Read all of this leaflet carefully before you start using this medicine.

**What Duraphat Toothpaste looks like and the contents of the pack**

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.

**Before you use Duraphat Toothpaste**

Duraphat Toothpaste has a high fluoride content. Fluoride tablets, drops, chewing gum, gels or varnishes, as well as humidified 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.

**Taking care with Duraphat Toothpaste**

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

**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.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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**Reporting of side effects**

If you report any side effects, tell your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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**Further information**

What Duraphat Toothpaste contains

1g of toothpaste contains 5mg fluoride (as sodium fluoride), corresponding to 5000 ppm fluoride.

Also contains: Liquid Sorbitol (non-crystallising), Dental Type Silica, Dental Type Silica (Precipitated), Macrogol 600, Tetrapotassium Pyrophosphate, Xanthan Gum, Sodium Benzoate (E211), Sodium Laurylethylphosphate, Spearmint flavoung (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 the contents of the pack

Duraphat Toothpaste is a blue coloured toothpaste. It is supplied in a 51g tube, enclosed in an outer carton.

**Manufacturer**


It is procured from within the EEC by Product Licence holder: MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER, UK.

Repackaged by: MPT Pharma Ltd.

PL: 33532/0521 Duraphat® 5000 ppm Fluoride Toothpaste

Leaflet dated 02 April 2015

Leaflet coded XXXXXXXXXX

Duraphat® is a registered trademark of Colgate-Palmolive Company, USA.
Do not use Fluoride Toothpaste
• in any other medicines that you are taking, including those to treat or help with cancer and other serious or long-term conditions and herbal or complementary medicines, including medicines obtained without a prescription.

1. WHAT FLUORIDE TOOTHPASTE IS AND WHAT IT IS USED FOR
Fluoride 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 preventives.

2. BEFORE YOU USE FLUORIDE TOOTHPASTE
Do not use Fluoride Toothpaste
• if you allergic (hypersensitive) to Sodium Fluoride or any of the other ingredients of Fluoride Toothpaste.

Take special care with 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 accumulation of fluoride, your total intake must be assessed before using this fluoride toothpaste.
• Ask your dentist or pharmacist concerning this matter.
• Fluoride Toothpaste is not intended for use in children and adolescents 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 Fluoride 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 Fluoride Toothpaste after meals.

Pregnancy and breast-feeding
There is no experience from the use of Fluoride 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 Fluoride Toothpaste
This toothpaste contains Sodium Benzoate. Sodium Benzoate is a mild irritant to the skin, eyes and mucous membrane.

3. HOW TO USE FLUORIDE TOOTHPASTE
Fluoride Toothpaste is for use by persons aged 16 years and above. Always use Fluoride Toothpaste exactly as your dentist or pharmacist has told you. You should check with your dentist or pharmacist if you are not sure. Use Fluoride 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 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: vomiting, diarrhoea, and abdominal pain, you must tell a doctor immediately as treatment may be required. Please take this leaflet with you.

If you have any further questions, ask your dentist or pharmacist.

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4. POSSIBLE SIDE EFFECTS
Like all medicines, Fluoride Toothpaste can cause side effects, although not everybody gets them. In some rare cases (i.e. less than 1 in 1000 patients 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.

5. HOW TO STORE FLUORIDE TOOTHPASTE
• Keep out of the sight and reach of children.
• Do not use Fluoride 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.
• If your toothpaste becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
• 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 Fluoride Toothpaste contains
1g of toothpaste contains 5mg fluoride (as sodium fluoride), corresponding to 5000 ppm fluoride.

Other medicines
Sodium, Brilliant Blue FCF (E133) and Purified Water.

Pyrophosphate, Xanthan Gum, Sodium Benzoate (E211), Sodium Laurilsulphate, Spearmint flavouring (containing Peppermint Oil, Carvone, Spearmint Oil, Menthol, Anethol and Lemon Oil), Saccharin Sodium, Brilliant Blue FCF (E133) and Purified Water.

What Fluoride Toothpaste looks like and the contents of the pack
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Manufacturer

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Repackaged by: MPI Pharma Ltd.

PL: 33532/0251 Fluoride 5000 ppm Toothpaste
Leaflet dated 02 April 2015
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