# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Brown & Burk Allergy relief 8mg Capsules, hard

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 8 mg acrivastine.

Excipient(s) with known effect: Each capsule contains 173.0 mg lactose monohydrate.
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsule, hard

White opaque cap and white opaque body, size "3" hard gelatin capsule shells filled with white to off white colored granular powder. Approximately 16 mm in length.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Acrivastine is indicated for symptomatic relief of allergic rhinitis, including hay fever.
Acrivastine is also indicated for chronic idiopathic urticaria.

### 4.2 Posology and method of administration

**Posology**

**Adults and adolescents 12 years – 65 years:**
One 8 mg capsule, as necessary up to three times a day.

**Use in the Elderly (over 65):**
As yet, no specific studies have been carried out in the elderly. Until further information is available, Acrivastine should not be given to elderly patients.

**Paediatric population**
The safety and efficacy of Brown & Burk Allergy relief in children under 12 years of age has not yet been established.

**Renal dysfunction**
This product is contraindicated in patients with severe renal impairment.

**Method of Administration**
For oral use.

### 4.3 Contraindications

Acrivastine is contraindicated in individuals with known hypersensitivity to acrivastine, triprolidine or to any of the excipients listed in section 6.1. Renal excretion is the principal route of elimination of acrivastine. Until specific studies have been carried out acrivastine should not be given to patients with significant renal impairment.

## 4.4 Special warnings and precautions for use

Concomitant administration of acrivastine with CNS depressants, including alcohol, sedatives, and tranquilizers, may produce additional impairment in mental alertness in some individuals.
Patients with renal impairment should consult with a physician before use.
This product may cause drowsiness (see section 4.8).
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

## 4.5 Interaction with other medicinal products and other forms of interaction

It is usual to advise patients not to undertake tasks requiring mental alertness whilst under the influence of alcohol and other CNS depressants. Concomitant administration of acrivastine may, in some individuals, produce additional impairment.

There are no data to demonstrate an interaction between acrivastine and ketoconazole, erythromycin or grapefruit juice. However, due to known interactions between these compounds and other non-sedating antihistamines, caution is advised.

## 4.6 Fertility, pregnancy and lactation

No information is available on the effects of administration of acrivastine during human pregnancy or lactation. Acrivastine, like most medicines, should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs any possible risk to the developing foetus/nursing infant.

**Fertility**
Systemic administration of acrivastine in animal reproductive studies did not produce embryotoxic or teratogenic effects and did not impair fertility.

**Pregnancy**
There are no adequate and well-controlled studies in pregnant women.

**Lactation**
There is no information on the levels of acrivastine which may appear in human breast milk after administration of acrivastine.

## 4.7 Effects on ability to drive and use machines

Acrivastine may cause dizziness and somnolence. As there is individual variation in response to all medication, it is sensible to caution all patients about engaging in activities requiring mental alertness, such as driving a car or operating machinery, until patients are familiar with their own response to the drug.

## 4.8 Undesirable effects

The safety of acrivastine is based on available data from 10 placebo-controlled clinical trials with a total population of 373 treated subjects, where adverse events reported by ≥1% were assessed. Additionally, adverse drug reactions (ADRs) identified during post-marketing experience are included.

The frequencies are provided according to the following convention: Very common ≥1/10, Common ≥1/100 and < 1/10, Uncommon ≥1/1,000 and <1/100, Rare ≥1/10,000 and <1/1,000, Very rare <1/10,000, Not known (cannot be estimated from the available data).

ADRs identified are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available or 2) when incidence is unavailable, frequency category is listed as Not known.

| *Adverse Drug Reactions Identified During Post-Marketing Experience with Acrivastine. Frequency Category Estimated from Clinical Trials or Epidemiology Studies* | |
|---|---|
| SOC | |
| *Frequency category* | *Adverse Event Preferred term* |
| ***Immune System Disorders*** | |
| *Not known* | *Hypersensitivity (including Dyspnoea and face swelling)* |
| ***Nervous system disorders*** | |
| *Very common* | *Somnolence* |
| *Common* | *Dizziness* |
| ***Gastrointestinal Disorders*** | |
| *Common* | *Dry Mouth* |
| ***Skin and Subcutaneous Tissue Disorders*** | |
| *Not Known* | *Rash* |

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

### 4.9 Overdose

**Symptoms**
Drowsiness, restlessness, hyperactivity and tachycardia have been reported in overdose.
When the recommended therapeutic dose has been exceeded, acrivastine has been found to impair the ability to drive. This effect is related to the amount of acrivastine taken beyond the recommended maximum daily dosage.
**Management**
Appropriate supportive therapy, including activated charcoal should be initiated if indicated.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antihistamines for system use.

ATC code: R06AX18

Acrivastine provides symptomatic relief in conditions believed to depend wholly or partly upon the triggered release of histamine.

It is a potent competitive histamine H1 receptor antagonist chemically related to triprolidine. Acrivastine lacks significant anti-cholinergic effects, and has a low potential to penetrate the central nervous system.

After oral administration of a single dose of 8 mg acrivastine to adults, the onset of actions, as determined by the ability to antagonise histamine induced weals and flares in the skin, is 15 minutes. Peak effects occur at 2 hours, and although activity declines slowly thereafter, significant inhibition of histamine induced weals and flares still occur 8 hours after dose.

In patients, relief from the symptoms of allergic rhinitis is apparent within 1 hour after the systemic administration of the drug.

### 5.2 Pharmacokinetic properties

Acrivastine is well absorbed from the gut. In healthy adult volunteers, the peak plasma concentration (Cmax) is approximately 150 NG/ML, occurring at about 1.5 hours (Tmax) after the administration of 8 mg acrivastine. The plasma half-life is approximately 1.5 hours. In multiple dose studies over 6 days, no accumulation of acrivastine was observed. Acrivastine is approximately 50% protein bound, principally to albumin. Acrivastine is largely excreted unchanged, in the urine. Renal excretion is the principal route of elimination of acrivastine.

### 5.3 Preclinical 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.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate
Sodium starch glycolate
Magnesium stearate
Titanium dioxide
Gelatin

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years

### 6.4 Special precautions for storage

Do not store above 30°C. Store in the original package.

### 6.5 Nature and contents of container

Alu-Alu blister pack and Alu-PVC/ACLAR blister pack
Blister: 9, 12, 21, 24 capsules

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements

## 7 MARKETING AUTHORISATION HOLDER

Brown & Burk UK Ltd
5, Marryat Close,

Hounslow West,

Middlesex TW4 5DQ

United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 25298/0231

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/11/2018

## 10 DATE OF REVISION OF THE TEXT

30/07/2020