康護寧® 消炎噴液劑1.5公絲/公撮 衛署藥製字第 045922 G-8139 號

Comfflam ANTI-INFLAMMATORY SPRAY 1.5mg/ml

成份：
每公撮含Benzydamine hydrochloride 1.5公絲。

性質：
康護寧消炎噴液劑爲一口味佳、綠色澄清溶液，含Benzydamine hydrochloride 0.15%W/V。
Benzydamine的化學名爲1-Benzyl-3-(3-dimethylaminopropoxy)-1h-indazole。
Benzydamine hydrochloride爲一白色、無臭、味苦之結晶性粉末，可溶於水、酒精、甲醇和氯仿，略溶於乙醚和石油醚。

藥理學特性：
Benzydamine爲一抗炎止痛劑，其化學結構爲非類固醇，並與其它的非固醇類抗炎藥性質不同，是一鹼類而非酸類。動物實驗顯示使用全身性的benzydamine可有效的治療發炎引起的疼痛及水腫，亦可抑制肉芽腫的生成。在局部的治療濃度下，benzydamine具有局部麻醉作用。大鼠口服benzydamine達劑量100mg/kg，並未造成胃黏膜潰瘍。
Benzydamine對發炎性的疼痛其止痛效果較非發炎性的疼痛爲佳，和aspirin類似藥品相同，benzydamine亦具有解熱作用。
貓靜脈注射benzydamine，會短暫抑制其周邊反射反應。

作用方式：
Benzydamine抗發炎的作用機轉與刺激腦下腺-腎上腺軸無關，其與其它的非固醇類抗炎藥相同，在某些情況下benzydamine的作用方式爲抑制前列腺素的合成，但其特性尚未完全闡明。穩定細胞膜亦爲其作用機轉之一。

藥物動力學特性：

吸收
Benzydamine口服吸收良好，投與局部作用之康護寧消炎噴液劑，benzydamine可被發炎的口腔黏膜完全吸收並產生抗發炎和局部麻醉作用。

排泄
Benzydamine和其代謝物大多由尿中排除，代謝主要是以氧化方式爲主，亦可見dealkylation產物。使用康護寧消炎漱口劑後在血及尿中可測得benzydamine，大部分被吸收的藥品可在最初的24小時內排除。持續給藥7天，benzydamine亦不會在血漿中蓄積。

適應症：
舒解口腔及咽喉疼痛，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。

用法用量：
本藥須由醫師處方使用
成人或年齡大於12歲的小孩：
直接噴液4-8次（1-2公絲）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4次（1公絲）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。

禁忌：對本藥及其賦型劑過敏的患者。

注意事項：
肝及腎功能不全的患者應小心使用之（請參考用法用量）。

藥品交互作用：
尚無已知會與benzydamine發生交互作用的藥物。

孕婦的使用：
孕婦使用benzydamine hydrochloride的安全性尚未建立，若要使用康護寧消炎噴液劑時必須評估過，其效益性勝過其潛在的危險性，始可使用。

孩童的使用：
由於缺乏足夠的臨床經驗，康護寧消炎噴液劑不建議使用於6歲以下的孩童。

不良反應：
一般而言康護寧消炎噴液劑的耐受性佳且副作用低，局部不良反應：最常被報告的不良反應爲口部麻木（2.6%）。偶而會灼熱及刺痛感被報告（約1.4%）。其它的局部不良反應則極少見，包括口乾或口渴（0.2%）、刺痛感(0.2%)、口部溫熱感及味覺改變（<0.1%）。
全身性的不良反應：極罕見且極輕微。主要是噁心、嘔吐、乾嘔、胃腸不適（0.4%）、頭昏(0.1%)、頭痛和嗜睡（<0.1%）。

腎功能不全患者的使用：
由於吸收的benzydamine和其代謝物大多由尿中排除，嚴重腎功能不全患者應考慮可能有全身性的作用。

肝功能不全患者的使用：
由於吸收的benzydamine大多在肝臟代謝，嚴重肝功能不全患者應考慮可能有全身性的效應。

過量：
尚無benzydamine hydrochloride溶液過量的病例報告。即使不小心吞下Comfflam亦不可能產生全身性的不良反應。
目前benzydamine無特定的解毒劑，若發生過量時，應針對其症狀來治療。

貯存：
避光貯存於25℃以下。

包裝：
康護寧消炎噴液劑1.5公絲／公撮：100公撮以下之玻璃瓶裝。

委託製造者：倍斯特醫藥生物科技股份有限公司
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Comfflam® ANTI-INFLAMMATORY SPRAY 1.5mg/ml

Composition
Each ml contains
Benzydamine hydrochloride.....1.5mg

Property
Comfflam Anti-inflammatory Spray are pleasant tasting, clear, green solutions, containing benzydamine hydrochloride 0.15% w/v.Benzydamine is 1-Benzyl-3-(3-dimethylaminopropoxy)-1hindazole.
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 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 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 Comfflam spray, benzydamine is well absorbed into the inflammed oral mucosa where it exerts anti-inflammatory and local anaesthetic action.
Excretion
Benzydamine and its metabolites are excreted largely in the urine. Metabolism is largely by oxidativepathways, although dealkylation can be shown.
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
Comfflam is indicated 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
Comfflam is contraindicated in patients with known hypersensitivity to the drug or to any of the components of the vehicle.

Precautions
Use with caution in patients with hepatic or renal impairment (see Dosage and Administration).
Comfflam contains methyl hydroxybenzoate as a preservative. This has been known to cause sensitisation.
Hypersensitivity 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 Comfflam is to be used in these patients.

Use in Children
Because of the lack of sufficient clinical experience, Comfflam spray are not recommended in children under 6 years of age.

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 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%).

Dosage and Administration
Comfflam spray should generally be used undiluted, but if stinging occurs it may be diluted with water.
Uninterrupted treatment should not exceed seven days.

Dosage in adults
Spray:
When used as spray the usual dose is 5-10 sprays directly onto the sore/inflamed area and swallow gently. Repeat every 1.5 to 3 hours as necessary.

Dosage in Children
Spray: spray 5 times directly onto sore/inflamed area and swallow gently. Repeat every 1.5 to 3 hours as necessary.

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 live 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. Comfflam is unlikely to causadverse esystemic effects, even if accidental ingestion should occur. There is no specific antidote for benzydamine and even if excessive quantities be ingested the treatment should be symptomatic.

Pharmaceutical Precautions
Protect from light Store below 25℃

Presentation
Comfflam Anti-Inflammatory Spray 1.5 mg/ml: below 100ml

Under the authority of
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