Aroneb™ Nebuliser solution

Arformoterol INN

Presentation
Aroneb™ Nebuliser Solution: Each ampoule contains 2 ml clear solution for inhalation of Arformoterol Tartrate INN equivalent to Arformoterol 15 mcg.

Description
Arformoterol tartrate is a salt of Arformoterol, the (R,R)-enantiomer of formoterol. Arformoterol is a selective beta$_2$-adrenergic bronchodilator. It has two-fold greater potency than racemic formoterol which contains both the (S,S) and (R,R)-enantiomers. The (S,S)-enantiomer is about 1,000-fold less potent as a beta$_2$-agonist than the (R,R)-enantiomer. In vitro tests show that arformoterol is an inhibitor of the release of mast cell mediators, such as histamine and leukotrienes, from the human lung.

Indications and Uses
Arformoterol is indicated for long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.
Important limitations of use: Arformoterol nebuliser solution is not indicated to treat acute deteriorations of COPD. People with asthma, who take long-acting beta$_2$-adrenergic agonist (LABA) medicines, such as Arformoterol, have an increased risk of death from asthma problems

Dosage and Administration
The recommended dose of Arformoterol nebuliser solution is one 15 mcg unit-dose ampoule administered twice daily (morning and evening) by nebulization. A total daily dose of greater than 30 mcg (15 mcg twice daily) is not recommended.

Pediatric Use: COPD does not occur in children. The safety and efficacy of Arformoterol nebuliser solution in pediatric patients have not been established.

Side-effects
Most common adverse reactions are pain, chest pain, back pain, diarrhea, sinusitis, leg cramps, dyspnea, rash, flu syndrome, peripheral edema and lung disorder. Arformoterol can cause serious side effects, including: People with asthma, who take LABA medicines, have an increased risk of death from asthma problems. Patient should get emergency medical care if:
• Breathing problems worsen quickly
• After the use of rescue inhaler medicine, it does not relieve breathing problems

Precautions
Arformoterol nebuliser should not be initiated in acutely deteriorating patients. It should be used with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis, or with sensitivity to sympathomimetic drugs. Life-threatening paradoxical bronchospasm can occur.

Use in Pregnancy and Lactation
Pregnancy Category C. Arformoterol nebuliser solution should be used during pregnancy, only if the potential benefit justifies the potential risk to the fetus. It is not known whether arformoterol is excreted in human milk.

Contraindications
Arformoterol nebuliser solution is contraindicated in patients with a history of hypersensitivity to Arformoterol, racemic formoterol or to any other components of this product. All LABA, including Arformoterol, are contraindicated in patients with asthma without use of a long-term asthma control medication.

Drug Interactions
Other adrenergic drugs may potentiate effect. Xanthine derivatives, steroids, diuretics, or non-potassium sparing diuretics may potentiate hypokalemia or ECG changes. MAO inhibitors, tricyclic antidepressants and drugs that prolong the QTc interval may potentiate effect on the cardiovascular system. Beta-blockers may decrease effectiveness.

Overdosage
As with all inhaled sympathomimetic medications, cardiac arrest and even death may be associated with an overdose of Arformoterol nebuliser solution.

Storage
Arformoterol nebuliser solution should be stored at 2-8°c, protected from light and excessive heat. Do not freeze. Keep out of the reach of children.

Commercial Pack
Aroneb™ Nebuliser Solution: Each box contains 5 ampoules in a blister pack.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
™ Trademark

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