

# VENTA

Syrup & Solution For Inhalation



## Composition:

**Syrup:** Each 5 ml VENTA Syrup contains:

Salbutamol Sulfate equivalent to Salbutamol 2 mg.

**Solution For Inhalation:** Each 1 ml VENTA Solution for Inhalation contains: Salbutamol Sulfate equivalent to Salbutamol 5 mg.

## Pharmacological Properties & Mechanism of Action:

VENTA contains Salbutamol which is a selective  $\beta_2$ -agonist providing short-acting (4 - 6 hours) bronchodilation with a fast onset (within 5 minutes) in cases of reversible airway obstruction. Its rapid onset of action makes it suitable for the prevention and management of asthma attacks.

## Pharmacokinetics:

Salbutamol is readily absorbed from the gastrointestinal tract and undergoes first-pass hepatic metabolism. Peak plasma concentrations are reached within 1-4 hours after an oral dose. After several oral doses of salbutamol (four times a day), steady-state plasma concentrations were obtained after 3 days. About half of the total dose is excreted in the urine after oral administration as inactive sulfate conjugates. The bioavailability of oral salbutamol is about 50%, while about (10-20)% of an inhaled dose of salbutamol reaches the lower airways, while the swallowed portion of an inhalation dose is absorbed in the gastrointestinal tract and undergoes hepatic metabolism.

## Indications:

VENTA is indicated for the treatment of acute severe asthma and for routine management of chronic bronchospasm-unresponsive to conventional therapy.

## Contraindications:

VENTA is contraindicated in patients with a history of hypersensitivity to any of the ingredients. Salbutamol preparations should not be used in the standard treatment of premature delivery or Pregnancy of threatened abortion.

## Warnings & Precautions:

- VENTA should be given with caution to patients who are hypersensitive or suffer from hyperthyroidism, diabetes, cardiac disorders or high blood pressure.

- Severe asthma requires regular medical assessment including lung functions testing as patients are at risk of severe attacks and even death.

- The metabolic effects of high doses of salbutamol may also be exacerbated by concomitant use high doses of cortisone.

- Long-term treatment with salbutamol may increase the risk of tooth decay.

## Pregnancy & Lactation:

**Pregnancy:** Pregnancy category C. VENTA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Lactation:** Since salbutamol is excreted in breast milk, it should not be used during breast-feeding without consulting a doctor.

## Drug Interactions:

- Salbutamol and non-selective beta-blocking drugs, such as propranolol, should not be prescribed together.

- VENTA should be used with caution in patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants or within 2 weeks discontinuation of such agents.

- The effect of salbutamol may also be enhanced by concomitant use of it with aminophylline.

- Corticosteroids may increase the risk of hyperglycemia.

- Rare cases of acute angle-closure glaucoma have been reported when salbutamol has been combined with ipratropium.

## Side Effects:

**common:** tremor, headache, tachycardia, palpitations and muscle cramps.

**Rare:** hypokalemia, and peripheral vasodilatation.

## Driving & Using Machines:

VENTA is not likely to affect you being able to drive or use machines.

## Dosage & Administration:

### VENTA Syrup:

**Adults:** The minimum starting dose is 2 mg (5 ml) three times a day. The usual effective dose is 4 mg (10 ml) three or four times a day, which may be increased to a maximum of 8 mg (20 ml) three or four times a day, if adequate bronchodilation is not obtained.

**Children 2-6 years:** 1 mg (2.5 ml), three or four times a day.

**Children 6-12 years:** 2 mg (5 ml), three or four times a day.

**Children over 12 years:** The minimum starting dose is 2 mg (5 ml), three or four times a day. This may be increased to 4 mg (10 ml), three or four times a day.

### VENTA Solution for Inhalation:

VENTA solution may be given intermittently or continuously:

#### • Administration with Intermittent doses system:

**Adults:** 0.5 ml of VENTA solution (2.5 mg salbutamol), diluted to a final volume of 2 ml using saline solution for injection (may be repeated 3 or 4 times a day). The dose may be increased to 1 ml (5 mg salbutamol), diluted to a final volume of 2.5 ml using saline solution for injection.

VENTA solution may be used without dilution in which 2 ml (10 mg salbutamol) is applied into the nebulizer and the patient is allowed to inhale the aerosol formed until bronchial dilatation is obtained.

### Children:

**Children under 12 years:** The minimum starting dose is 0.5 ml (2.5 mg salbutamol), diluted to 2 ml or 2.5 ml using saline solution for injection. Intermittent treatment may be repeated up to 4 times a day.

**Children 12 years of age and over:** the same dose as adults.

**In infants less than 18 months of age:** The clinical efficacy of salbutamol nebulizer is uncertain.

#### • Administration with continuous doses system:

VENTA solution is diluted with saline solution for injection, each 1 ml of diluted solution contains 50-100  $\mu$ g salbutamol (1-2 ml of VENTA solution is diluted to 100 ml using dilution). The diluted solution is used by suitable nebulizers for this purpose. The usual rate of administration is 1-2 mg per hour.

## Overdose:

**Symptoms:** Overdosage symptoms are those of excessive  $\beta$ -stimulation, e.g., seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache.

**Treatment:** Treatment consists of discontinuation of salbutamol together with appropriate symptomatic therapy. Administer a cardioselective  $\beta$ -adrenergic blocker (e.g. metoprolol), if necessary for cardiac arrhythmias. Hypokalemia may occur after an overdose of salbutamol.

serum potassium levels should be monitored,

## Storage:

Store below 25 °C.

Keep bottle tightly closed.

Keep out of reach of children.

Discard the remaining amount of VENTA solution for inhalation one month after opening the bottle. Do not use the solution if its color changes. The solution should not be injected or swallowed (for inhalation only).

## Packaging:

**Syrup:** Each VENTA Syrup carton box contains amber glass bottle of 100 ml.

**Solution for Inhalation:** Each VENTA Solution for Inhalation carton box contains amber glass bottle of 20 ml.

-A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.  
-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.  
-The doctor and the pharmacist experts in medicine, it's benefits and risks.  
-Do not repeat the same prescription without consulting your doctor.  
KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN  
Council of Arab Health Ministries, Union of Arab Pharmacies

Reva Pharma for Pharmaceutical Industries - Idlib - Syria

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