1.3.1 Summary of Product Characteristic (SmPC)

1.3.1.1 NAME OF THE MEDICINAL PRODUCT

AXCEL SALBUTAMOL SYRUP

1.3.1.2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:
Salbutamol 2mg

1.3.1.3 PHARMACEUTICAL FORM

Syrup

1.3.1.4 CLINICAL PARTICULARS

1.3.1.4.1 Therapeutic indications

For the relief of bronchospasm in asthma, chronic bronchitis and other conditions involving airways obstruction.

1.3.1.4.2 Posology and method of administration

Oral administration : 3 or 4 times daily.
Children 2 - 6 years : 2.5 - 5ml (1-2mg).
6 - 12 years: 5ml (2mg).
Over 13 years: 5 - 10ml (2-4mg).

1.3.1.4.3 Contraindication

Contraindicated in patients with a history of hypersensitivity to any of its component. Salbutamol should not be administered concurrently with beta-blocking drugs, such as propranolol.

1.3.1.4.4 Special warning and precaution for use

<u>Precautions</u>

Caution is required in serious cardiovascular disorder, hyperthyroidism, diabetes mellitus, closed-angle glaucoma and hypertension. Prolonged use in high dosage should be avoided as resistance may develop. Hypokalaemia is known to be a possible side-effect during treatment with salbutamol and this may be enhanced during concomitant therapy of corticosteroid, diuretics or theophylline and serum potassium should be monitored in these circumstances.

Newborn / Premature:
No special precaution stated for administration to newborn and premature infants.

1.3.1.4.5 Interaction with other medicinal products and other forms of interactions

An enhanced hypokalaemia effects may occur during co-administration with diuretics, theophylline, steroids and muscle relaxants.

1.3.1.4.6 Pregnancy and lactation

Unnecessary administration of Salbutamol during the first trimester of pregnancy is undesirable.

1.3.1.4.7 Effects on ability to drive and use machine

None stated.

1.3.1.4.8 Undesirable effects

The most common side effect is fine tremor of skeletal muscle (particularly the hands), palpitations, and muscle cramps. Hyperactivity in children. Slight tachycardia, tenseness, headaches, and peripheral vasodilation have been reported after large doses. Potentially serious hypokalaemia may result from beta-2 agonist therapy.

1.3.1.4.9 Overdose

Symptoms of overdosage generally include; tachycardia, CNS stimulation, tremor, hypokalaemia, and hyperglycemia. Symptomatic treatment of the adverse effects has proved successful.

1.3.1.5 PHARMACOLOGICAL PROPERTIES

1.3.1.5.1 Pharmacodynamic Properties

Salbutamol is a direct-acting sympathomimetic agent with a relatively selective action on beta-2 adrenoceptors. It is used as a bronchodilators in the management of reversible airways obstruction such as asthma and chronic obstructive pulmonary diseases. Salbutamol also decrease uterine contractility and may be given in delaying premature labour.

1.3.1.5.2 Pharmacokinetic Properties

Salbutamol is readily absorbed from the gastrointestinal tract. It is subject to first-pass metabolism in the liver and possibly in the gut wall; the main metabolite is an inactive sulfate conjugate. Salbutamol is rapidly excreted in the urine as metabolites and unchanged drug; there is some excretion in the faeces. Salbutamol does not appear to be metabolised in the lung, therefore its ultimate metabolism and excretion after inhalation depends upon the delivery method used, which determines the proportion of inhaled Salbutamol relative to the proportion inadvertently swallowed. It has been suggested that most of an inhaled dose is

swallowed and absorbed from the gut.
The plasma half-life of Salbutamol has been estimated to range from 4 to 6 hours.

1.3.1.5.3 Preclinical safety Data
None stated

1.3.1.6 PHARMACEUTICAL PARTICULARS

1.3.1.6.1 List of excipients
Hydroxypropyl Cellulose, Citric Acid Anhydrous, Sodium Citrate Dihydrate, Sodium Benzoate, Sodium Chloride, Saccharin Sodium, Mixed Fruit Flavour and Purified Water

1.3.1.6.2 Incompatibilities
None stated

1.3.1.6.3 Shelf life
3 years

1.3.1.6.4 Special precautions for storage
Keep container well closed. Store below 30°C. Protect from light.

1.3.1.6.5 Nature and contents of container
Available in 60ml & 100ml PET bottle.

1.3.1.7 MARKETING AUTHORIZATION HOLDER
Kotra Pharma (M) Sdn. Bhd.
1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.
Tel : +606-3362222
Fax :+606-3366122

1.3.1.8 MARKETING AUTHORIZATION NUMBER
Malaysia: MAL19992588AZ

1.3.1.9 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION
30th October 1999

1.3.1.10 DATE OF REVISION OF THE TEXT
30 January 2023