MANCARE PHARMACEUTICALS PVT. LTD.
PLOT NO.59,60,85,86. DHOWALI VILLAGE, VASAI MUNICIPAL IND.ESTATE, VASAI (W), DIST-PALGHAR.

1. Name of the medicinal product :

ASDREX

2. Qualitative and quantitative composition :

3. Each uncoated tablet contains:-
4. Theophylline(anhy.) B.P...150 mg
5. Salbutamol Sulphate B.P Eq.to
6. Salbutamol B.P.... 2 mg

Pharmaceuticals form : Tablets

Pink colour hexagonal embossed “ASDREX” on one side and break line on other side.

Clinical particulars :

1.1Therapeautic indication

Salbutamol&Theophylline Tablets are indicated in adults, adolescents and children aged 2 to 12 years.

1. For the relief of bronchospasm in bronchial asthmas of all types.

2. Chronic bronchitis.

3. Emphysema.

1.1 Posology and method of administaration

Adults:

The usual effective dose is salbutamol 2 mg and theophylline 120 mg: 1 or 2 tab 3-4 times daily. If adequate bronchodilation is not obtained each single dose may be gradually increased to as much as 8mg. However, it has been established that some patients obtain adequate relief with 2mg three or four times daily. In elderly patients or in those known to be unusually sensitive to beta-adrenergic stimulant drugs, it is advisable to initiate treatment with 2mg three or four times per day.

Children:

The following doses should be administered three or four times daily.

Emphysema, Chronic bronchitis, Asthma
Adult: Per tab contains salbutamol 2 mg and theophylline 120 mg: 1 or 2 tab 3-4 times daily.
Child: Child (under 6 years) salbutamol (0.5-1mg) + theophylline (25-50mg) t.i.d/q.i.d. SR (S 4mg+T 300mg) 1 tab b.i.d.

Method of administration

For oral use.

1.2Contraindications

Hypersensitivity, thyrotoxicosis

1.3Special warning and precaution for use

Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment including lung function testing as patients are at risk of severe attacks and even death. Physicians should consider using oral corticosteroid therapy and/or the maximum recommended dose of inhaled corticosteroid in those patients.

Patients should seek medical advice if treatment with salbutamol+theophylline tablets becomes less effective. The dosage or frequency of administration should only be increased on medical advice.

Patients taking salbutamol+theophylline tablets may also be receiving short-acting inhaled bronchodilators to relieve symptoms.

Increasing use of bronchodilators in particular short-acting inhaled $beta_2$-agonists to relieve symptoms indicates deterioration of asthma control. The patient should be instructed to seek medical advice if short acting relief bronchodilator treatment becomes less effective or they need more inhalations than usual.

In this situation patients should be reassessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroids or a course of oral corticosteroid). Severe exacerbations of asthma must be treated in the normal way.

Patients should be warned that if either the usual relief with salbutamol+theophylline tablets is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

Cardiovascular effects may be seen with sympathomimetic drugs, including salbutamol. There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with salbutamol. Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving salbutamol should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

salbutamol+theophylline should be administered cautiously to patients suffering from thyrotoxicosis.

Potentially serious hypokalaemia may result from beta-2 agonist therapy mainly from parenteral and nebulized administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives and steroids. It is recommended that serum potassium levels are monitored in such situations.

In common with other β-adrenoceptor agonists, salbutamol can induce reversible metabolic changes such as increased blood glucose levels. Diabetic patients may be unable to compensate for the increase in blood glucose and the development of ketoacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose – galactose malabsorption should not take this medicine.

salbutamol+theophylline tablets contain carmoisine (E122) which may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

1.4 Interaction with other medicinal products and other forms of interaction

Increased theophylline toxicity with propranolol, cimetidine, erythromycin (7-5 days), quinolone antibiotics. Reduced efficacy with rifampicin, phenobarbitone, phenytoin, carbamazepine, sulfinpyrazone and smoking. Increased risk of hypokalaemia with diuretics.

1.5 Pregnancy and lactation

Pregnancy

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

As with the majority of drugs, there is little published evidence of its safety in the early stages of human pregnancy, but in animal studies there was evidence of some harmful effects on the foetus at very high dose levels.

Breast-feeding

As salbutamol is probably secreted in breast milk its use in nursing mothers requires careful consideration.

It is not known whether salbutamol has a harmful effect on the neonate, and so its use should be restricted to situations where it is felt that the expected benefit to the mother is likely to outweigh any potential risk to the neonate.

Fertility

There is no information on the effects of salbutamol on human fertility. There were no adverse effects on fertility in animals

1.5Effects on ability to drive and use machines

None

1.6Undesirable effects

The frequencies of adverse reactions are ranked according to the following

Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very rare (<1/10,000); Not known (cannot be estimated from the available data).

System organ class	Common	Uncommon	Rare	Very rare	Not known
Immune system disorders				Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse	
Metabolism and nutrition disorders	Hypokalaemia (with high doses)	Hyperglycaemia			Lactic acidosis Metabolic change
Nervous system disorders	Tremor Headache Dizziness			Hyperactivity	
Cardiac disorders	Cardiac arrhythmias* Tachycardia Palpitations	Myocardial ischemia		Peripheral vasodilation	
Respiratory, thoracic and mediastinal disorders		Pulmonary oedema			
Gastrointestinal disorders	Nausea				Vomiting

Musculoskeletal and connective tissue disorders	Muscle cramps			Akathisia	Feeling of muscle tension

1.7Overdose

The most common signs and symptoms of overdose with The most common signs and symptoms of overdose with salbutamol+thephylline are transient beta agonist pharmacologically mediated events, including tachycardia, tremor, hyperactivity and metabolic effects including hypokalaemia (see sections 4.4 and 4.8).

Hypokalaemia may occur following overdose with salbutamol+thephylline. Serum potassium levels should be monitored.

Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

Nausea, vomiting and hyperglycaemia have been reported, predominantly in children and when salbutamol overdose has been taken via the oral route.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

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2. PHARMACOLOGICAL PROPERTIES :

2.1Pharmacodynamics properties

Pharmacotherapeutic group: Selective beta-2-adrenoreceptor agonists, ATC code: R03CC02

Salbutamol is a selective beta-2-adrenergic agonist. At therapeutic doses it acts on the beta-2 adrenoceptors of bronchial muscle providing short acting (4-6 hours) bronchodilation in reversible airways obstruction

1.1 Pharmacokinetic properties

Salbutamol is a selective β2-agonist. It causes bronchial smooth muscle relaxation via the cyclic adenyl cyclase (cAMP) system. Theophylline is a phosphodiesterase inhibitor. It enhances intracellular cAMP conc thereby contributing to bronchial smooth muscle relaxation. It also suppresses airway hyper-response to stimuli. Advantage of this combination is the additive effect allowing reduction of individual doses.

1.2Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

2. PHARMACETICAL PARTICULARS

2.1List of excipients

Maize starch,Sodium starch glycolate,Sodium lauryl sulphate,Magnesium stearate,Talcum,Microcrystalline cellulose,gelatin

2.2 Incompatibilities

Not applicable

2.3 Shelf life

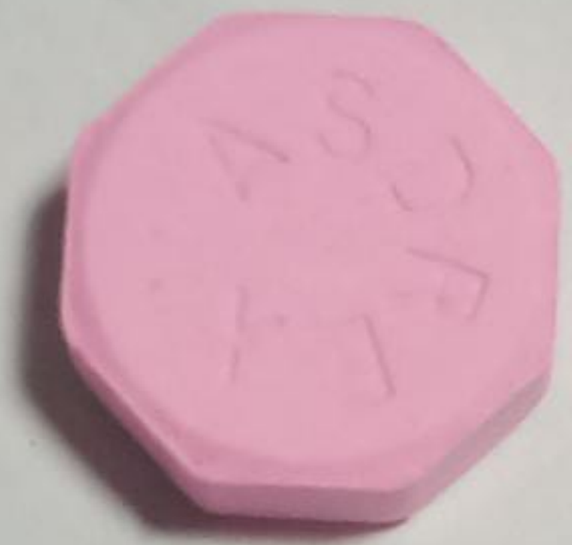
3 Years from the date of manufacturing

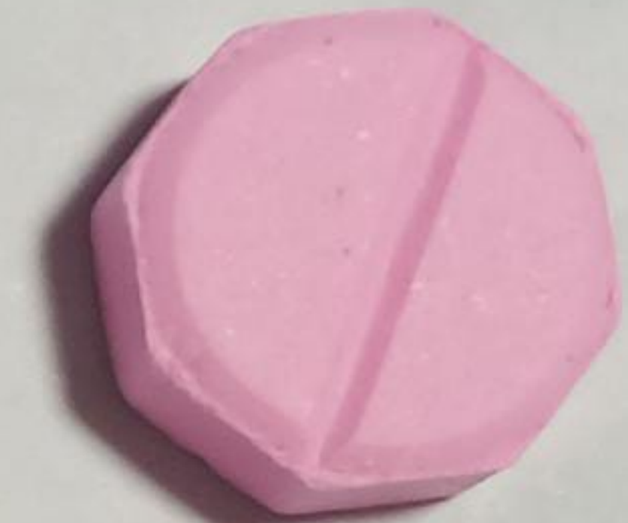
2.4 Special precaution for storage

Store in the original package and protect from moisture

2.5 Nature and contents of container and special and special equipment for use administration or implantation

Tablets are packed in alu pvc blisters of 10 tablets





Mancare

NAFDAC REG.NO.:04-7895

Asdrex

Theophylline and Salbutamol Tablets

10 Tablets in blister

90 (L) x 86(B) 45(H) mm

Prepared On : 02Jan2017

Theophylline and Salbutamol Tablets

Asdrex

10 Tablets in blister

Sole Agent:
Nkoyo Chemists
18, Ukpor Street, Fegge, Onitsha,
Anambra State, Nigeria.

Dosage : As directed by the physician.

Store in a cool, dark & dry place below 30°C.

Keep all medicines out of reach of children.

Mfg. Lic. No. : KD-493
Batch No. :
Mfg Date :
Exp Date :

Theophylline and Salbutamol Tablets

Asdrex

10 Tablets in blister

Manufactured By :
Mancare
PHARMACEUTICALS PVT. LTD.
Plot No. 59, 60, 85, 86, V.M.I.E, Dowali Village,
Vasai (W), Dist. Thane, Maharashtra, India.
E-mail: mancerp@yahoo.co.in

Composition :
Each uncoated tablet contains :

Theophylline (Anhydrous)	B.P.	150 mg
Salbutamol Sulphate equivalent Salbutamol	B.P.	2 mg

Indications :
See leaflet inside.

18906062950019

Indications:
See leaflet inside.

Mfg. Lic. No. : KD-493
Batch No.
Mfg Date
Exp Date
. . . . . .
Printed on the strip

Theophylline and Salbutamol Tablets

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Composition :
Each uncoated tablet contains :
Theophylline (Anhydrous) B.P. 150 mg
Salbutamol Sulphate B.P.
equivalent to Salbutamol 2 mg

Dosage and administration:
Adults.: 1 tablets, 2-3 times daily.
Children : 1/2 -1 tablet, 2-3 times daily, depend on age.
or as directed by the Physician.

Indications:
- Bronchial asthama
- Short-winded which occur in the chronic cough, either acute or chronic bronchitis.

88 (L) x 7(B) 40(H) mm

Prepared On : 02Jan2017

For the use of Registered medical Practitioner or a Hospital or a Laboratory only.

ASDREX (Theophylline & Salbutamol Tablets)

COMPOSITION

Each Uncoated Tablet Contains :
Theophylline(Anhydrous) BP.....150 mg
Salbutamol Sulphate BP
Equivalent to Salbutamol.....2 mg

INDICATIONS

ASDREX (Theophylline & Salbutamol Tablets) are indicated for the treatment of following :
As a bronchodilator for use in asthma, chronic bronchitis, emphysema and other conditions associated with airways obstruction.
Management of chronic obstructive lung disease.

CONTRAINDICATIONS

The only contraindication to theophylline is hypersensitivity to methylxanthines. As most of the population is continuously exposed to these compounds from dietary sources, hypersensitivity is exceedingly rare. Allergy to ethylenediamine in aminophylline has been reported infrequently. Patients showing an allergic response to aminophylline can safely be changed to an anhydrous theophylline formulation.
There are no absolute contraindications for use of salbutamol in the treatment of airways obstruction. Care is required in patients with thyrotoxicosis or ischemic heart disease. Inhaled preparations are unlikely to cause problems unless doses are used.
In the management of premature labor, antepartum hemorrhage or toxemia of pregnancy are contraindications and caution is necessary in the presence of cardiac disease.

DOSAGE

Route : Oral.
Adults : 1 or 2 tablets three to four times a day.
Children under 6 years of age : 0.5 to 1 mg salbutamol and 25 to 50 mg theophylline three times a day.
Above doses should be taken only after consultation with the Physician.

SPECIAL PRECAUTIONS

Diabetes mellitus, may aggravate any preexisting D. M. and D.K.A May require an increased dose of OHA/insulin. BHP, Hypertension, Renal or hepatic disease. Caution in patients with cardiovascular disease so reduced dose. Adverse effects unlikely along with the aerosol.

Cardiac disease, hypoxaemia, hepatic disease, hypertension, neonates. Dosage to be adjusted in elderly and children. Causes toxicity in the nursing infant. Crosses the placental barrier. So give only if clearly indicated in pregnancy.

DRUG INTERACTIONS

The risk of cardiac arrhythmias may increase particularly with halothane.
Metabolism of theophylline is inhibited by cimetidine with a 20% to 40% decrease in theophylline clearance. This interaction has been reported to cause severe theophylline toxicity, including vomiting, seizures and death. Theophylline clearance is not affected by ranitidine.
No interactions are described for salbutamol. But treatment with diuretics may augment the hypokalemia that occurs with large doses of salbutamol. There are no other significant adverse interactions but the effects of salbutamol are inhibited by -antagonists, especially those without 1-receptor selectivity.

STORAGE

Store at a controlled room temperature in a dry place.
Keep this and all drugs out of the reach of children.

PRESENTATION

10 Tablets in a blister in a catch cover. Such 10 catch covers in a carton.

Mfg. Lic. No.: KD-493

Nafdac Reg. No: 04-7895

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Sole Agent:
Nkoyo Chemists
18, Ukpor Street, Fegge, Onitsha,
Anambra State, Nigeria.

110 x 100mm Dated: 02Oct13

Theophylline and Salbutamol tablets

Mfg. Lic. No.: KD-493

ASDREX

Composition:

Each uncoated tablet contains :

Theophylline (Anhydrous) B.P. 150 mg.

Salbutamol Sulphate B.P.

equivalent to Salbutamol 2 mg.

Dosage :As directed by the Physician.

Store in a cool and dry place, protect from light

Keep all medicine out of reach of children

Nafdac Reg.no.: 04-7895

Sole selling Agent :

Mkoyo Chemist

Mfg. by :

Pharmaceuticals Pvt. Ltd.

Dist. Thane, Maharashtra, INDIA.

Mancare

B.No. TTK22

M.D.: 11/2018

E.D.: 10/2021

Theophylline and Salbutamol tab

ASDREX

Composition:

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Salbutamol Sulphate B.P.

equivalent to Salbutamol 2 mg.

Dosage :As directed by the Physician.

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