

## **Package Leaflet: Information for the User**

### **Duraphat® 5000 ppm Fluoride Toothpaste**

Fluoride (as Sodium Fluoride)

#### **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 signs of illness 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.

#### **In this leaflet:**

1. What Duraphat® Toothpaste is and what it is used for
2. Before you use Duraphat® Toothpaste
3. How to use Duraphat® Toothpaste
4. Possible side effects
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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. 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 for advice before using this toothpaste as for any medicine.

### **Important information about some of the ingredients of Duraphat® Toothpaste**

This medicine contains 5 mg sodium benzoate in each g of toothpaste.. Sodium Benzoate may cause local irritation.

This medicine contains a 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 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.

##### **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](http://www.mhra.gov.uk/yellowcard)

##### **Ireland**

HPRA Pharmacovigilance

Earlsfort Terrace

IRL-Dublin 2

Tel: + 353 1 6764971

Fax: + 351 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

e-mail: [medsafety@hpra.ie](mailto: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 this medicine out of the reach and sight 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 5000 ppm 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), 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 (UK) Limited  
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Guildford  
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**Manufacturer**

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