OROSTAT 8%- epinephrine hydrochloride solution
Gingi-Pak a Division of the Belport

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Orostat Solution

Active Ingredient

Active ingredient
8% DL-Epinephrine-HCl w/w.

Purpose

Purpose
. Hemostyptic

Description

DESCRIPTION Orostat® is designed for use as a retraction agent or a topically applied vasoconstrictor used to control capillary bleeding and oral tissue seepage, giving fast, positive action and leaving a clean, debris-free field.

Inactive Ingredient

purified water, sodium hydrosulfite, sodium thiosulfate, sodium monophosphate, sodium chloride, EDTA, methylparaben, propylparaben, benzyl alcohol

Keep out of reach if children

Keep out of reach of children.

Storage

Store in a cool dark place. Avoid excessive heat above 40C (104F). A brown color change indicates onset of oxidation with reduced potency.

Uses

Uses For the control of bleeding or topical hemostasis in routine dental procedures including: implantation, root canals, gingivectomy, frenectomy, tissue retraction, oral surgery, and crown and bridge preparations.

Do not use

Do not use in individuals with cardiovascular disease, diabetes, hyperthyroidsm , hypertension, arteriosclerosis or treated with tricyclic antidepressants. Systemic reactions are intensified by inhalation of anesthetics containing halogen or cyclopentane.

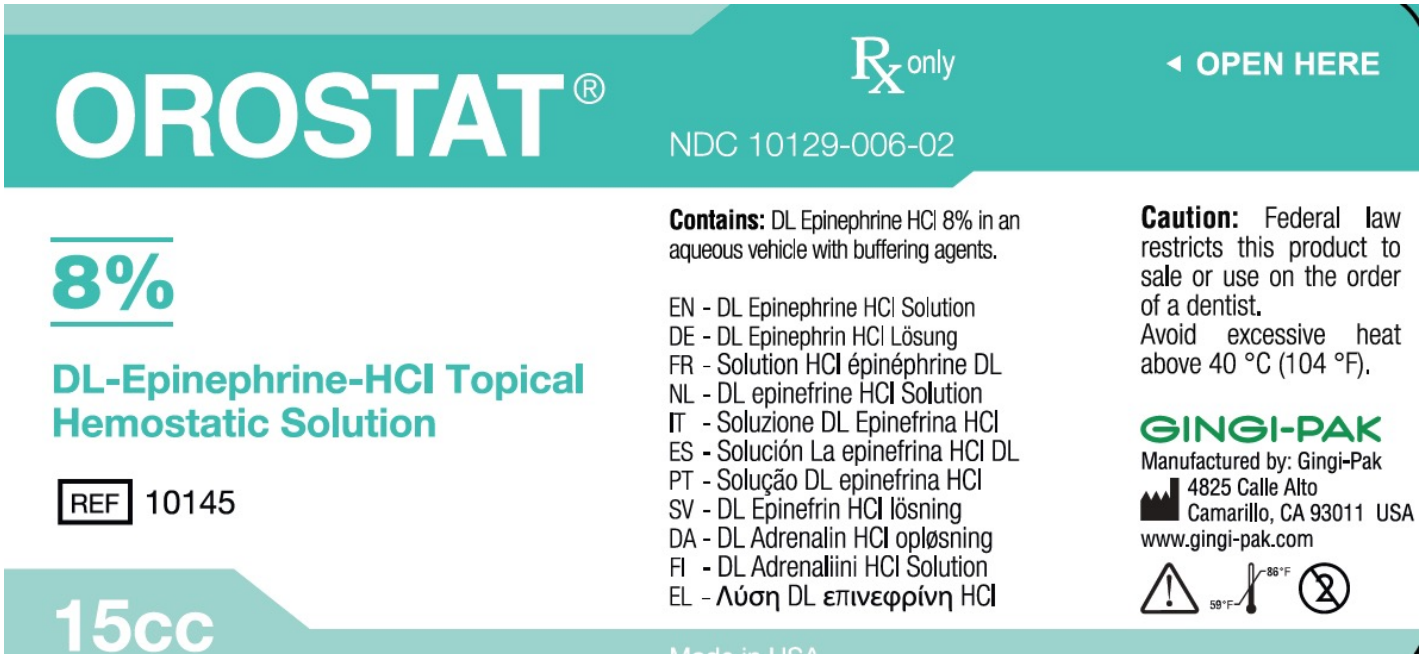
Warnings

Warnings For topical applications only.

Directions

Orostat should be used at room temperature with cotton pellets, sponge or syringe with tips. Orostat can be soaked into unmedicated retraction cord or braid which is then packed into the gingival sulcus. Remove the cord after several minutes and rinse or flush well before taking the impression. The area along with the preparation should be thoroughly dried for silicone and rubber-based impression materials. The area and the preparation should be rinsed and very wet for impressions. If persistent bleeding should occur, apply Orostat with pressure to the exposed capillaries using cotton tipped applicators. Scrubbing or bumishing is of questionable value and could be injurious to gingival tissue and is not recommended.

Principal Display-Orostat 8%



OROSTAT 8%

epinephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10129-006
Route of Administration	SUBGINGIVAL, PERIODONTAL, DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
EPINEPHRINE HYDROCHLORIDE (UNII: WBB047OO38) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE HYDROCHLORIDE	1200 mg in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM DITHIONITE (UNII: 2K5B8F6ES1)	37.5 mg in 15 mL
SODIUM THIOSULFATE (UNII: HX1032V43M)	15 mg in 15 mL
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	37.5 mg in 15 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	49.5 mg in 15 mL
PROPYLPARABEN (UNII: Z8IX2SC1OH)	4.95 mg in 15 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.15 mL in 15 mL
EDETIC ACID (UNII: 9G34HU7RV0)	1.995 mg in 15 mL
METHYLPARABEN (UNII: A2I8C7HI9T)	10.05 mg in 15 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:10129-006-02	15 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/04/1990	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/04/1990	

Labeler - Gingi-Pak a Division of the Belport (008480121)

Registrant - Jeff Nichols (008480121)

Establishment

Name	Address	ID/FEI	Business Operations
Gingi-Pak a Division of the Belport		008480121	manufacture(10129-006)