

HYBENX® Root Canal Cleanser

For Professional Use Only

INSTRUCTIONS FOR USE

INDICATIONS:

HYBENX Root Canal Cleanser is indicated for use as an adjunctive rinse of tooth root canal systems and adjacent tooth surfaces during standard professional dental procedures to enhance the removal of post-instrumentation dentinal debris and smear-layer within the root canal systems.

DESCRIPTION:

HYBENX Root Canal Cleanser is an opaque purple, semi-viscous liquid or gel. It contains sulfonated phenolics and sulfuric acid in an aqueous solution.

DIRECTIONS:

HYBENX Root Canal Cleanser is to be used topically only with an irrigation syringe or vial chosen by the dental professional, to the pulpal canal for endodontic treatment. As with any irrigation, it should start with the deepest portion of the canal and be irrigated thoroughly to the more superficial areas. Product is applied for up to one minute.

NOTE: If the patient has not been given a local anesthetic the product may elicit a stinging sensation after application until it is rinsed off. To remove HYBENX Root Canal Cleanser, thoroughly irrigate with water and evacuate with high speed suction. Removal of the product is required to stop the cleaning process. Incidental contact with any oral tissue will cause it to temporarily turn "white" until the tissue rehydrates itself. Properly dispose of any remaining product.

HYBENX Root Canal Cleanser is contraindicated for use with calcium hydroxide paste and similar, related products. HYBENX Root Canal Cleanser is intended to be used in its original semi-viscous state. Diluting with water and/or combining HYBENX Root Canal Cleanser with another product will render the product ineffective and potentially harmful. If using HYBENX Root Canal Cleanser during Etching procedures, HYBENX Root Canal Cleanser should only be applied and removed prior to the subsequent application of etching solutions.

WARNINGS:

Keep out of sight and reach of children. Do not use if the patient is allergic to a material that contains sulfur in any form. Because of its nature, prolonged use on normal tissue should be avoided. HYBENX Root Canal Cleanser will eventually slough any tissue to which it is applied if excess volume is used and an application time is grossly extended. It is important to use high speed evacuation/suction to limit overflow of any excess material to areas that do not need to be treated.

PRECAUTIONS:

HYBENX Root Canal Cleanser is for use in the oral cavity only. Avoid eye contact. If eye exposure occurs, immediately remove contact lenses and irrigate eyes for at least 15 minutes with lukewarm water and contact a physician. If skin contact occurs, immediately rinse thoroughly with water. HYBENX Root Canal Cleanser will damage clothes or fabric. Safety and effectiveness in pregnant women and children under the age of 12 has not been established.

ADVERSE REACTIONS:

Do not use if patient is allergic to a material that contains sulfur in any form. HYBENX Root Canal Cleanser may cause local irritation and swelling upon administration. If excess irritation occurs during use continue to irrigate liberally with water and evacuate with high speed suction. If excess irritation occurs discontinue use. If condition persists contact a health care professional.

CONTAINS:

Hydroxybenzenesulfonic Acid, Hydroxymethoxybenzenesulfonic Acid, Sulfuric Acid, Water, FD&C Red #40 (Gel contains: Colloidal Silica).

HOW SUPPLIED:

2 ml glass vial that contains 2 ml of product or 1 ml prefilled gel or liquid in an irrigation syringe. Store at room temperature, 15–30°C or 59–86°F.


Syringe Filling from Vial

Use a large bore/gauge irrigation tip to assist in filling the syringe.

Irrigation Tip

Depending on the clinician's preference, a blunt-locking tip needle or a closed-end side-port needle may be used for product application and irrigation. Only the blunt-locking is enclosed.

Manufacturer:

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single use/single treatment

