



**康護寧®**  
**Comfflam**

加強消炎噴液劑3.0毫克/毫升

衛部藥製字第058080號  
本藥需由醫師處方使用

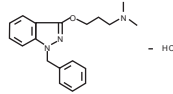
**forte Anti-inflammatory Throat Spray** 3.0mg/ml



#### 成份

每毫升含有3.0毫克Benzydamine hydrochloride。  
本品含有Tween 80、Brilliant blue FCF、Glycerin、Tartrazine、Methyl paraben、Propyl paraben、Sucralose、Alcohol、Purified Water。蘋果口味另含有Apple Flavour。薄荷口味另含有Peppermint Oil、Menthol。

Benzydamine hydrochloride結構式：



#### 藥理學

Benzydamine為一抗炎止痛劑，其化學結構為非類固醇，與其他非類固醇之消炎藥性質不同，是鹼基而不是酸基。動物實驗顯示，使用全身性benzydamine可有效治療炎症引發的疼痛和水腫，亦可抑制肉芽腫的形成。在局部治療的濃度下，benzydamine具有局部麻醉的作用。大老鼠口服benzydamine達劑量100毫克/公斤時，並未引起胃黏膜潰瘍。在動物實驗中，benzydamine對於發炎疼痛的止痛效果較非發炎的止痛效果為佳。和阿司匹林藥物一樣，benzydamine具有解熱作用。貓靜脈注射benzydamine之後，會短暫抑制其周邊反射反應。

#### 藥效學

Benzydamine的抗發炎作用機轉和刺激腦下腺-腎上腺功能無關。像其他非類固醇消炎藥一樣，benzydamine的作用方式為抑制前列腺素之合成，但其特性尚未完全釐清。穩定細胞膜亦為其作用機轉之一。

#### 藥物動力學

Benzydamine口服吸收良好。局部噴液後，benzydamine可被發炎的口腔黏膜完全吸收，並產生消炎及局部麻醉之作用。使用康護寧消炎噴液劑後，其血漿中的benzydamine濃度很低，而且濃度與食入的劑量成正比。Benzydamine和其代謝物多由尿液排出，代謝主要以氧化方式為主，亦可見去烷基產物。以康護寧消炎噴液劑漱口後，可從血液及尿液中檢測出benzydamine。大部分被吸收的藥品可在最初的24小時從身體排除。持續給藥7天，benzydamin亦不會於血漿中蓄積。

#### 適應症

舒緩口腔及咽喉疼痛，包括下列疾病或症狀引起的疼痛：扁桃腺炎，喉嚨痛，放射治療引起的黏膜炎，鵝口瘡潰瘍，口腔與牙周手術後疼痛。

#### 禁忌

對benzydamine或其他所列成份過敏者。

#### 注意事項

若咽喉疼痛為細菌感染或病發感染，在使用本品外，應考慮其他抗菌藥劑的治療。肝臟或腎臟功能不全之患者應小心使用。

#### 孕婦使用

類別B2。動物研究資料顯示未有足夠的證據會增加其對胎兒的傷害。孕婦使用benzydamine hydrochloride的安全性尚未建立，孕婦使用本品前，須評估其效益性是否勝過其潛在的危險性。

#### 孩童使用

因缺乏足夠的臨床經驗，本品不建議使用在六歲以下孩童。

#### 藥物交互作用

沒有已知的藥物與benzydamine之間有相互的影響。

#### 不良反應

康護寧消炎噴液劑耐受性良好且副作用輕微。以下藥物不良反應曾被報告於使用benzydamine hydrochloride溶液之後。

#### 局部不良反應

一般最常通報的不良反應是口腔的麻木感，約佔治療比例的2.6%，偶爾的灼熱和刺痛感(佔1.4%)，其他的局部不良反應較不常見，包括乾燥或口渴(0.2%)，刺痛(0.2%)，口腔發熱以及味覺改變(0.1%)。

#### 全身性不良反應

全身性不良反應的狀況是罕見的，大部分為噁心、嘔吐、反胃、胃腸功能失調(0.4%)，頭昏(0.1%)，頭痛和嗜睡(0.1%)。過敏反應的發生極為少見，但皮膚搔癢，紅疹，尋麻疹，日光性皮炎和偶發的喉痙攣或支氣管痙攣或許和過敏反應有些關連。

#### 用法用量

本藥需由醫師處方使用

成人或年齡大於12歲的小孩：直接噴液2-4次(1-2毫克)於疼痛紅腫部位後緩慢吞服。如有必要每1.5-3小時可重複使用。

年齡6-12歲的小孩：直接噴液2次(1毫克)於疼痛紅腫部位後緩慢吞服。如有必要每1.5-3小時可重複使用。

6歲以下孩童：不建議使用。

除非在醫師指示之下，連續治療不應超過7天。

清潔說明：使用後，用乾淨的面紙擦乾噴嘴以避免阻塞。

#### 藥劑過量

尚無藥劑過量案例。曾有過量使用高劑量康護寧消炎噴液劑溶液導致中樞神經系統不良反應的報告。Benzydamine沒有特定的解毒劑，藥劑過量的治療視症狀需要。

#### 包裝

康護寧加強消炎噴液劑3.0毫克/毫升：4000毫升以下PE塑膠瓶裝，玻璃瓶裝。

#### 保存

應避開光線。

儲存於25°C以下。

有效期限標示於外盒



製造廠：旭能醫藥生技股份有限公司

苗栗縣竹南鎮科研路25號

委託者：BEST PHARMA Co., Ltd.

倍斯特醫藥生物科技股份有限公司

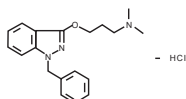
總公司：台中市北屯區崇德路二段51號3樓之3、之5



# Comfflam<sup>®</sup> Forte Anti-inflammatory Throat Spray 3.0mg/ml

### Composition

Each ml contains  
 Benzydamine hydrochloride.....3.0mg  
 It also contains Tween 80 、 Brilliant blue FCF 、 Glycerin 、 Tartrazine 、 Methyl paraben 、 Propyl paraben 、  
 Sucralose 、 Alcohol and Purified Water  
 Apple flavor contains Apple Flavour.Mint Flavor contains Peppermint Oil and Menthol.



### Pharmacology

Benzydamine is 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 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 analgesic action. Benzydamine does not cause erosion of the gastric mucosa when given orally to rats at doses up to 100mg / kg. The analgesic activity of Benzydamine was more pronounced in models involving an experimental inflammation rather than a non-inflammatory pain. In common with the aspirin-like drugs, Benzydamine possesses an antipyretic 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 stabilizing effect on cellular membranes may also be involved in the mechanism of action.

### Pharmacokinetics

Benzydamine is well absorbed following oral administration. Following topical administration, Benzydamine is well absorbed into the inflamed oral mucosa where it exerts anti-inflammatory and local anesthetic action. Benzydamine and its metabolites are excreted largely in the urine. Metabolism is largely by oxidative pathway, although dealkylation can be shown. Most of the absorbed dose was the eliminated in the first 24 hours. Repeated administration for 7 days did not result in accumulation of Benzydamine in plasma.

### Indication

For the relief of painful conditions of the mouth and throat including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post orosurgical and periodontal procedures.

### Contraindications

Benzydamine is contraindicated in patients with known hypersensitivity to the drug or to any of the components.

### Precautions

Painful conditions of the mouth and throat infected by bacteria or virus, should consider combination with other antibiotics or anti-bacteria agents. Use with caution in patients with hepatic or renal impairment.

### Use During Pregnancy

Class B2, The safety of Benzydamine hydrochloride has not been established in pregnant patients. Risk and benefit ratio should be take into consideration.

### Use in Children

Because of the lack of sufficient clinical experience, Benzydamine is not recommended in child under 6 years of age.

### Drug Interactions

There are no known drug interactions with Benzydamine.

### Adverse Reactions

Comfflam spray are 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 (1.4%). 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 of a serious nature. They consisted mainly of nausea, vomiting, retching, gastro-intestinal disorders (0.4%), dizziness (0.1%), headache and drowsiness (0.1%).

### Dosage and Administration

For prescription use,  
 Dosage in adults: 2-4 times (1-2mg) sprays directly onto the sore/inflamed area and swallow gently. Repeat every 1.5-3 hours as necessary.  
 Dosage in Children: 2 times sprays directly onto sore/inflamed area and swallow gently. Repeat every 1.5-3 hours as necessary.  
 Not recommended in child under 6 years of age.  
 Uninterrupted treatment should not exceed seven days, unless directed by physicians.  
 Note: Use tissue papers to clean up the mouth of spray every usage.

### Overdosage

There are no known cases of overdosage with Benzydamine hydrochloride. There is no specific antidote for Benzydamine and even if excessive quantities be ingested the treatment should be symptomatic.

### Presentation

Comfflam Forte Anti-Inflammatory Throat Spray 3.0 mg/ml: 4000ml in PE Bottle or Glass Bottle.

### Pharmaceutical Precautions

Protected from light.  
 Store below 25°C.  
 Shelf life marked on the outer box.



Under the authority of  
**BEST PHARMA Co.,Ltd.**  
 3F.-3-5, No.51. Sec 2 Chungde Rd.,  
 Taichung, Taiwan, R.O.C