

Package Leaflet: Information for the User

Duraphat® 5000ppm Fluoride Toothpaste

Fluoride (as Sodium Fluoride)

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 dentist or pharmacist has 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 dentist 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.

In this leaflet:

1. What Duraphat® Toothpaste is and what it is used for
2. What you need to know before you use Duraphat® Toothpaste
3. How to use Duraphat® Toothpaste
4. Possible side effects
5. How to store Duraphat® Toothpaste
6. Further information

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. WHAT YOU NEED TO KNOW 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.

Warnings and Precautions

- 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, pharmacist or oral hygienist concerning this matter.
- Duraphat® Toothpaste is not intended for use in adolescents and children under 16 years of age.

Other medicines and Duraphat Toothpaste

No interactions with other medicines are known. Tell your dentist or doctor if you are taking, have recently taken or might take any other medicines.

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 think you may be pregnant or are planning to have a baby, ask your doctor, dentist or pharmacist for advice before using this medicine.

Duraphat® Toothpaste contains 5 mg Sodium Benzoate (E211) in each g of toothpaste. Sodium Benzoate (E211) may cause local irritation.

This medicine also contains a spearmint flavouring with limonene, linalool, citral, geraniol, and citronellol which may cause allergic reactions.

3. HOW TO USE DURAPHAT® TOOTHPASTE

Duraphat® Toothpaste is for use by persons aged 16 years of age and over only .

Always use Duraphat® Toothpaste exactly as described in this leaflet or 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 the 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or dentist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance

Website: www.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 this medicine out of the sight and reach of children. Do not use Duraphat® Toothpaste after the expiry date which is stated on the tube and carton after "Expiry date". The expiry date refers to the last day of that month.

Do not store above 25°C.

6. FURTHER INFORMATION

What Duraphat® Toothpaste contains

- The active substance is fluoride (as sodium fluoride).

1 g of toothpaste contains 5 mg fluoride, corresponding to 5000ppm fluoride.

- The other ingredients are Liquid Sorbitol (Non-crystallising), Dental Type Silica, Dental Type Silica (Precipitated), Macrogol 600, Tetrapotassium Pyrophosphate, Xanthan Gum, Sodium Benzoate (E211), Sodium Laurilsulfate, Spearmint flavouring (containing Peppermint Oil, Carvone, Spearmint Oil, Menthol, Anethol, and Lemon Oil) [please refer section 2 for excipients with known effects], Saccharin Sodium, Brilliant Blue FCF (E133), and 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 sizes: 1 x 51g tube or 3 x 51g tubes.

Marketing Authorisation Holder

Colgate-Palmolive A/S,
Bredevej 2 A, Virum,
Hovedstaden, 2830,
Denmark.

Manufacturer

Thepenier Pharma & Cosmetics
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