

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.

Excipient with known effect:
Lactose 206.80 mg per capsule

Sodium (in sodium starch glycollate) 1.90mg 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 - 65 years:

One 8 mg capsule, as necessary up to three times a day.

Elderly

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.

Paediatric population

The safety and efficacy of Benadryl 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

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 Benadryl Allergy Relief should not be given to patients with severe 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.

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

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

Acrivastine 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 or 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 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).

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.

<i>Adverse Drug Reactions Identified During Post-Marketing Experience with Acrivastine. Frequency Category Estimated from Clinical Trials or Epidemiology Studies</i>	
SOC	
<i>Frequency category</i>	<i>Adverse Drug Reaction (Preferred term)</i>

<i>Immune System Disorders</i>	
<i>Not known</i>	<i>Hypersensitivity (including Dyspnoea and Face swelling)</i>
<i>Nervous System Disorders</i>	
<i>Very common</i>	<i>Somnolence</i>
<i>Common</i>	<i>Dizziness</i>
<i>Gastrointestinal Disorders</i>	
<i>Common</i>	<i>Dry mouth</i>
<i>Skin and Subcutaneous Tissue Disorders</i>	
<i>Not known</i>	<i>Rash</i>

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 systemic use.
ATC code: R06AX18

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

Acrivastine is a competitive 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 (C_{max}) is approximately 150 NG/ML, occurring at about 1.5 hours (T_{max}) 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

Sodium starch glycollate

Magnesium stearate

The capsule shell contains the following constituents:

Gelatin

Purified water

Titanium Dioxide

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

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
50 – 100 Holmers Farm Way,
High Wycombe,
Buckinghamshire, HP12 4EG,
UK

8. MARKETING AUTHORISATION NUMBER(S)

PL 15513/0128

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/10/2025

10 DATE OF REVISION OF THE TEXT

16/10/2025