



Comfflam-C[®] Anti-inflammatory Antiseptic Solution

康護寧[®]

消炎、殺菌漱口液劑

衛署藥製字第057903號

本藥需由醫師處方使用



成份

每毫升含Benzydamine hydrochloride 1.5 毫克，Chlorhexidine gluconate 1.27毫克及ethanol14毫克。本品含有Tween 80、Glycerin、Sucralose。薄荷口味另含有Brilliant blue FCF、Tartrazine、Peppermint oil，橘子口味另含有Blood orange、Sunset yellow。

性質

康護寧消炎殺菌漱口液劑為一口味佳，含Benzydamine hydrochloride 0.15% W/V，Chlorhexidine gluconate 0.12% W/V。Benzydamine的化學名為1-Benzyl-3-(3-dimethylamine)-1H-indazole，為一白色、無臭、味稍苦之結晶粉末，可溶於水、酒精、甲醇和氯仿，略溶於乙醚和石油醚。Chlorhexidine 的化學名為 1,1-hexamethylenebis(5-(4-chlorophenyl)biguanide)。

藥理特性

Benzydamine為一消炎止痛劑，化學結構不同於類固醇，且與其他的非類固醇的抗炎藥物化學性質不同，是屬於鹼性而非酸性。動物實驗顯示Benzydamine 使用於全身時可有效治療發炎引起的疼痛和水腫，及抑制肉芽腫生成。在局部治療的濃度下，Benzydamine 具有局部麻醉作用。給予大鼠口服Benzydamine 100mg/kg 並未造成胃粘膜糜爛。Benzydamine 對發炎性疼痛的止痛效果較非發炎性疼痛為佳，和Aspirin之類的藥品相同，Benzydamine亦具解熱作用。給予貓靜脈注射Benzydamine會短暫抑制其週邊反射反應。Chlorhexidine 屬於雙胍類抑菌劑，在口腔衛生不佳狀況下可減少牙齒斑及牙周炎的發生，它的強鹼性會親合口腔結構包括牙釉質的羶基磷灰石、牙表面薄膜、細菌及唾液蛋白。

藥效動力學

Benzydamine 的抗炎作用機轉與刺激腦腺脲-腎上腺軸無關，與其他非類固醇抗炎藥類似，某些情況下Benzydamine抑制前列腺素的合成，但其特性尚未完全闡明，細胞膜穩定亦為其作用之一。康護寧消炎殺菌漱口液劑的局部作用，Chlorhexidine產生立即的殺菌效果，及較長的抑菌作用。Chlorhexidine 具有廣泛對抗微生物作用，包括革蘭氏陽性和陰性細菌，酵母菌、某些黴菌和病毒。Chlorhexidine 會被吸附及吸收在微生物的細胞壁，造成細胞膜破裂而延緩細菌成長。

藥品動力學特性

吸收

Benzydamine口服吸收良好，局部授予康護寧消炎殺菌漱口液劑，Benzydamine 可被發炎的口腔粘膜吸收，並產生抗發炎和局部麻醉作用。持續使用後被攝取進入血漿的 Benzydamine濃度很低。Chlorhexidine被胃腸道吸收很低，持續口服使用並未發現影響血糖，經皮膚吸收亦不明顯。

排泄

Benzydamine和其代謝物大多由尿液排除，代謝主要以氧化型式為主，亦可見dealkylation產物。使用康護寧消炎殺菌漱口液劑後，在血及尿中亦可測得 Benzydamine，大多數被吸收的藥品可在二十四小時內排除，持續給藥七天，亦不會在血漿中蓄積。大約30%的 Chlorhexidine會殘留在口腔，但在最初的二十四小時會慢慢溶入口腔液中，Chlorhexidine被胃腸道吸收很低，主要經由糞便排除。

適應症

舒緩口腔及咽喉疼痛；包括喉嚨痛、扁桃腺炎、咽喉炎、口腔潰爛、因口腔和喉部手術引起的疼痛、及牙科手術後疼痛。口腔內之殺菌消毒。但除非在醫師的建議下，否則不建議長期使用。

禁忌

對Benzydamine、Chlorhexidine及其賦型劑過敏的患者。

注意事項

康護寧消炎殺菌漱口液劑用於潤濕或漱口，應於漱口後吐掉不應吞服；一般狀況不需稀釋直接使用，但若有灼熱或刺痛感可用水稀釋。若因細菌感染引起的喉嚨疼痛，除了使用康護寧消炎殺菌漱口液劑外，亦應考量合適的抗菌治療。對於口腔消炎殺菌液劑，能降低喉部感染的嚴重性及減少治療期間的臨床效益，並未獲得證明。

腎功能不全患者的使用:請參考用法用量。

肝功能不全患者的使用:請參考用法用量。

孕婦的使用

藥物分級B2孕婦使用Benzydamine的安全性並未建立，若要使用康護寧消炎殺菌漱口液劑，需先評估效益性大過於潛在危險性方得使用。

孩童的使用

尚缺乏足夠的臨床經驗，康護寧消炎殺菌漱口液劑不建議使用於六歲以下孩童。

藥物交互作用

尚無已知會與Benzydamine產生交互作用的藥物

不良反應

一般而言，康護寧消炎殺菌漱口液劑的耐受性佳，且副作用低。Benzydamine hydrochloride，以下的不良反應曾被報告於液劑的使用：

局部不良反應

為口部麻木 (2.6%)、偶有灼熱或刺痛感 (1.4%)。其它的局部不良反應則極罕見，包括口乾或口渴 (0.2%)、麻刺感 (0.2%)、口部溫熱及味覺改變(<0.1%)。

全身性不良反應

極為罕見和輕微，主要為惡心、嘔吐、乾嘔、胃口不適 (0.4%)頭昏 (0.1%)、頭痛和嗜睡 (0.1%)，過敏反應非常罕見，可能會有皮膚瘙癢、皮疹、蕁麻疹、光照性皮炎、喉頭痙攣和支氣管痙攣等。

Chlorhexidine gluconate，較常見的不良反應，為使用於口腔潤濕時，產生的牙齒斑點、口腔表面的結石及味覺改變；無害的牙齒斑點可藉由刷牙改善。臨床上並未發現嚴重的全身性不良反應。

用法用量

每次以10–15mL之漱口液劑於口腔內漱口並停留30–60秒後吐出，可於早晚或需要時使用。未滿6歲兒童不得使用，6歲以上12歲以下兒童須在成人指導下使用。

成人劑量：

當用於漱口，通常劑量為15mL (約一湯匙)，漱口30秒，必要時每1.5–3 小時重複使用。當用於口腔病變潤濕使用時，通常劑量為15mL (約一湯匙)，含於口內浸潤至少30秒，一天內每1.5–3 小時如此反覆使用。康護寧消炎殺菌漱口液劑中Chlorhexidine在口腔衛生不佳狀況下可減少牙齒斑及牙周炎的發生，如果當做口腔清潔液替代品時，至少應含於口內浸潤一分鐘。康護寧消炎殺菌漱口液劑最好在刷牙後使用，可避免牙齒變色。除非在醫師的建議下，否則不建議長期使用。

孩童6–12歲劑量：5–15mL 用於漱口或潤濕如同成人一般。

腎功能不全患者的使用：因為被吸收的Benzydamine代謝物經由尿液排泄，對於嚴重的腎功能不全患者須考慮可能發生全身性不良反應。

肝功能不全患者的使用:因為被吸收的Benzydamine大多在肝臟代謝，嚴重肝功能不全的患者，應考慮可能有全身性的作用。

過量

尚無高劑量使用康護寧消炎殺菌漱口液劑的過量病例報告。目前Benzydamine無特定解毒劑，若發生過量時應針對症狀治療。

包裝

薄荷口味：澄清、綠色液劑，4000毫升以下HDPE塑膠瓶裝、玻璃瓶裝。【須由醫師處方使用】

橘子口味：澄清、橘色液劑，4000毫升以下HDPE塑膠瓶裝、玻璃瓶裝。【須由醫師處方使用】

貯存

避光貯存於25 °C 以下，有效期限標示於外盒。



製造廠：歐帕生技醫藥股份有限公司
新竹縣湖口鄉光復路1號

委託者：倍斯特醫藥生物科技股份有限公司
Best Medical Biotechnology Co., Ltd.
台中市崇德路二段51號3樓之5



Comfflam-C Anti-inflammatory Antiseptic Solution

Composition

Each ml contains Benzydamine Hydrochloride----1.5mg Chlorhexidine gluconate--1.27mg And Ethanol----14mg It also contains tween 80, glycerin, sucalose. Mint flavors also contains brilliant blue FCF,tartrazine,peppermint oil. Orange flavors also contains blood orange, sunset yellow.

Description

Benzydamine. Chemical name:1-benzy-3-(3dimethylaminopropoxy)-1H-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. Chlorhexidine. Chemical name: 1,1-hexamethylenebis(5-(4-chlorophenyl)biguanide).

Pharmacology

Benzydamine is anti-inflammatory analgesic agent structurally unrelated to the steroid group. Benaydamine differs chemically from other nonsteroidal anti-inflammatory drugs 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, benaydamine possesses local anaesthetic action. Benzydamine does not cause erosion of the gastric mucosa when given orally to rats at doses of up to 100 mg/kg. The analgesic activity of benzydamine was more pronounce in models involving an experimental inflammation rather than in noninflammatory pain. In common with the aspirin-like drugs, benzydamin possesses antipyretic activity. Peripheral reflexes were transiently inhibited after intravenous administration to cats. Chlorhexidine is a bisbiguanide antiseptic and helps to reduce the development of plaque and gingivitis when usual oral hygiene measures are interrupted. It is a strong base, with affinity for oral structures including hydroxyapatite of tooth enamel, pellicle of tooth surface, bacteria and salivary proteins. C

Pharmacodynamics

The mechanism of anti-inflammatory action of benzydamine is not related to stimulation of the pituitary-adrenal axis. Like other nonsteroidal anti-inflammatory drugs, 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.

Following normal topical application of Comfflam–C Anti-inflammatory Antiseptic Solution, chlorhexidine produces an immediate bactericidal effect, followed by a prolonged bacteriostatic action. Chlorhexidine is active against a wide range of microorganisms, including Gram positive bacteria, Gram negative bacteria, yeasts and some fungi and viruses. Chlorhexidine appears to delay bacterial growth by a delayed surface action. It is attracted to and absorbed onto microbial cell walls, and causes membrane leakage.

Pharmacokinetics

Absorption

Benzydamine is well absorbed following oral administration. Following topical administration of Comfflam-C Solution and spray, benzydamine is well absorbed into the inflamed local mucosa where it exerts anti-inflammatory and local anaesthetic actions. Plasma benzydamine levels following use of Comfflam-C solutions are low and parallel the amount actually ingested.

Chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. No detectable blood levels have been found in humans following oral use, and percutaneous absorption, if it occurs at all, is insignificant.

Excretion.

Benzydamine and its metabolites are excreted largely in the urine. Metabolism is largely by oxidative pathways, although dealkylation can be shown.

Benzydamine has first 24 hours. Repeated administration for seven days did not result in accumulation of benzydamine in plasma.

Approximately 30% of the applied chlorhexidine gluconate is retained in the oral cavity and is slowly released into the oral fluids for up to 24 hours. Chlorhexidine is poorly absorbed from the gastrointestinal tract and is primarily excreted in the faeces.

Indications

Temporary relief of painful conditions of the mouth and throat including sore throat, tonsillitis, pharyngitis, mouth ulcers, pain following mouth or throat surgery, pain following dental procedures. Temporary relief of painful conditions of the mouth and throat.

Comfflam-C is not intended for prolonged use except under dental or medica supervision.

Contraindications

Known hypersensitivity to benzydamine or to any of the components of the vehicle. Additionally, known hypersensitivity to chlorhexidine.

Precautions

Comfflam-C Anti-inflammatory Antiseptic Solution is indicated for use as a rinse or gargle. It should not be swallowed but rather should be expectorated after each use. It should generally be used undiluted but if burning or stinging occurs, 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 Comfflam-C Anti-inflammatory Antiseptic Solution.

The clinical efficacy of an antiseptic agent in oral solution in reducing the severity or duration of throat infections has not been clinically established.

Impaired renal function See Dosage and Administration.

Impaired hepatic function See Dosage and Administration.

Use in pregnancy (Category B2)

The safety of benzydamine hydrochloride has not been established in pregnant patients. Risk to benefit ratio should be established if Comfflam-C is to be used in these patients.

Use in children

Because of the lack of sufficient clinical experience, Comfflam-C Anti-inflammatory Antiseptic Solution is not recommended in children under 6 years.

Interactions with other medicines

There are no known drug interactions with benzydamine.

Adverse effects

Comfflam-C Anti-inflammatory Antiseptic solution is generally well tolerated and side effects are minor. Benzydamine hydrochloride. The following adverse reactions have been reported after use of benzydamine hydrochloride in solution form.

Local adverse reactions.

The most commonly reported reaction is oral numbness(2.6%). Occasional burning or stinging sensations may occur and have been reported in 1.4% of treated patients. 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, gastrointestinal disorders(0.4%), dizziness(0.1%), headache and drowsiness (0.1%). Hypersensitivity reactions occur very rarely but may be associated with pruritus, rash, urticaria, photodermatitis and occasionally laryngospasm or bronchospasm. Chlorhexidine gluconate. The most common side effects associated with chlorhexidine gluconate oral rinses are an increase in staining of teeth and other oral surfaces, an increase in calculus formation and an alteration in taste perception. Chlorhexidine tooth staining is harmless and can be minimized by thorough brushing of teeth before administration. No serious systemic adverse reactions associated with its use have been observed in clinical testing.

Dosage and administration

Used as a gargle, the usual dose is 10–15 ml which should be gargled for at least 30–60 seconds at intervals of 12 hours, as needed.

Not recommended for children under 6 years.

Children 6 to 12 years should be used under adult supervision.

Dosage in adults:When used as a gargle, the usual dose is 15 mL (approximately one tablespoon) which should be gargled for at least 30 seconds at intervals of 1.5 to 3 hours, as needed.

When used as a rinse for oral lesions, the usual dose is 15 mL(approximately one tablespoon) which should be held in the mouth and swirled around for at least 30 second, with repeat use every 1.5 to 3 hours throughout the day.

Chlorhexidine in Comfflam-C Anti-inflammatory Antiseptic Solution helps to reduce the development of plaque and gingivitis during the period of treatment when usual oral hygiene measures are interrupted. If used as an alternative to usual oral hygiene procedures, Comfflam-C Anti-inflammatory Antiseptic Solution should be swirled around in the mouth for at least a minute. Comfflam-C Anti-inflammatory Antiseptic Solution is best used after brushing teeth to minimize chlorhexidine induced discoloration. Comfflam-C Anti-inflammatory Antiseptic Solution is not intended for prolonged use except under dental or medical supervision.

Children 6 to 12 years: 5 to 15 mL 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 should be considered in patients with severe renal impairment.

With impaired liver function: Since absorbed benzydamine is highly metabolized in the liver, the possibility of systemic effects should be considered in patients with severe hepatic impairment.

Overdosage

Adverse central nervous system effects have been reported following overdosage with high doses of Comfflam-C Anti-inflammatory Antiseptic Solution. There is no specific antidote for benzydamine. And should excessive.

Presentation

Mint flavors: To clarify, the green liquid, 4000 ml HDPE following plastic bottles, glass bottles.[Medicinal product subject to medical prescription.]

Tangerine: To clarify, orange liquid, 4000 ml HDPE following plastic bottles, glass bottles.[Medicinal product subject to medical prescription.]

Pharmaceutical Precautions

Protect from light and Store below 30°C. Expiration date stamped on the carton



Under the authority of Best Medical Biotechnology Co., Ltd. 3F-5 NO.51 Sec 2 Chung Der Road, Tai-Chung, Taiwan, 406 R.O.C

9169421. 00