25 8 52 5 40

Font Type: ITC Avant Garde Gothic Medium
Font Size: 11.00 pt

Font Type: Helvetica Cond Bold Tr Condensed Bold
Font Size: 6.00 pt

42

Font Type: Helvetica Bold/Regular
Font Size: 5.20 pt
Horizontal Scale: 71%

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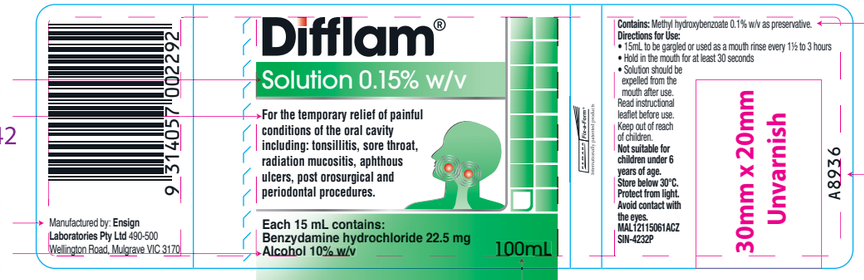

Base : 42mm x 130mm

5mm

Font Type: Helvetica Neue LT Std 77 Bold Condensed/57 Condensed
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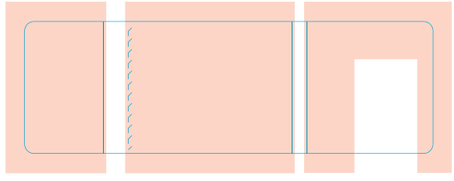
Font Size: 7.60 pt

Please change the following settings in Acrobat Reader to view this file correctly.
For PC: Edit > Preferences > Categories: Page Display > Use Overprint Preview > Select "Always"
For Mac: Adobe Reader > Preferences > Categories: Page Display > Use Overprint Preview > Select "Always"

Varnish thumbnail - Scale to 50%



***All text must be 2mm away from diecut outline and glue area.**

Font Type: Helvetica LT Std Bold Condensed/Condensed
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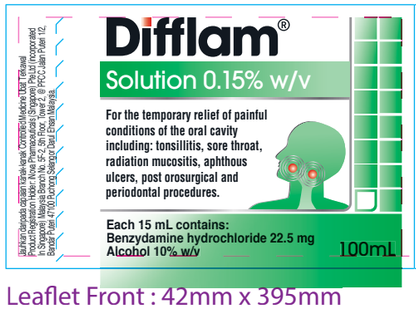
8 57 5 43 47 46 46 47 48 48

42



Dosage and Administration
Difflam® should generally be used undiluted, but if stinging occurs it may be diluted with water. The solution should be expelled from the mouth after use. Uninterrupted treatment should not exceed seven days.
Dosage in Adults
When used as a gargle, the usual dose of Difflam® is 15 mL (approximately one tablespoon) which should be gargled for at least 30 seconds at 1 ½ to 3 hourly intervals, as needed. When used as a rinse for oral lesions, the usual dose is again 15 mL (approximately one tablespoon) which should be held in the mouth and swirled around for at least 30 seconds, with repeat use every 1 ½ to 3 hours throughout the day.
Dosage in Children
5 - 15mL as a gargle if able to do so, or as an oral rinse.
With Impaired Renal Function
Since absorbed benzydamine and its metabolites are excreted in the urine, the possibility of systemic effects should be considered in patients with severe renal impairment.
With Impaired Liver Function
Since absorbed benzydamine is highly metabolised in the liver, the possibility of systemic effects should be considered in patients with severe hepatic impairment.
Overdosage
There are no known cases of overdosage with benzydamine hydrochloride solution. Difflam® is unlikely to cause adverse systemic effects, even if accidental ingestion should occur. There is no specific antidote for benzydamine and should excessive quantities be ingested the treatment should be symptomatic.
Storage conditions
Protect from light. Store below 30°C
Presentation
100 mL, 200 mL, 500 mL and 2 L
Not all pack sizes are available in all countries.

Manufactured by:
Ensign Laboratories Pty Ltd
490-500 Wellington Road,
Mulgrave VIC 3170
Made in Australia.
Revision date: August 2024

inova pharmaceuticals

Font Type: Helvetica LT Std Bold Condensed/Condensed
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Font Size: 11.99 pt

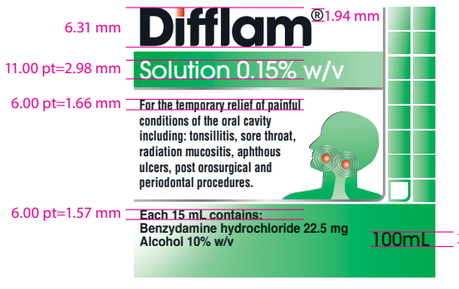
48 48 47 46 46 47 48 57 8

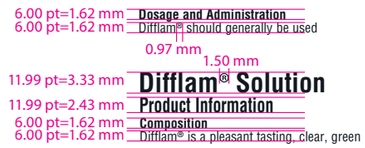
42

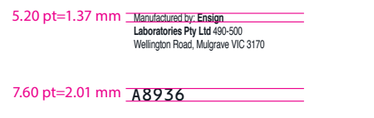
Difflam® Solution
Product Information
Composition
Difflam® is a pleasant tasting, clear, green solution, containing benzydamine hydrochloride 0.15% w/v. Benzydamine is 1-Benzyl-3-(3-dimethylaminopropoxy)-1 H-indazole. Benzydamine hydrochloride is a white, odourless, crystalline powder with a bitter taste, soluble in water, ethanol, methanol and chloroform. It is sparingly soluble in ether and petroleum ether.
Pharmacology
Benzydamine is an anti-inflammatory-analgesic agent structurally unrelated to the steroid group. Benzydamine differs chemically from other non-steroidal anti-inflammatory agents in that it is a base rather than an acid. Animal models show that when administered systemically benzydamine is effective against pain and oedema due to inflammatory conditions. It also inhibits granuloma formation. At concentrations used for topical treatment, benzydamine possesses local anaesthetic action. Benzydamine does not cause erosion of the gastric mucosa when given orally to rats at doses up to 100 mg/kg. The analgesic activity of benzydamine was more pronounced in models involving an experimental inflammation rather than in non-inflammatory pain. In common with the aspirin-like drugs, benzydamine possesses an anti-pyretic activity. Peripheral reflexes were transiently inhibited after intravenous administration to cats.
Mode of Action
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 of action.
Pharmacokinetics
Absorption
Benzydamine is well absorbed following oral administration. Following topical administration of Difflam® Solution, benzydamine is well absorbed into the inflamed oral mucosa where it exerts anti-inflammatory and local anaesthetic action. Plasma benzydamine levels following use of Difflam® are low and parallel the amount actually ingested.
Excretion
Benzydamine and its metabolites are excreted largely in the urine. Metabolism is largely by oxidative pathways although dealkylation can be shown. Benzydamine has been detected in blood and urine following gargling with Difflam®. 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
Difflam® is indicated for the temporary relief of painful conditions of the oral cavity including: tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post orosurgical and periodontal procedures.
Contraindications
Difflam® is contraindicated in patients with known hypersensitivity to the drug or to any of the components of the vehicle.
Precautions
Difflam® is indicated for use as a rinse or gargle. It should not be swallowed but rather should be expectorated after each use. The product should generally be used undiluted but if burning or stinging occur, it may be diluted with water. If a sore throat is either caused or complicated by a bacterial infection, appropriate antibacterial therapy should be considered in addition to the use of Difflam®. Use with caution in patients with hepatic or renal impairment (see Dosage and Administration). Difflam® contains methyl hydroxybenzoate as a preservative. This has been known to cause sensitisation. Hypersensitive reactions due to the product or any of its components may occur in susceptible individuals.
Drug Interactions
There are no known drug interactions with benzydamine.
Use During Pregnancy
The safety of benzydamine hydrochloride has not been established in pregnant patients. Risk to benefit ratio should be established if Difflam® is to be used in these patients.
Use in Children
Because of the lack of sufficient clinical experience, Difflam® is not recommended in children under 6 years of age.
Adverse Reactions
Difflam® is generally well tolerated and side-effects are minor.
Local Adverse Reactions
The most commonly reported reaction is oral numbness (2.6%). Occasional burning or stinging sensation may occur and has been reported in 1.4% of treated cases. Other local adverse effects were less common and included dryness or thirst (0.2%), tingling (0.2%), warm feeling in mouth and altered sense of taste (<0.1%).
Systemic Adverse Reactions
These were very uncommon and never of a serious nature. They consisted mainly of nausea, vomiting, retching, gastro-intestinal disorders (0.4%), dizziness (0.1 %), headache and drowsiness (<0.1%). Hypersensitivity reactions occur very rarely but may be associated with pruritis, rash, urticaria, photodermatitis and occasionally laryngospasm.

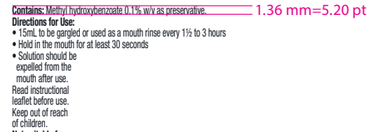
A8936

Leaflet Inside : 42mm x 395mm









80% Barcode Magnification as per GS1

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For MAC: Adobe Reader > Preferences > Categories: Page Display > Use Overprint Preview > Select "Always"

RE-TYPESET ARTWORK. Due to the nature of the files received, this artwork has been re-typeset.

GROUP 24|7 WORLDWIDE™

inova pharmaceuticals

ARTWORK

Job No. : JB-03122
UIC : A8936
SKU : 100486
V1

09.08.24 - V0 - Artwork build - Soravit
19.08.24 - V1 - Amend - Pornpawee

A8936_DIFFLAM SOLUTION 100ML SEA
Component : FAF LABEL-LEAFLET
Country : MY SG

Dieline Ref: PP-0875
EMO: ENSIGN
Printer: Xxxxxx Xxxxxxxxxxx

G247 File Name:
104983_A8936_DIFFLAM SOLUTION 100ML SEA_MY SG_LL_V1

Colour
100%

PMS Black 6C | PMS 485C | PMS 354C | Varnish | Guide

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Supplier information may be present on the packaging

EMO/Printing Vendor:

Please share the Artwork PDF to Printer for checks on:

- Colours - No. of colours, Sequence, CMYK/PMS
- Text - Line Thickness, Font Size
- Dieline - Size, Eyemark, Print Direction
- Coding - Size, Location, VFA, Format Bkg Colour

Moving forward when possible any additonal information and technical check required by EMO on the Artwork BEFORE APPROVING.