SALBUTAMOL

VENTAR®

2 mg/5 mL Syrup
2 mg Tablet

BRONCHODILATOR

Rx

FORMULATIONS:
Each 5 mL syrup contains SALBUTAMOL (as sulfate), PP..... 2mg
Each tablet contains SALBUTAMOL (as sulfate), USP..... 2mg

DESCRIPTION:
Salbutamol (Ventar ®) is a clear, colorless, apple-flavored syrup.
Salbutamol (Ventar ®) is a white round, film-coated tablet.

PHARMACODYNAMICS:
Salbutamol (Ventar ®) is a direct-acting sympathomimetic agent with predominantly β-adrenergic activity and a selective action on β2-receptors. It is used as bronchodilator by stimulating β2-adrenergic receptors in the lungs to relax bronchial smooth muscle thereby relieving bronchospasm, increasing vital capacity, decreasing residual volume and reducing airway resistance. As a predominantly β-receptor stimulant, it has a more selective action. Its bronchodilating action being more prominent than its effect on the heart. Such β-adrenoceptor stimulants are preferred to other bronchodilator like isoprenaline for the management of asthma.

PHARMACOKINETICS:
After oral administration, salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine. The bioavailability of orally administered salbutamol is about 50%.

INDICATIONS:
For the relief of bronchospasm in bronchial asthma, chronic bronchitis, bronchiectasis, emphysema and other reversible obstructive pulmonary diseases.

DOSAGE AND ADMINISTRATION:
Syrup/Tablet (To be taken every 6 to 8 hours)
Usual Adult Dose: 4 mg or 10 mL (2 teaspoonfuls) or as prescribed by the physician. If adequate bronchodilation is not obtained, each single dose may be gradually increased to as much as 8 mg or 20 mL (4 teaspoonfuls).

Some patients obtain adequate relief with 5 mL known to be unusually sensitive to β-adrenergic stimulant drugs. It is advisable to initiate treatment with 5 mL (1 teaspoonful) three or four times a day.

	TABLET	SYRUP
Children over 12 years	1-2 tablets	5.0 mL – 10 mL (1-2 teaspoonfuls)
Children 6-12 years	1 tablet	5.0 mL (1 teaspoonful)
Children 2-6 years	1/2-1 tablet	2.5 mL - 5.0 mL (1/2-1 teaspoonful)

(5 mL is equivalent to 1 teaspoonful)

CONTRAINDICATIONS AND PRECAUTIONS:
It is contraindicated to patients with history of hypersensitivity to Salbutamol. Salbutamol should be administered with caution to patients suffering from thyrotoxicosis. Special care is advisable to patients receiving antihypertensive therapy. It should not be prescribed to patients under treatment with β-blockers. Great care in administration is also needed in patients with cardiac arrhythmias, coronary insufficiency,

hypertension, ischemic heart disease, Diabetes mellitus, hyperthyroidism, Ketoacidosis, pheochromocytoma, sensitivity to sympathomimetics. It should also be used with caution in patients undergoing anaesthesia with cyclopropane or halothane and those receiving cardiac glycosides, quinidine or tricyclic antidepressants.

PREGNANCY:
Unnecessary administration of drugs during the first trimester or pregnancy is undesirable.

INTERACTIONS:
Use of salbutamol and other beta$_2$ agonist with corticosteroids, diuretics, or xanthines increases the risk of hypokalaemia, and monitoring of potassium concentrations is recommended in severe asthma, where such combination therapy is common.

ADVERSE EFFECTS:
To some patients, oral salbutamol may cause fine tremor of skeletal muscle particularly the hands, nausea, pounding heartbeat, nervousness or restlessness. The side effects are dose-related and are common to all β-adrenergic stimulants. In large doses than recommended, it may cause slight tachycardia, peripheral vasodilation and occasional headache have been reported. Few patients feel tense due also to the effect on skeletal muscle and not direct CNS stimulation.

OVERDOSAGE:
Reports of overdosage with salbutamol have generally only described the features that may be expected with beta$_2$ agonists such as tachycardia, CNS stimulation, tremor, hypokalaemia, and hyperglycaemia. Symptomatic treatment of the adverse effects has proved successful although it is unlikely to be required after repeated inhalation. Activated charcoal may be considered after oral overdose in patients who have taken a potentially toxic amount and present within 1 hour. The plasma potassium concentration and pulse rate have been found to correlate with the plasma concentration of salbutamol.

WARNING:
Salbutamol administered intravenously or orally during labor or delivery inhibits uterine contraction.

Patients taking this medication should consult their physician if they do not respond to the usual dose of this medication for reassessment of therapy.

STORAGE RECOMMENDATION:
Store at temperatures not exceeding 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

AVAILABILITY:
2mg/5mL Syrup Amber Glass Bottle x 60mL – DR-XY16562.
2mg Alu-Clear PVC Blister Pack x 10's (Box of 100's) DR-XY17858.

DATE OF FIRST AUTHORIZATION:
2mg/5mL Syrup – August 03, 2014
2mg Tablet – March 03, 2011

DATE OF REVISION OF PACKAGE INSERT:
October 2021

Manufactured by:
HIZON LABORATORIES, INC.
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For:
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RMG Corporate Center
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