medicine is available by scanning the QR code below and the outer carton with a smartphone.</p> <p>The same information is also available on the following URL: www.fortacin.eu</p> <div>www.fortacin.eu</div>