

IFU Size : 161 H x 104 W

ORAFIL PLUS

TEMPORARY FILLING MATERIAL WITH SODIUM FLUORIDE



Product Description : Orafil Plus is a radiopaque, temporary filling material for temporary filling of dental cavities. Addition of sodium fluoride helps reduce dentine hyper-sensitivity and post operative pain due to preparations for direct and indirect restorations.

Composition : Zinc oxide, Calcium Sulphate, Sodium Fluoride, Accelerators and Flavoring Agent.

Intended Purpose / Intended Use : It is intended to be used for temporary restoration of cavities.

Indications for Use : Recommended for temporary restoration of cavities in the interval between tooth preparation and the permanent cementation of completed inlays and as a cementing medium for all types of temporary crowns.

Instructions for Use : Use any suitable instrument to introduce the paste directly into wet cavity. Press and spread with the instrument to fill the cavity and adapt to the cavity walls. Remove any excess paste by wiping it off with a moist cotton pellet towards the margins of the cavity. Hardened paste can be removed with the use of rotary instrument or any suitable hand instrument. It is advised not to fill very deep cavities up to the base of cavity. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings : Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. Avoid prolonged inhalation. Do not take internally contact with the skin may cause irritation, burns of hypersensitivity. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician.

Precautions : Do not use if allergic to any of its components. In sensitive persons, the product may cause sensitization. If allergic reaction occurs remove the filling immediately and consult physician.

Contraindications :

It should not be used with patients who have a history of severe allergic reaction to any of the components.

Storage Conditions : Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place.

Shelf Life : 3 years from the date of manufacturing.

Presentation :

Ref : 11002

1 x 40g Jar.

Disposal conditions : To be disposed off based on the prevailing rules of the country in which it is used.

Prevest DenPro Limited
Unit II, Export Promotion Industrial Park,
(EPIP), Bari Brahmana, Jammu-181133,
India. www.prevestdenpro.com
Customer Care No. : + 91 8899074151
Email : customercare@prevestdenpro.com
Made in India

EC REP
Obelis s.a
Boulevard General Wahis 53
1030 Brussels, Belgium
Tel: +(32) 2 732 59 54, Fax: +(32) 2 732 60 03
E-mail : mail@obelis.net

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Revision :	08
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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"
 Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTION FOR USE" **REF** Symbol for "CATALOGUE NUMBER"
EC REP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"
 Symbol for "DO NOT USE IF PACKAGE IS DAMAGE" Symbol for "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER"
 Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" **MD** Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.