

Package leaflet: Information for the user

Fluoride 5000 ppm Toothpaste

Read all of this leaflet carefully before you start using 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, dentist or pharmacist.
- 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, dentist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

This medicine is available as Fluoride 5000 ppm Fluoride Toothpaste but will be called Fluoride Toothpaste throughout the rest of this leaflet.

What is in this leaflet

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

1. What Fluoride Toothpaste is and what it is used for

Fluoride Toothpaste is used to help prevent tooth decay (dental caries) in adolescents aged 16 years and older, and adults, particularly amongst patients at risk from multiple caries. The toothpaste contains fluoride as sodium salt, which belongs to a group of medicines called caries preventing agents.

2. What you need to know before you use Fluoride Toothpaste

Do not use Fluoride Toothpaste:

- if you are allergic to sodium fluoride or any of the other ingredients of this medicine, listed in section 6.
- if you are an adolescent or child aged under 16 years.

Warnings and precautions

Talk to your doctor or dentist, or pharmacist before using Fluoride Toothpaste:

- Fluoride Toothpaste has a high fluoride content. Fluoride tablets, drops, chewing gum, gels or varnishes, as well as fluoridated water or salt, should be avoided during the use of Fluoride Toothpaste. In order to prevent build up of fluoride, your total intake must be assessed before using this fluoride toothpaste. Ask your doctor, dentist, or pharmacist about this.

Children and adolescents

Fluoride Toothpaste is not intended for use by children and adolescents aged younger than 16 years.

Other medicines and Fluoride Toothpaste

No interactions with other medicines are known.

Tell your doctor, dentist or pharmacist if you are taking or using, or have recently taken or used, or might take or use any other medicines, including medicines obtained without a prescription.

Fluoride Toothpaste with food and drink

Fluoridated water and salt should be avoided while using this toothpaste. Food and drink, if taken immediately after brushing your teeth, may reduce the amount of tooth remineralisation that occurs. You should therefore brush your teeth with Fluoride Toothpaste after meals.

Pregnancy, breast-feeding, and fertility

There is no experience with the use of Fluoride Toothpaste in pregnant women. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, dentist, or pharmacist for advice before taking this medicine.

Driving and using machines

Using Fluoride Toothpaste will not affect your ability to drive or use machinery.

Fluoride Toothpaste contains sodium benzoate, sorbitol solution and propylene glycol:

- sodium benzoate is a mild irritant to the skin, eyes, and mucous membranes.
- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicinal product.
- propylene glycol may cause skin irritation.

3. How to use Fluoride Toothpaste

Fluoride Toothpaste is only for use by persons aged sixteen years and older.

Always use this medicine exactly as described in this leaflet or as your doctor, dentist, or pharmacist has told you. Check with your doctor, dentist or pharmacist if you are not sure.

Use Fluoride Toothpaste three (3) times a day for brushing your teeth:

- apply a 2 cm ribbon of toothpaste onto your toothbrush for each brushing (2 cm provides between 3 mg and 5 mg of fluoride).
- brush your teeth after each meal.
- brush your teeth vertically, from the gum to the tip of the tooth.
- spit out excess foam and do not swallow.

Careful brushing of your teeth takes about three minutes.

Use in children and adolescents

This toothpaste is not for use by adolescents and children aged less than 16 years.

If you use more Fluoride Toothpaste than you should, or if you have swallowed the toothpaste

If you swallowed a large amount of toothpaste by mistake, and if you experience digestive problems such as being sick, diarrhoea, and pain in the stomach or abdomen, you must tell a doctor immediately as treatment may be required. Please take this leaflet with you.

If you constantly swallow too much of the toothpaste over several months, or years, you may get stained or speckled appearance of tooth enamel, and enamel fragility (dental fluorosis), or increased bone density, osteosclerosis (bone fluorosis).

If you forget to use Fluoride Toothpaste

Use as soon as you remember, but do not use a double dose to make up for a missed dose.

Continue treatment as usual after the next meal.

If you have any further questions on the use of this medicine, ask your doctor, dentist, or pharmacist.

4. Possible side effects

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

In some rare cases (less than 1 in 1,000 users) allergic (hypersensitivity) reactions can occur, such as rash, itching, swelling, and redness.

Burning oral sensation has also been reported.

Reporting of side effects

If you get any side effects, talk to your doctor, dentist, or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system, the Yellow card scheme; website www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluoride Toothpaste

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 tube and carton after Exp.

The expiry date refers to the last day of that month. Discard 6 months after opening.

Replace the tube cap after use. This product requires no special storage conditions.

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.

6. Contents of the pack and other information**What Fluoride Toothpaste contains**

- The active substance is fluoride, as sodium fluoride. Each 1 g of toothpaste contains 5 mg fluoride (as sodium fluoride), which is 5,000 ppm fluoride.

The other ingredients (excipients) are: Sorbitol solution (non – crystallising) (E420), dental type silica (precipitated) (E551), macrogol 600 (E1521), tetrapotassium pyrophosphate (E340), xanthan gum (E415), sodium benzoate (E211), sodium laurilsulfate, spearmint flavouring (containing menthol, propylene glycol, carvone, spearmint oil, peppermint oil, anethole, and vanillin), saccharin sodium (E954), brilliant blue FCF (E133) and purified water.

What Fluoride Toothpaste looks like and contents of the pack

Fluoride Toothpaste is a smooth, blue coloured translucent paste with the odour and taste of spearmint.

It is supplied in a 51 g collapsible tube enclosed in an outer carton.

Marketing Authorisation Holder:

Morningside Healthcare Ltd., Unit C, Harcourt Way, Leicester, LE19 1WP, UK

Manufacturer:

Morningside Pharmaceuticals Ltd., 5 Pavilion Way, Loughborough, LE11 5GW, UK

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