SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Duraphat 50 mg/ml Dental Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of suspension contains 50 mg Sodium Fluoride equivalent to 22.6 mg of Fluoride

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Dental Suspension

Brown/yellow, opaque suspension

4 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 0.25ml (=5.65mg Fluoride)

For mixed dentition: up to 0.40ml (=9.04mg Fluoride)

For permanent dentition: up to 0.75ml (=16.95mg 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.

Method of administration: For dental use.

4.3 Contraindications

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. Prolonged daily ingestion of excessive fluoride may result in varying degrees of fluorosis.

Tubes: The container of this medicinal product contains latex rubber. May cause severe allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

The presence of alcohol in the Duraphat formula should be considered.

4.6 Fertility, pregnancy and lactation

As this product contains 33.8% of ethanol (each dose contains up to 0.2g 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

Gastrointestinal disorders:

Very rare (<1/10,000): Stomatitis, gingivitis ulcerative, retching, oedema mouth and nausea may occur in sensitive (allergic) individuals - if necessary, the dental suspension layer can easily be removed from the mouth by brushing and rinsing.

Skin and subcutaneous tissue disorders:

Very rare (<1/10,000): Irritation in sensitive individuals, angioedema

Respiratory, thoracic and mediastinal disorders:
Very rare/Isolated report (<1/10,000): Asthma

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard.

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 may cause nausea vomiting and diarrhoea.

Tetany and convulsions can occur, as well as cardiovascular disorders.

The dental suspension layer can easily be removed from the mouth by brushing and rinsing.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Stomatological preparations, caries prophylactic agents
ATC code: A01A A01

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.

Due to the slow release of Fluoride, the exposure level would be well below the level that could cause toxic signs and symptoms in children.

Doses of fluoride associated with dental fluorosis and risk of bone fracture would be well above the expected exposure level from Duraphat dental suspension.

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 0.75ml 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.

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, carcinogenic potential and toxicity to reproduction and development.

The results of in vitro and in vivo genotoxicity studies are mixed. The significance of these findings to man are unclear.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
White wax (E901)
Shellac (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 25ºC

6.5 Nature and contents of container

Boxes of 1 x 10ml or 5 x 30ml tubes made of internally lacquer-coated aluminium, externally printed, with white plastic screw cap with sealing plug.

Boxes of 1 x 1.6ml or 5 x 1.6ml 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 Special precautions for disposal

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 targetted, 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 and rinsing.

Instruments, clothing, etc. which comes into contact with Duraphat can be cleaned with alcohol.

7 MARKETING AUTHORISATION HOLDER

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Guildford Business Park
Middleton Road
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GU2 8JZ

8 MARKETING AUTHORISATION NUMBER(S)

PL 00049/0042

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/03/1998 / 05/09/2007

10 DATE OF REVISION OF THE TEXT

20/11/2014