Patient Information Leaflet

SCHEDULING STATUS:

S4

Duraphat® Varnish 50 mg/ml Dental Suspension

Sodium Fluoride

Sugar free

Read all of this leaflet carefully before you start using Duraphat® Varnish 50 mg/ml Dental Suspension

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What Duraphat® Varnish 50 mg/ml Dental Suspension is and what it is used for
2. What you need to know before you use Duraphat® Varnish 50 mg/ml Dental Suspension
3. How to use Duraphat® Varnish 50 mg/ml Dental Suspension
4. Possible side effects
5. How to store Duraphat® Varnish 50 mg/ml Dental Suspension
6. Contents of the pack and other information

1. What Duraphat® Varnish 50 mg/ml Dental Suspension is and what it is used for

The active ingredient of Duraphat Varnish 50 mg/ml Dental Suspension is Sodium Fluoride.

Duraphat Varnish 50 mg/ml Dental Suspension prevents tooth decay and is used to reduce the sensitivity of very sensitive teeth. When Duraphat Varnish 50 mg/ml Dental Suspension is applied on to the teeth, fluoride is released which penetrates deep into the tooth and provides long-term protection against tooth decay.

2. What you need to know before you use Duraphat® Varnish 50 mg/ml Dental Suspension

Duraphat® Varnish 50 mg/ml Dental Suspension should not be administered to you

- if you are hypersensitive (allergic) to Sodium Fluoride, colophony or any of the other ingredients of Duraphat® Varnish 50 mg/ml Dental Suspension (listed in section 6).
- if you have mouth ulcers or gum disease.
- if you have stomatitis (inflammation of the mouth).
- if you have bronchial asthma.

Warnings and precautions

Take special care / Special care should be taken with Duraphat® Varnish 50 mg/ml Dental Suspension:

Ensure you have eaten a meal before Duraphat Varnish 50 mg/ml Dental Suspension is used, particularly if it is applied to all of your teeth.

On the day when Duraphat Varnish 50 mg/ml Dental Suspension 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 Varnish 50 mg/ml Dental Suspension. Tubes: The container of this medicinal product contains latex rubber. May cause severe allergic reactions.

Other medicines and Duraphat® Varnish 50 mg/ml Dental Suspension

Please tell your dentist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular:

Fluoride supplements (e.g. drops or gels), do not use on the day of your treatment with Duraphat Varnish 50 mg/ml Dental Suspension or several days afterwards.

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Duraphat® Varnish 50 mg/ml Dental Suspension with food and drink

Ensure you/ your child has eaten a meal before Duraphat Varnish 50 mg/ml Dental Suspension is used, particularly if it is applied to all of your teeth.
Do not chew food for 4 hours after Duraphat Varnish 50 mg/ml Dental Suspension has been applied to your teeth. You may drink liquids or eat soft foods during this time.

Pregnancy and breastfeeding

This medicine contains alcohol and should be avoided during pregnancy and breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent Duraphat® Varnish 50 mg/ml Dental Suspension may interfere with your daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which Duraphat® Varnish 50 mg/ml Dental Suspension affects you.

3. How to use Duraphat® Varnish 50 mg/ml Dental Suspension

Do not share medicines prescribed for you with any other person.

Duraphat Varnish 50 mg/ml Dental Suspension is intended for use in children and adults.

This medicine is applied on to your teeth by your dentist, who will decide how much Duraphat Varnish 50 mg/ml Dental Suspension to use. The dosage will vary due to the type of teeth (e.g. milk teeth or permanent teeth) and the reason for treatment.

The dentist will remove plaque by brushing your teeth; you may be asked to brush your own teeth.

Excess saliva will then be removed to ensure your teeth are dry.

The suspension is then painted on to the teeth using a brush, probe or swab.

All your teeth or only those susceptible to tooth decay may be painted. The patient should not brush their teeth or chew food for 4 hours after treatment.

Recommended dosage for single applications:

- For milk teeth, up to 0.25 ml to be applied.
- For mixture of milk and permanent teeth, up to 0.40 ml to be applied.
- For permanent teeth, up to 0.75 ml to be applied.

To prevent tooth decay:

- The application is usually repeated every six months, but more frequent applications (every 3 months) may be made if required.

To reduce the sensitivity of very sensitive teeth

Treatment is repeated 2 or 3 times in a few days. Should be used alongside a suitable toothpaste for sensitive teeth.

If you have any further questions about how this medicine is used please speak to your dentist or doctor.

If you use more Duraphat® Varnish 50 mg/ml Dental Suspension than you should

As Duraphat Varnish 50 mg/ml Dental Suspension is applied to your teeth by your dentist it is very unlikely that too much of the product will be used. However, in the event of overdosage your doctor will manage the overdosage. If fluoride enters your bloodstream at very high dose, it may have a toxic effect. Doses of several milligrams of fluoride per kg

body weight may cause nausea, vomiting, diarrhoea, muscular spasms, convulsions and heart problems.

If you forget to use Duraphat® Varnish 50 mg/ml Dental Suspension

Do not receive a double dose to make up for forgotten individual doses. Since a health care provider will administer Duraphat® Varnish 50 mg/ml Dental Suspension, it is unlikely that the dose will be missed.

4. Possible side effects

Duraphat Varnish 50 mg/ml Dental Suspension can have side effects.

You are most likely to experience side effects if you are allergic to any of the ingredients of Duraphat Varnish 50 mg/ml Dental Suspension. If necessary, the Duraphat Varnish 50 mg/ml Dental Suspension can be removed by brushing the teeth and rinsing.

The following side effects have been reported by patients after using this medicine:

Very rare, but serious side effects (occurs in fewer than 1 in 10.000 patients).

If you think you may have any of the following side effects, see a doctor as soon as possible:

- **swelling of the face, lips, mouth or throat** which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to Duraphat Varnish 50 mg/ml Dental Suspension. You may need urgent medical attention or hospitalisation.

Other very rare side effects:

- Irritation, inflammation and ulceration of the gums and mouth.
- Nausea and retching.
- Asthma.

Not all side effects reported for Duraphat® Varnish 50 mg/ml Dental Suspension are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Duraphat® Varnish 50 mg/ml Dental Suspension, please consult your health care provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Duraphat® Varnish 50 mg/ml Dental Suspension.

5. How to store and dispose of Duraphat® Varnish 50 mg/ml Dental Suspension

Store all medicines out of reach of children.

Store at or below 25°C

Do not use this medicine after the expiry date which is stated on the tube and outer packaging.

The expiry date refers to the last day of that month. Your dentist will check that the product has not passed this date.

Once opened the contents of the Duraphat Varnish 50 mg/ml Dental Suspension tube should be used within 3 months.

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.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Duraphat® Varnish 50 mg/ml Dental Suspension contains

The active ingredient of Duraphat Varnish 50 mg/ml Dental Suspension is Sodium Fluoride. 1ml of this suspension contains 50 mg of sodium fluoride equivalent to 22.6 mg of fluoride.

The other ingredients are: 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)

What Duraphat® Varnish 50 mg/ml Dental Suspension looks like and contents of the pack

Dental Suspension.

Brown/yellow, opaque suspension.

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

Holder of Certificate of Registration

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