

IFU Size : 161 H x 104 W

EDTA SOLUTION

(17% EDTA SOLUTION)



Product Description : 17% EDTA Solution buffered to neutral pH used for preparation of roots canals by rapid cleansing and enlarging of roots canals.

Composition : Disodium Edetate, purified water and excipients.

Intended Purpose / Intended Use : It is intended to be used as an irrigant during root canal treatment.

Indications for Use : For root canal cleansing and shaping during instrumentation. EDTA Solution helps in opening calcified canals and smear layer removal.

Instructions for Use : Transfer portion of solution from the bottle to a disposable syringe fitted with a disposable needle. Insert the needle into the root canal until resistance is felt and withdraw about 2mm. Inject the solution slowly into the canal to irrigate debris and to chelate the canal walls. The dispensed material shall not be placed back in the container and the dose once applied or used shall not be reused.

Warning : 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 : Avoid injecting solution beyond apex of canal.

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 : 40004

1 x 15ml Glass Bottle, Dispensing Dropper.

Ref : 40004-1

1 x 100ml Glass Bottle, Dispensing Dropper.

Disposal conditions :

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

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

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