

Duraphat® 5000ppm Fluoride Toothpaste

(fluoride)

Patient Information Leaflet

Read all of 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 dentist or pharmacist.
- * This medicine has been prescribed for you. 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 serious, or if you notice any side effects not listed in this leaflet, please tell your dentist or pharmacist.

Your medicine is called Duraphat® 5000ppm Fluoride Toothpaste, but will be referred to as Duraphat® Toothpaste throughout this leaflet.

In this leaflet:

- 1 What Duraphat® Toothpaste is and what it is used for
- 2 Before you use Duraphat® Toothpaste
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1 What Duraphat® Toothpaste is and what it is used for

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

2 Before you use Duraphat® Toothpaste

Do not use Duraphat® Toothpaste

- * if you are allergic (hypersensitive) to Sodium Fluoride or any of the other ingredients of Duraphat® Toothpaste.

Take special care with Duraphat® Toothpaste

- * Duraphat® 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 Duraphat® Toothpaste. In order to prevent accumulation of fluoride, your total intake must be assessed before using this fluoride toothpaste. Ask your dentist or pharmacist concerning this matter.
- * Duraphat® Toothpaste is not intended for use in adolescents and children under 16 years of age.

Using other medicines

No interactions with other medicines are known. Please tell your dentist or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Using Duraphat® Toothpaste with food and drink

Fluoridated water and salt should be avoided during the use of this toothpaste.

Food and drink, if taken immediately after brushing, may have an inhibitory effect on the remineralisation of the teeth. Therefore brush your teeth with Duraphat® Toothpaste after meals.

Pregnancy and breast-feeding

There is no experience from the use of Duraphat® in pregnant women. If you are pregnant or breast-feeding, ask your doctor, dentist or pharmacist before using this toothpaste as for any medicine.

Important information about some of the ingredients of Duraphat® Toothpaste

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

3 How to use Duraphat® Toothpaste

Duraphat® Toothpaste is for use by persons aged 16 years and above. Always use Duraphat® Toothpaste exactly as your dentist or pharmacist has told you. You should check with your dentist or pharmacist if you are not sure.

- Use Duraphat® Toothpaste 3 times a day for brushing your teeth
 - * apply a 2 cm ribbon onto your toothbrush for each brushing (2 cm provides between 3 mg and 5 mg of fluoride).
 - * brush your teeth after each meal.
 - * vertically, from the gum to the tip of the tooth.
 - * spit out excess foam and do not swallow
- Careful brushing takes approximately 3 minutes.

If you use more Duraphat® 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: vomiting, diarrhoea, and abdominal pain, you must tell a doctor immediately as treatment may be required. Please take this leaflet with you.

Duraphat® contains menthol which if accidentally ingested at excessive amounts may cause convulsions, particularly in infants and children.

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

If you forget to use Duraphat® Toothpaste

Simply use as soon as you remember, but do not use a double dose to make up for the missed dose. Continue treatment as usual after the next meal.

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

4 Possible side effects

Like all medicines, Duraphat® Toothpaste can cause side effects, although not everybody gets them.

In some rare cases (i.e. less than 1 in 1000 people treated) allergic (hypersensitivity) reactions can occur e.g. rash, itching swelling and redness. Burning oral sensation has also been reported.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your dentist or pharmacist.

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Patient Information Leaflet (continued)

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Duraphat® Toothpaste

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not store above 25°C.

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 the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Duraphat® Toothpaste contains:

The active substance in fluoride (as sodium fluoride) 1g of toothpaste contains 5mg fluoride (as sodium fluoride), corresponding to 5000ppm fluoride

The other ingredients are: Sorbital solution 70% (non-crystallising), silica, precipitated silica, macrogol 600, potassium diphosphate, xanthan gum, sodium benzoate, sodium dodecyl sulfate, spearmint flavour (containing peppermint oil, carvone, spearmint oil, levomenthol, anethole and lemon oil), saccharin sodium, brilliant blue FCF, purified water.

What Duraphat® Toothpaste looks like and contents of the pack

Duraphat® Toothpaste is a blue coloured toothpaste. It is supplied in a 51g tube, enclosed in an outer carton. Pack size: 1 x 51g tube

The Parallel Product Authorisation Holder is:

Procured from within the EU. Parallel Product Authorisation Holder: LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Re-packaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Manufacturer

Manufactured by: Colgate-Palmolive (UK) Ltd., The Dental Health Unit, Williams House, Lloyd Street North, Manchester Science Park, Manchester M15 6SE, United Kingdom or GABA GmbH, Berner Weg 7, 79539 Lörrach, Germany.

Duraphat® is a registered trademark of Colgate-Palmolive Company.

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Is this leaflet hard to see or read?
Phone LTT Pharma Limited,
Tel: +44 (0) 1527 505414
for help.