WITH YOU EVERY STEP OF THE WAY

Ventipulmin® (clenbuterol HCl)



Selected Comments from the Manufacturer's Perspective

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Following a long and difficult approval process, Ventipulmin Syrup became legally available in the United States for use in horses on May 11th, 1998



Ventipulmin® Syrup (clenbuterol hydrochloride syrup)

Potent Bronchodilator

Mucolytic

Increases Mucociliary Transport

Anti-inflammatory







Indications: VENTIPULMIN Syrup (clenbuterol hydrochloride) is indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

The indications section (as approved by the FDA) is somewhat dated and imprecise.

"... lower airway obstruction, ..." would be more specific and appropriate verbiage, as there are myriad upper airway obstructive problems that occur frequently in the horse that Ventipulmin would not be indicated for.

Two years after Ventipulmin's approval, equine respiratory experts from all over the world met and decided that the term "chronic obstructive pulmonary disease" (COPD) was an inappropriate name for the lower airway conditions Ventipulmin is indicated for.

The "experts" now prefer the following terminology: "Recurrent Airway Obstruction", "Heaves" (a traditional term), "Inflammatory Airway Disease", and/or "Equine Asthma"

Most practitioners, however, still recognize (and use) the term "COPD".





WE SEE THINGS DIFFERENTLY

Inflammatory Airway Disease

- Common in young, stabled performance horses
 - 2-5 years of age
 - Insidious clinical presentation
 - Incidence 30 -70%







Ventipulmin® Syrup (clenbuterol HCl syrup)

Ventipulmin Syrup offers potential beneficial effects for all four major clinical abnormalities associated with equine non-infectious lower airway disease



WE SEE THINGS DIFFERENTLY

Bronchodilation Misconceptions







Ventipulmin® (clenbuterol HCl)

Problematic Aspects

• Pharmacologic threshold is short

• Detection threshold is prolonged in urine

- Repartitioning effects
 - High doses
 - For prolonged periods of time



PR/Perception Issues

- The widespread use of Ventipulmin, particularly in racing, makes it an easy target for suspicion/criticism by those who don't understand its therapeutic purpose, pharmacology and the physiology of the respiratory system.
- Isolated instances of misuse of the drug (real or perceived) are easily sensationalized or misrepresented by the press (intentionally or unintentionally).
- The press and general public (as well as some racetrack regulators) do not fully understand Ventipulmin and the legitimate rationale for its use.
- Most people (both professional and lay) cannot get their heads wrapped around the fact that full dilation is the normal state of the bronchial tree and that Ventipulmin cannot significantly dilate the bronchial tree beyond normal.



PR/Perception Issues

Those opposed to the use of Ventipulmin sometimes put forth the argument that if the horse is "sick enough" to put on this type of medication that they should not be competing.

They cannot fathom the concept that the conditions this drug is being utilized for could be considered "occupational diseases" of stabled racing horses (as well as other sport, performance and working horses).





- Ventipulmin is neither a "steroid" or an "anabolic steroid" drug preparation.
- The terms "anabolic steroid", "anabolic effect", "steroid" are substituted by both professional and laypersons for the terms "repartitioning agent" and "repartitioning effect" as if they were equivalent.
- "Anabolic" and "steroid" are terms that are far more sensational and provocative.
- Reported problems, untoward effects, and misuse usually involve use of the drug at higher than the normal 0.8 micrograms/kg. for extended periods of time.
- Administering the approved drug at these higher levels is extraordinarily expensive and not as widespread as many who are not familiar with the economics of this drug may assume.





Human Abuse of Ventipulmin

- Ventipulmin's action as a repartitioning agent as well as it's frequent misclassification as an "anabolic steroid" has made it attractive as an (unapproved) weight-loss drug and as an adjunctive agent for bodybuilders, and atheletes in the U.S. and throughout the world.
- Clenbuterol is not approved for human use in many countries, including the U.S., as other bronchodilators have proven to be safer and more effective in people. It is banned as a performance-enhancing drug in most human sports.







WE SEE THINGS DIFFERENTLY

Human Abuse of Ventipulmin

- Where clenbuterol is approved for human use, it is generally available in tablet form, while veterinary preparations are presented as a syrup. Both tablets and syrups are used abusively.
- There is currently a huge illicit market for clenbuterol for inappropriate human use . . . much of this occurs via the internet.
- As usually occurs in these situations, counterfeit preparations find their way into this type of marketplace, further increasing risk.
- Athletes , body builders, and those seeking to lose weight are using clenbuterol preparations without professional guidance and with no proof of a particular preparations effectiveness or safety for their intended application.





Human Abuse of Ventipulmin

- Clenbuterol is a potentially dangerous drug for humans
- The most common problems experienced by clenbuterol users include:
 - Headaches
 - Tremors (especially hand shakes)
 - Cramps
 - Restlessness/ nervousness
 - Anxiety
 - Insomnia
 - Sweating
 - Increased appetite
 - Nausea
 - Heart palpitations and rapid heart rate (tachycardia)
 - Hypertension (high blood pressure)

