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INTRODUCING DYCLOPRO TOPICAL ANESTHETIC (Dyclonine Hydrochloride Topical Solution 0.5%)

Dyclonine, an old favorite, has returned to the United States market. DycloPro is a topical rinse indicated for use in root planing and scaling, for blocking the gag reflex and prior to the injections of local anesthetics.

Product	Item #	FEATURES	BENEFITS
Topical Anesthetic	99510	30g jar	Multiple doses in each jar
		2-10 minute onset within 30 minute duration	For use in root planing and scaling

BRIEF SUMMARY OF PRESCRIBING INFORMATION
INDICATIONS: DycloPro (Dyclonine HCl Topical Solution) is a topical anesthetic indicated for anesthetizing accessible mucous membranes prior to various endoscopic procedures and may also be used to block the gag reflex and to relieve the pain of oral ulcers or stomatitis.
ALTERNATIVE INDICATIONS: DycloPro is useful to suppress the gag reflex in the positioning of x-ray films, making prosthetic impressions, and doing surgical procedures in the molar areas. It is also useful as a preinjection mucous membrane anesthetic or applied to the gums prior to scaling (prophylaxis). The anesthetic can be applied as a mouthwash or gargle and the excess spit out.
CONTRAINDICATIONS: Do not inject into tissue or use in the eyes. DycloPro is contraindicated in patients known to be allergic to the local anesthetic or to other components of Dyclonine HCl Topical Solution. DycloPro should not be injected into tissue or used in the eyes because of highly irritant properties. DycloPro should be used with extreme caution in the presence of sepsis or severely traumatized mucosa in the area of application since under such conditions there is the potential for rapid systemic absorption.
PRECAUTIONS: The safety and effectiveness of DycloPro depends on proper dosage, correct technique, adequate precautions, and readiness for emergencies. The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Repeated doses

of DycloPro may cause significant increases in blood levels with each repeated dose because of slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients, acutely ill patients and children should be given reduced doses commensurate with their age, weight and physical condition. DycloPro should also be used with caution in patients with severe shock or heart block or with known drug sensitivities.
INFORMATION FOR PATIENTS: When topical anesthetics are used in the mouth or throat, the patient should be aware that the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason, food should not be ingested for 60 minutes following use of local anesthetic preparations in the mouth or throat area. This is particularly important in children because of their frequency of eating. Numbness of the tongue or buccal mucosa may increase the danger of biting trauma. When Dyclonine HCl Topical Solution is used to relieve the pain of oral ulcers or stomatitis which interferes with eating, patients should be warned about the risk of biting trauma before they accept this treatment; caution should be exercised in selecting food and eating. Following other uses in the mouth and throat area, food and/or chewing gum should not be used while the area is anesthetized.
PREGNANCY/PEDIATRIC USE: Animal reproduction studies have not been conducted with dyclonine. It is also not known whether dyclonine can cause

fetal harm when administered to a pregnant woman or can affect reproduction capacity. Safety and effectiveness in children under the age of 12 have not been established.
ADVERSE REACTIONS: Adverse experiences following the administration of DycloPro are similar in nature to those observed with other local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature.
HOW SUPPLIED: Sterile, in one fluid ounce bottles. Dyclonine HCl Topical Solution 0.5% (NDC-0362-3971-05) Keep tightly closed. Store at controlled room temperature 20°-25°C (68°-77°F). Avoid excessive heat (temperatures above 40°C [104°F]). Subject to damage by freezing. For Complete prescribing information visit www.septodontusa.com/dyclopro You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

