SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

BENADRYL Allergy Relief

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benadryl Allergy Relief contains 8 mg Acrivastine per capsule.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

BENADRYL Allergy Relief is indicated for the symptomatic relief of allergic rhinitis, including hayfever. BENADRYL Allergy Relief is also indicated for chronic idiopathic urticaria.

4.2 Posology and method of administration

Posology

Adults and children 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, Benadryl Allergy Relief should not be given to elderly patients.

Method of Administration

For oral use.
4.3 Contraindications

Benadryl Allergy Relief is contraindicated in individuals with known hypersensitivity to acrivastine, tripolidine 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 Benadryl Allergy Relief should not be given to patients with significant renal impairment.

4.4. Special Warnings and Special Precautions for Use

The following statements will appear on the pack:

Do not store above 30°C. Store in the original package. Keep out of the reach and sight of children.

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 Benadryl Allergy Relief 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.

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

There is no information on the levels of acrivastine which may appear in human breast milk after administration of Benadryl Allergy Relief.

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 $\geq 1\%$ 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 $\geq 1/10$, Common $\geq 1/100$ and $< 1/10$, Uncommon $\geq 1/1,000$ and $< 1/100$, Rare $\geq 1/10,000$ and $< 1/1,000$, Very rare $< 1/10,000$, Not known (cannot be estimated from the available data).

<table>
<thead>
<tr>
<th>SOC</th>
<th>Frequency category</th>
<th>Adverse Event Preferred term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune System Disorders</td>
<td>Not known</td>
<td>Hypersensitivity (including Dyspnoea and Face swelling)</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td>Very common</td>
<td>Somnolence</td>
</tr>
<tr>
<td></td>
<td>Not known</td>
<td>Dizziness</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td>Common</td>
<td>Dry mouth</td>
</tr>
<tr>
<td>Skin and Subcutaneous Tissue Disorders</td>
<td>Not known</td>
<td>Rash</td>
</tr>
</tbody>
</table>

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

4.9. Overdose
There is no experience of overdosage with BENADRYL Allergy Relief. Appropriate supportive therapy, including gastric lavage 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 antagonist which 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. Renal excretion is the principal route of elimination of acrivastine.

### 5.3. Pre-clinical 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
Sodium starch glycollate
Magnesium stearate
The capsule shell contains the following constituents:
Gelatin
Purified water
Titanium Dioxide

6.2. Incompatibilities

None known

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

PVC/aluminium foil blister packs – 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

McNeil Products Limited  
Foundation Park  
Roxborough Way  
Maidenhead  
Berkshire  
SL6 3UG  
UK

8. MARKETING AUTHORISATION NUMBER(S)

PL 15513/0128

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

08/03/2005

10 DATE OF REVISION OF THE TEXT

17/02/2017