1.3.1 Summary of Product Characteristic (SmPC)

1.3.1.1 NAME OF THE MEDICINAL PRODUCT

AXCEL CETIRIZINE SYRUP 5MG/5ML

1.3.1.2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains
Cetirizine Dihydrochloride 5mg

1.3.1.3 PHARMACEUTICAL FORM

Syrup

1.3.1.4 CLINICAL PARTICULARS

1.3.1.4.1 Therapeutic indications

For symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticaria of allergic origin.

1.3.1.4.2 Posology and method of administration

For oral administrations.
Adult : 10ml (10mg) once daily.
Children above 6 years : 5ml (5mg) twice daily or 10ml (10mg) once daily.
Children 2-6 years : 2.5ml (2.5mg) twice daily or 5ml (5mg) once daily.
Children 1-2 years : 2.5ml (2.5mg) twice daily.
In patients with renal insufficiency, dosage should be reduced to half the daily dose.

1.3.1.4.3 Contraindication

Contraindicated in those patients with known hypersensitivity to any of its ingredients. Cetirizine should not be administered to pregnant women during the first 3 month of pregnancy and women who are breastfeeding

1.3.1.4.4 Special warning and precaution for use

Precautions

Activities Requiring Mental Alertness: In clinical trials, the occurrence of somnolence has been reported in some patients taking cetirizine; due caution should therefore be exercised when driving car or operating potentially dangerous machinery. Concurrent use of cetirizine with alcohol or other CNS depressants should be avoided because additional reductions in alertness and additional impairment of CNS performance may occur.

Carcinogenesis, Mutagenesis and Impairment of Fertility: In a 2-year carcinogenicity study in rats, cetirizine was not carcinogenic at dietary doses up to 20mg/kg. In a 2-year carcinogenicity study in mice, cetirizine caused an increased incidence of benign liver tumors in males at a dietary dose of 16mg/kg. No increase in the incidence of liver tumors was observed in mice at a dietary dose of 4 mg/kg. The clinical significance of these findings during long-term use of cetirizine is not known. Cetirizine was not mutagenic in the Ames test, and not clastogenic in the human lymphocyte assay, the mouse lymphoma assay, and *in vivo* micronucleus test in rats. In a fertility and general reproductive performance study in mice, cetirizine did not impair fertility at an oral dose of 64 mg/kg.

Pediatric Under 2 Years Old: The safety and effectiveness of cetirizine in pediatric patients under the age of 2 years have not yet been established unless when necessary it should be used under supervision of physician.

Pregnancy and Lactation: Safe uses of cetirizine during pregnancy and lactation have not been established, therefore it is not recommended.

1.3.1.4.5 Interaction with other medicinal products and other forms of interactions

To date there are no known interactions with other drugs. Nevertheless, Axcel Cetirizine should be used with caution if sedatives are also being taken.

1.3.1.4.6 Pregnancy and lactation

Pregnancy and Lactation: Safe uses of cetirizine during pregnancy and lactation have not been established, therefore it is not recommended.

1.3.1.4.7 Effects on ability to drive and use machine

May cause drowsiness. Avoid driving or operating machinery.

1.3.1.4.8 Undesirable effects

There have been occasional reports of mild and transient subjective side-effects such as, headache, dizziness, drowsiness, agitation, dry mouth and gastrointestinal discomfort. In objective tests of psychomotor function, the incidence of sedation with cetirizine was similar to that of placebo. Occasionally symptoms of hypersensitivity have been reported.

1.3.1.4.9 Overdose

In initial observation, overdosage of cetirizine may cause restlessness and irritability, followed by drowsiness. Should overdose occur, treatment should be symptomatic or supportive, taking into account any concomitantly ingested medications. In the case of massive overdosage, gastric lavage should be performed as soon as possible. Usual supportive measures should be provided and routine observation carried out regularly.

1.3.1.5 PHARMACOLOGICAL PROPERTIES

1.3.1.5.1 Pharmacodynamic Properties

Cetirizine is an antihistamine as its principal effects are mediated via selective inhibition of peripheral H1 receptors.

1.3.1.5.2 Pharmacokinetic Properties

Cetirizine is rapidly absorbed from the gastrointestinal tract after oral administration, peak plasma concentrations being attained in about 1 hour. It is highly bound to plasma proteins and has an elimination half-life of about 11 hours. Cetirizine has been detected in breast milk. It is excreted primarily in the urine mainly as unchanged drug.

1.3.1.5.3 Preclinical safety Data

None stated

1.3.1.6 PHARMACEUTICAL PARTICULARS

1.3.1.6.1 List of excipients

Sodium Citrate, Sodium Saccharin, Methylparaben, Propylene Glycol, Sorbitol, Glycerin, Refined Sugar, Banana 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: MAL20040893AZ

1.3.1.9 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

29 May 2009

1.3.1.10 DATE OF REVISION OF THE TEXT

30 January 2023