coltosol® F

Instructions for use

EN

Definition

Coltosol F is a moisture-curing, radio-opaque, white filling material for temporary filling of dental cavities. Coltosol F is a zinc oxide/zinc sulphatebased cement and is designed for short-term temporary applications (designed to be used for max. 1-2 weeks).

Composition

Zinc oxide Zinc sulphate-1-hydrate Calcium sulphate-hemihydrate Diatomaceous earth EVA resin Natrium fluoride Peppermint aroma

Setting

Surface hardens within: 20-30 min Subjected to mastication pressure after: 2 - 3 h

Indications

- Temporary fillings of Class I and II cavities.
- Temporary sealing in endodontics.

Contra-indications

Established allergy to one of the components of Coltosol F.

Long-lasting (more than 2 weeks) temporary filling of cavities in vital teeth.

Temporary filling of cavities which include multiple areas and extend up to or under the gingiva (subgingival).

Side effects

Coltosol F hardens by absorbing water. Dehydration in the cavities of vital teeth can cause shortterm pain. The cavity should therefore be kept moist using a water spray before applying Coltosol

Coltosol F expands during hardening. This creates a very dense filling with good marginal seal although care must be taken with very thin enamel margins as fracture may result.

Interactions with other agents

Interactions with other agents are unknown.

Preparation

Assembling the syringe: The dispensing mechanism (screw spindle with nut) is packed separately, it can be used repeatedly; i.e. when one syringe body is empty, the screw spindle is turned back completely and attached to the next syringe body.

Application of Coltosol F

Moisten the cavity with a water spray. Take up prepared Coltosol F form the pad using a spatula or an instrument and apply into the cavity. Condense Coltosol F into the cavity using a condenser and adapt to the cavity walls by gently condensing. Remove occlusal contact points with a scaler. It is advisable not to fill very deep cavities up to the base of the cavity, so that Coltosol F can be re-

moved more easily from the cavity.

The surface of Coltosol F hardens within 20-30 min by absorbing water (e.g. saliva action). After 2-3 h the temporary filling can be subjected to mastication pressure. To speed up setting, Coltosol F can be kneaded with wet gloves prior to application.

Removing Coltosol F from the cavity

Coltosol F can easily be removed from the cavity in large pieces with a drill or a scaler. Rinse off any residue from the cavity with a water spray.

Emergency measures, symptoms, antidotes

Acute danger due to incidental swallowing of Coltosol F can be excluded due to the small quantity applied and the lack of toxicity. In the case of direct contact with the oral mucosa, rinsing with tap water is sufficient. In the case of contact with the eyes, rinse thoroughly with water (10 min) and consult an ophthalmologist showing this instructions for use.

Toxicological characteristics

Coltosol F is non-toxic and non-sensitizing. Shortterm pains can be attributed to dehydration during hardening.

Only supplied to dentists and dental laboratories or upon their instructions.

Keep out of the reach of children!

Should not be used after expiry date.

Seal the glass jar tight after every application or turn back the screw spindle once or twice and put the cap back on the syringe.

Federal law restricts this device to sale by or on the order of a dentist.

Shelf life and marking

Shelf life/storage

Coltosol F is susceptible to moisture.

The syringe bodies, furnished with a protective covering, are vacuum-packed and sealed in barrier bags (tropic-proof).

Opened syringes have a reduced shelf life and should be used up quickly.

Close the jars immediately after removal of the material.

Coltosol F (in glass jars or used syringes) must be stored tightly sealed at temperatures not over 23°C/73°F and 50% relative humidity. Avoid exposure to direct sunlight or other heat sources. Coltosol F fulfills the intended purpose until the expiry date, which is marked on the containers.

The expiry date and LOT number are marked on the containers.

Hygiene tips

Compliance with the following instructions ensures optimal hygienic conditions when using Coltosol F:

- The portions should not be dispensed close to the chair; ideally this should be performed in the area for instruments.
- · Excess material should under no circumstances be returned to the glass jar.





SAFETY DATA SHEET www.coltene.com

Glossary

Consult instructions for use

Keep away from sun light **Temperature limitation**

Humidity limitation

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Notified body registration number

6

Identification for Russia

Identification for Ukraine

Legal manufacturer

Expiry date

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