PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

Duraphat® 5000ppm Fluoride Toothpaste

Sodium Fluoride

Contains sweetener: Liquid Sorbitol

Read all of this leaflet carefully because it contains important information for you

Duraphat® 5000ppm Fluoride Toothpaste is available without a doctor's prescription, for you to prevent dental caries (tooth decay) in adolescents ages 16 and over and adults. Nevertheless, you still need to use Duraphat® 5000ppm Fluoride Toothpaste carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Duraphat® 5000ppm Fluoride Toothpaste with any other person.
- Ask your health care provider, dentist, or pharmacist if you need more information or advice.

What is in this leaflet

1. What Duraphat® 5000ppm Fluoride Toothpaste is and what it is used for
2. What you need to know before you use Duraphat® 5000ppm Fluoride Toothpaste
3. How to use Duraphat® 5000ppm Fluoride Toothpaste
4. Possible side effects
5. How to store Duraphat® 5000ppm Fluoride Toothpaste
6. Contents of the pack and other information

1. What Duraphat® 5000ppm Fluoride Toothpaste is and what it is used for

Duraphat® 5000ppm 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 preventing agents.

2. What you need to know before you use Duraphat® 5000ppm Fluoride Toothpaste

- if you are hypersensitive (allergic) to Sodium Fluoride or any of the other ingredients of Duraphat® 5000ppm Fluoride Toothpaste (listed in section 6).

Warnings and precautions

Duraphat® 5000ppm 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 Duraphat® 5000ppm Fluoride Toothpaste. In order to prevent accumulation of fluoride, your total intake

must be assessed before using this fluoride toothpaste. Ask your doctor, dentist or pharmacist concerning this matter.

Children and adolescents
Duraphat® 5000ppm Fluoride Toothpaste is not intended for use in adolescents and children under 16 years of age.

Other medicines and Duraphat® 5000ppm Fluoride Toothpaste
No interactions with other medicines are known.
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Duraphat® 5000ppm 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 your teeth, may have an inhibitory effect on the remineralisation of the teeth. Therefore, brush your teeth with Duraphat® 5000ppm Fluoride Toothpaste after meals.

Pregnancy and breastfeeding
There is no experience from the use of Duraphat® 5000ppm Fluoride Toothpaste in pregnant women. Therefore, this toothpaste should not be used 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® 5000ppm Fluoride Toothpaste may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which Duraphat® 5000ppm Fluoride Toothpaste affects you.

Duraphat® 5000ppm Fluoride Toothpaste contains Sodium Benzoate
Sodium Benzoate is a mild irritant to the skin, eyes and mucous membrane.

Duraphat® 5000ppm Fluoride Toothpaste contains sorbitol solution

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicinal product.

3. How to use Duraphat® 5000ppm Fluoride Toothpaste

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

Duraphat® 5000ppm Fluoride Toothpaste is for use by persons aged 16 years and above.

Always use Duraphat® 5000ppm Fluoride Toothpaste exactly as described in this leaflet or as your doctor, dentist or pharmacist have told you. Check with your doctor, dentist, or pharmacist if you are not sure.

Use Duraphat® 5000ppm 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. Brush your teeth 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® 5000ppm Fluoride Toothpaste than you should

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® 5000ppm Fluoride Toothpaste 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).

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Duraphat® 5000ppm Fluoride 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 doctor, dentist, or pharmacist.

4. Possible side effects

Duraphat® 5000ppm Fluoride Toothpaste can have side effects.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

Not all side effects reported for Duraphat® 5000ppm Fluoride Toothpaste are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Duraphat® 5000ppm Fluoride Toothpaste, please consult your health care provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor, dentist, 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® 5000ppm Fluoride Toothpaste.

5. How to store Duraphat® 5000ppm Fluoride Toothpaste

Store all medicines out of reach of children.

Store at or below 25°C.

Do not use Duraphat® 5000ppm 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.

6. Contents of the pack and other information

What Duraphat® 5000ppm Fluoride Toothpaste contains

The active ingredient of Duraphat® 5000ppm Fluoride Toothpaste is Sodium Fluoride. 1 g of toothpaste contains 5 mg fluoride (as sodium fluoride), corresponding to 5000 ppm fluoride. Excipient: 1 g of toothpaste contains 5 mg sodium benzoate.

The other ingredients are Brilliant Blue FCF (E133), dental type silica, dental type silica (precipitated), liquid sorbitol (non-crystallising), macrogol 600, purified water, sodium benzoate (E211), sodium laurilsulfate, spearmint flavouring (containing peppermint oil, carvone, spearmint oil, menthol, anethol, and lemon oil), saccharin sodium, tetrapotassium pyrophosphate, xanthan gum.

What Duraphat® 5000ppm Fluoride Toothpaste looks like and contents of the pack

Duraphat® 5000ppm Fluoride Toothpaste is a blue coloured toothpaste.

Holder of Certificate of Registration

MC Pharma (Pty) Ltd
62 Constantia Avenue
Mnandi
Centurion
0149
Tel: 0126683019
Email: Pharmacist@mcpharma.co.za

This leaflet was last revised in

25 August 2025

Registration number

51/32.10/0102