1. **Name of the medicinal product**
   CONTROCAR

2. **Qualitative and quantitative composition**
   1 ml of dental suspension contains 50 mg of sodium fluoride (corresponding to 22.6 mg of fluoride)

   Full list of excipients, see section 6.1

3. **Pharmaceutical form**
   Dental suspension for application to the teeth

4. **Clinical particulars**

4.1 **Therapeutic indications**
   CONTROCAR serves the prevention of dental caries, especially in sites of raised susceptibility to caries (e.g. brace-bearing teeth in patients with dental braces, other orthodontic appliances or partial dentures).
   CONTROCAR serves the treatment of hypersensitive dental necks.
   CONTROCAR serves in support of the treatment of primary dental caries (remineralisation).

4.2 **Posology and method of administration**
   CONTROCAR is applied by the dentist

   **Dosage**
   The amount of CONTROCAR required depends on the local factors. Following dosage is recommended:
   Immerse an applicator (e.g. Apply-Tip) once and dab three times. This corresponds to ca 3 times 0.03 ml of CONTROCAR which is equivalent to 3 x 0.68 mg of fluoride, hence a total of ca 2 mg of fluoride.

   **Method of application**
   Dry the tooth surface after thorough cleaning. Before use, shake CONTROCAR well until the sodium fluoride particles are evenly distributed in the liquid.
   Immerse an applicator (e.g. Apply-Tip) once and dab three times to produce a sufficiently thick coating.
   Allow to dry after each dabbing. Do not dry with the air-syringe or the active particles will be unevenly distributed. The liquid evaporates very quickly leaving a natural resin layer in which the sodium fluoride particles are embedded. The application may be realised 4 to 6 times a year.
   If the shaking up of the suspension causes any problems, we recommend to put the bottle with CONTROCAR into an ultrasonic bath until the sediment will be completely dispersed.
   To insure a long duration of action, the patient should not eat any solid food for some hours following the application to avoid a premature abrasion of the natural resin coating.

4.3 **Contraindications**
   CONTROCAR may not be used for:
   Patients with known hypersensitivity to any ingredient in CONTROCAR.
   Children aged under 6 years should not be treated with CONTROCAR.

4.4 **Special warnings and precautions for use**
   CONTROCAR may be used with caution in persons in whom the control of the swallowing reflex is not guaranteed (e.g. children prior to their enrolment in school, handicapped people). Exactly dosable alternatives such as NaF-tablets should be preferred.
   In the case of a systemic fluoride administration (e.g. fluoride tablets or fluoridated common salt) this should be discontinued for some days following the application of CONTROCAR.

4.5 **Interactions with other medicinal products and other forms of interactions**
   None known
4.6 Pregnancy and lactation

**What to consider during pregnancy?**
There is no evidence that fluorides pose risks for the embryo.

**What to consider during breastfeeding?**
Fluorides are excreted into breast milk. CONTROCAR is to be used with caution during lactation.

4.7 Effects on ability to drive and and use machines
There have been no studies on the effects on the ability to drive and use machines.

4.8 Undesirable effects
In the assessment of adverse events following frequencies are used:
Very common (≥ 10%), common (≥ 1% - <10%), uncommon (≥ 0.1% - <1%),
uncommon (≥ 0.01% - <0.1%), very rare (<0.01%, or unknown).

In very rare cases, hypersensitivity reactions (allergies) cannot be excluded. Patients are asked to inform their dentist, if they notice any side effects, particular such which are not mentioned in this leaflet.
When used as directed (see Posology and method of administration), side effects have not become known.

4.9 Overdose and other dosage mistakes

a.) Symptoms of overdose

**Acute:**
In the extreme case and depending on the dosage, larger amounts of fluoride may be applied in the oral cavity. The swallowing of such amounts may lead to nausea, vomiting, and diarrhoea. An inadvertent overdosage by swallowing very large amounts may lead to hypocalcaemia and cardial disturbances.

**Chronic:**
The regular exceeding of a total daily intake of 2 mg of fluoride (systemically and locally) during the period of tooth development may lead to disturbances in the mineralisation of the tooth enamel. This disturbance, also known as dental fluorosis, manifests itself by mottled enamel.

b.) Therapeutic measures (in acute overdose):
Supply immediately sufficient of fluid per os in the form of milk, then induce vomiting by irritating the posterior pharyngeal wall. Gastric lavages with an addition of calcium gluconate. Immediate intravenous injection of 20 ml of a 10% calcium gluconate solution at 15- to 30-minute intervals monitoring the calcium level. As a prophylaxis of ventricular fibrillation lidocaine is given. Shock treatment. Fluid- or electrolyte substitution.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The mechanism of the caries protective and the therapeutic effect is mainly attributed on the following three components:

1. Increased resistance to the decay of the dental hard substance by acidic noxae generated in the plaque as, for example, through the bacterial breakdown of sugar-containing substrates. This occurs by the incorporation of fluoride into the enamel crystals, which primarily consist of hydroxylapatite, with partial formation of a more resistant fluoroapatite.

2. Promotion of the natural remineralisation of primary caries lesions by the saliva.

3. Retarding effect on the sugar breakdown of acid-producing micro-organisms in the dental plaque.
A lasting success is only assured by a lifelong supply of fluoride in therapeutically effective dosages. In this case, frequent doses of low-concentrated fluoride compounds are preferred to less frequent administrations of higher concentrations. In sodium fluoride compounds, the cation has no influence on the caries-preventing effect.

**5.2 Pharmacokinetic properties**

Profiles of fluoride concentrations in the serum following the local application of fluoride-containing jellies, enamels or solutions fundamentally differ from the course of concentrations which arise after swallowing, i.e. after the oral administration without contact with tissues of the oral cavity. Depending on the mode of application (brushing, enamelling), the retention capacity of the denture (influenced by the tooth position, dental protheses, flow of saliva), material-specific features (adhesiveness, surface affinity) as well as other individual factors, (e.g. consumption of food and drink), at different times varying portions of the fluoride impacted in the oral cavity following the local application are desorbed from their supporting base, swallowed, and absorbed. Therefore, statements on the moment and the height of peak concentrations are not possible. Fluoride is a natural body constituent and is present in bone and dental hard tissues.

**5.3 Preclinical safety data**

If larger amounts of fluoride are swallowed during the application, serum concentrations of fluoride may be attained which exceed the values following the oral application of 1 or 2mg of fluoride (e.g. in the form of NaF-tablets). To sum up, it can be said that in no case toxic concentrations in the serum will arise when the said ingredient is used as directed.

**6 Pharmaceutical particulars**

**6.1 List of excipients**

Canada balsam and butane-2-one

**6.2 Incompatibilities**

Since no studies on compatibility have been conducted, this medicinal product must not be mixed with other drugs.

**6.3 Shelf life**

3 years

CONTROCAR is to be used up within four weeks after the first opening. Do not use CONTROCAR after the expiry date, which is printed on the label and on the package.

**6.4 Special precautions for storage**

After use, the CONTROCAR container must be tightly closed or the liquid will quickly evaporate.

The liquid is easily inflammable and hence should not come into contact with open flames. Do not store above 25 °C

**6.5 Nature and contents of container**

Brown glass bottle with plastic cap containing 10 ml

**6.6 Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines, if you no longer need it. These measures are helping to protect the environment. Any unused product or waste material should be disposed of in accordance with local requirements.
7. **Marketing authorisation holder**
lege artis Pharma GmbH + Co. KG
P. O. Box 60, D-72132 Dettenhausen
Breitwasenring 1, D-72135 Dettenhausen
Telephone +49 (0) 71 57 / 56 45 - 0
Fax +49 (0) 71 57 / 56 45 50
E-Mail: info@legeartis.de
Internet: www.legeartis.de

8. **Marketing authorisation number**
6030277.00.00

9. **Date of renewal of the authorisation**
28. February 2005

10. **Date of revision of the text**
January 2012

11. **Deferred sales**
Prescription ("Only for dental use")

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**Special advice for the patients' acceptance**
CONTROCAR shows an intensive signal-odour. For the patients' better acceptance it has been proved useful to inform the patient before the application of CONTROCAR that it will smell – for example – like nail polish remover.

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