

Title: Fluoritop HF 5000 PPM
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Package leaflet: Information for the user

FLUORITOP® HF

5000 PPM Fluoride Toothpaste

Fluoride (as Sodium Fluoride)

Read all of this 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, please 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

What is in this leaflet:

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

1. WHAT FLUORITOP TOOTHPASTE IS AND WHAT IT IS USED FOR

Fluoritop toothpaste contains fluoride as sodium salt, which belongs to a group of medicines called caries preventing agents.

This 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FLUORITOP TOOTHPASTES

Do not use Fluoritop toothpastes;

- 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 under 16 years of age.

Warnings and precautions

Talk to your doctor, dentist or pharmacist before using Fluoritop toothpastes;

Fluoritop Toothpaste has high fluoride content. In order to prevent build up of fluoride, your total intake must be assessed before using this Fluoritop toothpaste.

Fluoride tablets, drops, chewing gum, gels or varnishes, as well as fluoridated water or salt, should be avoided during the use of Fluoritop Toothpaste.

Children and adolescents

Fluoritop Toothpaste is not intended for use by children and adolescents under 16 years of age.

Other medicines and Fluoritop 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.

Fluoritop 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 Fluoritop Toothpaste after meals.

Pregnancy, breast feeding and fertility

There is no adequate data from 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 Fluoritop Toothpaste will not affect your ability to drive or use machinery.

Important information about some of the ingredients of Fluoritop toothpaste

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This toothpaste contains Sodium Benzoate. Sodium Benzoate is a mild irritant to the skin, eyes and mucous membrane.

3. HOW TO USE FLUORITOP TOOTHPASTE

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

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Fluoritop toothpaste is only for use by persons aged 16 years and above.

Use this toothpaste three times a day for brushing your teeth;

- apply a 2 cm ribbon of toothpaste onto your toothbrush for each brushing (2 cm provides between 3mg and 5mg 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:

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

If you use more toothpaste than you should or if you have swallowed the toothpaste:

Consult your doctor immediately, 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 as you may require treatment. 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 take Fluoritop toothpaste:

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

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 FLUORITOP TOOTHPASTE

Keep this medicine out of the sight and reach of children.

Replace the tube cap after use. This medicinal product does not require any special storage conditions.

Do not use Fluoritop toothpaste after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of the month. Discard 6 months after opening.

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 Fluoritop toothpaste contains

Each 1gm of toothpaste contains 5 mg fluoride (as sodium fluoride), which is 5000 ppm fluoride.

The other ingredients are; glycerol E422, sorbitol liquid (non-crystallising) E420, brilliant blue, carmellose sodium, sodium saccharine, sodium benzoate E211, macrogols 600, dental type silicas, tetra potassium pyrophosphate, sodium laurilsulfate, flavour mint sc and purified water

What Fluoritop toothpaste looks like and contents of the pack

Fluoritop toothpaste is a blue colored, opaque smooth gel with characteristic odour and taste.

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Rx Farma, Colonial Way, Watford, Hertfordshire, WD24 4YR.

Manufacturer

Rx Farma Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR

If you would like this leaflet in different format or want to report any side effects please contact marketing authorisation holder listed above.

This leaflet was last revised in February 2019

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