

Local Adverse Reactions: Pharmacodynamics The mechanism of anti-inflammatory action is not related to stimulation of the pituitary-adrenal axis. Like other non-steroidal anti-inflammatory agents, benzydamine inhibits the biosynthesis of prostaglandins under certain conditions but its properties in this respect have not been fully elucidated. The stabilising effect on cellular membranes may also be involved in the mechanism Pharmacokinetics is well absorbed following oral Benzydamine administration. Following topical administration of benzydamine hydrochloride, benzydamine is well absorbed into the inflamed oral mucosa where it exerts anti-inflammatory and local anaesthetic action. Plasma benzydamine levels following use of benzydamine orally are low and paralled the amount actually ingested. 2. Benzydamine and its metabolites are excreted largely in the urine. Metabolism is largely by oxidative pathways 3. although dealkylation can also be shown. Benzydamine 4. has been detected in blood and urine following use of oral solutions of benzydamine. Most of the absorbed dose was eliminated in the first 24 hours. Repeated administration for 7 days did not result in accumulation of benzydamine in plasma INDICATIONS Temporarily relieves painful inflamed conditions of the mouth, including mouth and denture ulcers and sore CONTRAINDICATIONS Difflam Mouth Gel is contraindicated in patients with known hypersensitivity to benzydamine or cetylpyridinium chloride or to any of the components of PRECAUTIONS symptomatic If symptoms persist, see your doctor or dentist. For use in patients with impaired renal or hepatic function see Dosage and Administration section. 10 g tube. Use in Pregnancy Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurence of foetal damage. The safety of benzydamine hydrochloride has not been established in pregnant tients. Risk to benefit ratio should be established if Difflam Mouth Gel is to be used in these patients. Use in Children Because of the lack of sufficient clinical experience, Difflam Mouth Gel is not recommended in children under **Drug Interactions** There are no known drug interactions with benzydamine. ADVERSE REACTIONS Difflam in topical oral preparations is generally well

152

140

times/dav.

With Impaired Renal Function

With Impaired Liver Function

OVERDOSAGE

PRESENTATION

STORAGE Store below 30°C.

Revision date: January 2018

Manufactured by: Ensign Laboratories Pty Ltd 490-500 Wellington Road, Mulgrave, VIC 3170

tolerated and side effects are minor. The following adverse reactions have been reported after use of benzydamine hydrochloride in solution form

-

PLEASE NOTE: This is a Low Resolution PDF & is not to be used for printing

 						
PRODUCT	PRINTER DETAILS	COLOURS	FONTS	AMENDS	ARTWORKER INFO	
Brand: Difflam	Dieline Ref: XXX	Black	Fonts Used: HeleticaRegular	02/03/18 : New Artwork Build - Elaine	18 : New Artwork Build - Elaine Artwork Software: Illustrator CC 2017	
Product Variant: Mouth Gel	Printer: XXX		Helvetica Bold			
Pack Size: 10g	EMO: Ensign	- 	Helvetica Neue 77 Bold Condensed Helvetica Neue 57 Condensed		Barcode %:	
Country: SG, MY	SKU No: 100037	-	Bauhaus Heavy			
Date: 02/03/2018	CODES					
	JOB NO: 81923		Body copy size: 6.5pts	APPROVALS		ROVALS
			Min. font size: 1.268mm		Artworker:	Signed:
Component: Leaflet	VERSION: 0					
Dimensions: 152mm w x 220mm h	UIC: LT0045	GROUP			Date: 00/00/2018	



