6.0 Pharmaceutical particulars

6.1 List of excipients
Ethanol 96%, White Wax (E901), Shellac DAB (E904), Colophony, Mastic, Saccharin (E954), Raspberry Essence (containing Ethyl Butyrate, Geraniol, Iris Resinoid, Isoamyl Acetate, Jasmine Absolute, Vanillin and Propylene Glycol).

6.2 Incompatibilities
None known.

6.3 Shelf life
Unopened 3 years. For aluminium tube: after opening, use within 3 months.

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
Boxes of 1 x 10 ml or 5 x 30 ml tubes made of internally lacquer-coated aluminium, externally printed, with white plastic screw cap with sealing plug.
Boxes of 1 x 1.6 ml or 5 x 1.6 ml glass cylinders with a cream bromobutyl rubber stopper and gold aluminium cap at the top and dark blue chlorobutyl rubber stopper at the bottom.

6.6 Instructions for use/handling
If necessary the teeth should be cleaned, especially at the sites most susceptible to caries. When groups of patients (e.g. children) are to be treated, they should clean the teeth themselves using a toothbrush.
To start, clear one or two quadrants of excessive saliva using an air syringe (or dabbing with cellulose). Duraphat 50mg/ml Dental Suspension is applied from the tube using a miniature cotton swab, probe or brush, painting and dabbing repeatedly to form a thin layer. Then treat the next quadrants in the same manner. It is advisable to begin by applying the dental suspension to teeth in the lower jaw before too much saliva collects and interferes. It may not be necessary to paint the lingual surfaces since these are generally more caries-resistant; Duraphat should preferably be applied to those spots most susceptible to caries attack.
Application of Duraphat from the cylinder is particularly suited to targeted, low-dose application. A blunt cannula is used with the end bent to an angle to facilitate application to approximal and distal surfaces. For application to approximal surfaces place the cannula between adjacent teeth and deliver a small amount of Duraphat. The dental suspension should be applied from both sides of the interproximal space and occlusally.
For fissures, a drop of Duraphat should be spread along the fissure using the cannula. Edges of fillings and crowns and hypersensitive tooth necks can be treated in the same way.
The smooth surfaces of the teeth should be treated when caries activity is high, particularly if decalcification is evident. The cannula should be placed tangentially to the teeth and Duraphat distributed with the side of the curved cannula end.
Areas around fixed orthodontic devices can be treated with Duraphat using the cannula.
The yellowish colour of Duraphat facilitates its application and control. Duraphat sets in the presence of saliva. The effect of Duraphat depends upon the prolonged activity of the fluoride. The dental suspension film should not be removed prematurely. Patients should be advised not to brush their teeth or chew food for at least 4 hours after treatment; during this time, soft foods and liquids may be consumed. However, if you need to, the dental suspension layer can easily be removed by brushing or rinsing.
Instruments, clothing, etc. which comes into contact with Duraphat can be cleaned with alcohol.

7.0 Marketing Authorization Holder
Colgate-Palmolive (U.K.) Limited
Guildford Business Park
Middleton Road
Guildford, Surrey GU2 8JZ, UK

8.0 Marketing Authorization Number
PL No: 00049/0042

9.0 Date of (partial) revision of the text
February 2003

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Colgate®

Patient Information Leaflet

Duraphat 50mg/ml Dental Suspension
Sodium fluoride

Please read this leaflet carefully. It gives an outline of the more important things you should know about your medicine. If you want to know more about this medicine, or you are not sure about anything, ask your dentist. You should keep this leaflet throughout the course of your treatment.
The name of your medicine is Duraphat 50mg/ml Dental Suspension.
1 ml of Duraphat contains 50 mg of the active ingredient Sodium Fluoride equivalent to 22.6 mg of Fluoride. Other ingredients are Ethanol, White wax (E901), Shellac (E904), Colophony, Mastic, Saccharin (E954) and Raspberry Essence (which contains Ethyl Butyrate, Geraniol, Iris Resinoid, Isoamyl Acetate, Jasmine Absolute, Vanillin and Propylene Glycol).
Duraphat is a brown/yellow opaque suspension. It is supplied in tubes of 10 ml or 30 ml or cylinders of 1.6 ml.

How does your medicine work?
The active ingredient, Sodium Fluoride is an anti-caries agent. When Duraphat is applied on to the teeth, globules of calcium fluoride form on the enamel. These globules break down to release fluoride which penetrates deep into the tooth and provides long-term protection against tooth decay.

Who makes Duraphat 50mg/ml Dental Suspension
Manufactured by: Pharbil Waltrop GmbH, Im Wirrigen 25, D-45731 Waltrop, Germany. For the Product Licence Holder: Colgate-Palmolive (U.K.) Ltd, Guildford, Surrey, GU2 8JZ, UK.

What is Duraphat 50mg/ml Dental Suspension for?
Duraphat prevents tooth decay and desensitises hypersensitive teeth.

Before taking this medicine
Duraphat contains 33.8 % of alcohol, each dose containing up to 0.2 grams. It is therefore recommended to avoid its use during pregnancy and breast feeding. This may also be harmful for those suffering from liver disease, alcoholism, epilepsy, and brain disease or injury. It may modify or increase the effect of other medicines.
You should advise your dentist before use if:
- You are hypersensitive to any of the ingredients.
- You have asthma.
- You have mouth ulcers or gum disease.

Do not take fluoride supplements (tablets or drops) while using Duraphat.
Tell your dentist if you are taking any other medicines, including those you may have bought yourself.
It is best to have eaten a meal before Duraphat is used.

Using this medicine
Duraphat 50mg/ml Dental Suspension is applied on to your teeth by your dentist. The dentist will decide how much Duraphat to use. He may paint all your teeth or only those susceptible to caries.
First, the dentist will remove plaque by brushing your teeth; you may be asked to brush your own teeth. The dentist will then dry your teeth by removing excess saliva. Duraphat is painted on to the teeth using a brush, probe or swab.
To prevent caries, the treatment can be repeated after 3 or 6 months.
To desensitise hypersensitive teeth, the treatment is repeated 2 or 3 times in a few days.

After treatment
You should not brush your teeth or chew food for at least 4 hours after Duraphat has been applied on to your teeth. You may drink and eat soft foods like soup.

Are there any side effects?
Like any medicine, Duraphat 50mg/ml Dental Suspension may cause unwanted effects in some patients. These are most likely in patients who are allergic to any of the ingredients.

Very rarely, patients have reported swelling of the tissues in the mouth, mouth ulcers or gingivitis. If you have asthma, the dental suspension may cause an asthma attack. If necessary, the varnish dental suspension can be removed by brushing the teeth and rinsing.
Occasionally, sensitive patients have felt sick especially after the application of a large amount of Duraphat.
If you develop any of the effects described above or any other unwanted effect, tell your dentist or pharmacist.

Safe keeping of this medicine
Duraphat 50mg/ml Dental Suspension should not be used beyond the expiry date given on the label. The tube should be discarded 3 months after opening.

Do not store above 25°C.

Keep Duraphat in a safe place where children cannot reach it.

Date of revision: February 2003

TECHNICAL INFORMATION

Duraphat 50mg/ml Dental Suspension Sodium fluoride

1.0 Product name
Duraphat 50mg/ml Dental Suspension

2.0 Qualitative and quantitative composition
1 ml of suspension contains 50 mg Sodium Fluoride equivalent to 22.6 mg of Fluoride.

3.0 Pharmaceutical form
Dental suspension

4.0 Clinical particulars

4.1 Therapeutic Indications
For the prevention of caries in children and adults as part of a comprehensive control programme.
For the:
- prevention of recurring (or marginal) caries
- prevention of progression of caries
- prevention of decalcification around orthodontic appliances
- prevention of pit and fissure (occlusal) caries.

For the desensitisation of hypersensitive teeth as part of a treatment regimen which includes the daily use of a suitable toothpaste.

4.2 Posology and method of administration
Duraphat 50mg/ml Dental Suspension is to be applied by the dentist. Before applying Duraphat, excess plaque should be removed and the teeth dried. Duraphat is applied as a thin layer to the most susceptible areas of dentition using a brush, probe or swab.
Recommended dosage for single application:
For milk teeth: up to 0.25 ml (=5.65 mg Fluoride)
For mixed dentition: up to 0.40 ml (=9.04 mg Fluoride)
For permanent dentition: up to 0.75 ml (=16.95 mg Fluoride)
For caries prophylaxis, the application is usually repeated every 6 months but more frequent applications (every 3 months) may be made.
For hypersensitivity, 2 or 3 applications should be made within a few days.
The patient should not brush the teeth or chew food for 4 hours after treatment.

4.3 Contra-indications
Hypersensitivity to colophony and/or any other constituents.
Ulcerative gingivitis.
Stomatitis.
Bronchial asthma.

4.4 Special warnings and precautions for use
Application of Duraphat 50mg/ml Dental Suspension to the whole dentition should not be carried out on an empty stomach.
On the day when Duraphat has been applied, no high dose Fluoride preparations, such as fluoride gels, should be used. The administration of fluoride supplements should be suspended for several days after applying Duraphat.

4.5 Interactions with other medicaments and other forms of interactions
The presence of alcohol in the Duraphat formula should be considered.

4.6 Pregnancy and lactation
As this product contains 33.8% of ethanol (each dose contains up to 0.2 g of alcohol), it is recommended to avoid its use in pregnant women and during lactation.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable effects
In subjects with a tendency to allergic reactions, oedematous swelling of the oral mucosa has been observed in exceptional cases, especially after extensive application. If necessary, the dental suspension layer can easily be removed from the mouth by brushing and rinsing. Ulcerative gingivitis and stomatitis have been reported by sensitive individuals.
In rare cases, asthma attacks may occur in patients who have bronchial asthma.
In patients with gastric sensitivity, retching may exceptionally occur after a high dosage and extensive application.

4.9 Overdose
In very high doses, Fluoride has an acute toxic action through inhibition of enzymes resulting in hypocalcaemia. Doses of several milligrams of Fluoride per kg body weight cause nausea and vomiting.
The dental suspension layer can easily be removed from the mouth by brushing and rinsing.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties
Sodium Fluoride applied topically after tooth eruption reduces caries by inhibiting demineralisation and promoting remineralisation of the tooth surface and by inhibiting the cariogenic microbial process.
Duraphat 50mg/ml Dental Suspension also reduces dentinal hypersensitivity.
In the management of dental erosion associated with the frequent consumption of acidic beverages or gastric reflux, high concentration topical Fluoride agents are considered to be of value. Duraphat is at least as effective as 2% Sodium Fluoride solution in inhibiting erosion in vitro.

5.2 Pharmacokinetic properties
After oral administration, Fluoride absorption is rapid and extensive (90-100%) with peak fluoride plasma levels reached within 30 to 60 minutes after ingestion. Fluoride is widely distributed through the body and concentrates in bone and teeth. About 50% of Fluoride is stored. Excretion is primarily through the kidneys with less than 10% being excreted in the faeces and less than 1% in sweat and saliva.
Duraphat covers teeth with a film of suspension which hardens in the presence of saliva and then persists, and which over the following hours causes fluoride to accumulate at a measurable depth in the tooth enamel.

5.3 Preclinical safety data
The product is used under total control of the dentist and the amount of Fluoride introduced to the patient at one time is within acceptable safety limits. The recommended doses are up to 0.75 ml for permanent dentition. Treatment is recommended every 6 months or a maximum of every three months. For hypersensitivity 2-3 applications are recommended within a few days. These levels of Fluoride introduced are again within acceptable safety limits.
Due to the slow release of Fluoride, the plasma levels are even lower than levels known to produce no side effects in children.