

# ALUSTAL House Dust Mites Extract®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using ALUSTAL House Dust Mites Extract?

ALUSTAL House Dust Mites Extract contains the active ingredients American (*D. farinae*) and European (*D. pteronyssinus*) House dust mite allergen extracts. ALUSTAL House Dust Mites Extract is used in the treatment of seasonal or perennial rhinitis, conjunctivitis and rhino-conjunctivitis with or without associated asthma.

For more information, see Section [1. Why am I using ALUSTAL House Dust Mites Extract?](#) in the full CMI.

### 2. What should I know before I use ALUSTAL House Dust Mites Extract?

Do not use if you have ever had an allergic reaction to ALUSTAL House Dust Mites Extract or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ALUSTAL House Dust Mites Extract?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ALUSTAL House Dust Mites Extract and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ALUSTAL House Dust Mites Extract?

- The therapy consists of an initiation phase with dose escalation (weekly injections) and a maintenance phase with a constant dose (monthly injections)
- Alustal HDM is given as a subcutaneous treatment

More instructions can be found in Section [4. How do I use ALUSTAL House Dust Mites Extract?](#) in the full CMI.

### 5. What should I know while using ALUSTAL House Dust Mites Extract?

<b>Things you should do</b>	Remind any doctor, dentist or pharmacist you visit that you are using ALUSTAL House Dust Mites Extract. The use of ALUSTAL HDM should be supervised by a physician experienced in allergology and allergen immunotherapy (AIT) and The patient should remain under medical supervision for 30 minutes after each injection.
<b>Things you should not do</b>	It is recommended to avoid any activity that may increase blood flow through the injection site such as strenuous exercise, hot baths, sauna, application of local heat or rubbing, for the remainder of the day.
<b>Driving or using machines</b>	No effect on the capacity to drive or use machines has been observed
<b>Drinking alcohol</b>	Drinking alcohol are not recommended on the day of the injection
<b>Looking after your medicine</b>	Alustal HDM is usually stored in the doctor's surgery. However, if you need to store it, keep it in the refrigerator (between 2° to 8°C). Do not freeze.

For more information, see Section [5. What should I know while using ALUSTAL House Dust Mites Extract?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects: allergic reactions at the application site and/or symptoms which may affect the whole body.

These reactions can occur at the beginning of therapy, or later during treatment.

Serious side effects: allergic symptoms that affect the whole body (i.e. rapid onset of an illness associated with involvement of the skin and/or mucosa, breathing difficulty, abdominal pain or symptoms related to a drop in blood pressure).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ALUSTAL House Dust Mites Extract<sup>®</sup> (al-u-stal)

**Active ingredient(s):** American (*D. farinae*) and European (*D. pteronyssinus*) House dust mite allergen extracts

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ALUSTAL House Dust Mites Extract. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using [medicine name].**

**Where to find information in this leaflet:**

- [1. Why am I using \[medicine name\]?](#)
- [2. What should I know before I use \[medicine name\]?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use \[medicine name\]?](#)
- [5. What should I know while using \[medicine name\]?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ALUSTAL House Dust Mites Extract?

ALUSTAL House Dust Mites Extract contains the active ingredient American (*D. farinae*) and European (*D. pteronyssinus*) House dust mite allergen extracts. ALUSTAL House Dust Mites Extract belongs to a group of medicines called anti-allergy preparations and is given as a subcutaneous treatment, and this is often referred to as AIT (allergen immunotherapy)

**ALUSTAL House Dust Mites Extract is used in the treatment of seasonal or perennial rhinitis, conjunctivitis and rhino-conjunctivitis with or without associated asthma.**

ALUSTAL House Dust Mites Extract works by slowly increasing your tolerance to specific allergens and decreases the severity of your allergic reactions.

The injection is specifically designed according to individual patient needs.

Alustal House Dust Mites Extract helps to increase your tolerance to allergens and may decrease the severity of your allergic reactions.

## 2. What should I know before I use ALUSTAL House Dust Mites Extract?

### Warnings

**Do not use ALUSTAL House Dust Mites Extract if:**

- if you are hypersensitive (allergic) to any of the other ingredients of Alustal House Dust Mites Extract
- if you suffer from an ongoing disease that attacks your own immune system or if you are taking medicines which affect your immune system
- if your immune system is very weakened
- if you are currently suffering from a malignant disease (for example cancer)
- if you suffer from severe or uncontrolled asthma, or if you have a poor lung function (as assessed by your doctor), or if you have had a significant worsening of your asthma within the last 3 months (as assessed by your doctor)
- for treatment initiation, if you are pregnant or think you may be pregnant
- if you suffer from renal insufficiency

### Check with your doctor if you:

- have symptoms of allergy which should be stabilised with appropriate symptomatic therapy, if necessary, before starting treatment”
- have personal or familial medical history which could affect your immune system, any disease you recently had, or if your allergic disease recently worsened

If over the course of the treatment you experience the following symptoms, contact a doctor immediately:

- allergic symptoms that affect the whole body (i.e. intensive itching in palms of hand and soles of the feet, hives, swelling of the mouth or of the throat leading to difficulty in swallowing, in breathing, or voice modification, nausea, vomiting)
- your asthma deteriorates suddenly. Your doctor will reconsider the continuation of ALUSTAL House Dust Mites Extract

As systemic allergic reactions (that could be life-threatening when very severe) might occur, the treatment is performed in presence of or by a physician with experience in allergen immunotherapy and in conditions allowing immediate emergency treatment if necessary (including ephedrine/ adrenaline).

Your doctor will decide if the risk from allergen exposure is greater than the risk of exacerbating the autoimmune disease.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

There is no experience with the use of ALUSTAL House Dust Mites Extract during pregnancy or breast-feeding. Therefore, you should not start immunotherapy if you are pregnant, unless this is considered necessary by your doctor.

If you become pregnant or if you start breastfeeding, while taking ALUSTAL HDM, speak to your doctor about whether it is appropriate for you to continue the treatment.

### **Important information about some of the ingredients of Alustal House Dust Mites Extract**

ALUSTAL House Dust Mites Extract contains sodium chloride and aluminium hydroxide

ALUSTAL House Dust Mites Extract contains 4 mg of aluminium (5 mL vial). You should take this into account if you are taking other medicines containing aluminium.

## 3. WHAT IF I AM TAKING OTHER MEDICINES?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

### **Some medicines may interfere with ALUSTAL House Dust Mites Extract and affect how it works.**

Before starting treatment tell your doctor:

- if you are taking any allergy medicines.
- if you are taking medicine(s) containing aluminium(eg:anti-acid drugs). Risk of accumulation of aluminium into tissues (central nervous system, bones) should be kept in mind, especially in case of renal insufficiency.
- if you recently had or plan to have a vaccination.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALUSTAL House Dust Mites Extract.**

## 4. How do I use ALUSTAL House Dust Mites Extract?

### **How much to take / use**

- Your treatment schedule will include Initial treatment and maintenance treatment:
- Your doctor will tell you how much medicine will be given during each treatment.
- Follow the instructions provided and use Alustal House dust mite until your doctor tells you to stop.

## When to take / use ALUSTAL House Dust Mites Extract

Normally initial treatment will be weekly injections lasting for approximately 14 weeks. This will be of the allergen that you are allergic to in increasing concentrations up to the highest dose you can tolerate.

Maintenance treatment will be of monthly injections of the highest concentration that you can tolerate comfortably.

Where two different courses are being given concurrently, the two extracts must never be mixed within the same syringe.

Injections of the two extracts may be given at the same visit, but in separate arms. However, mixtures of allergens may have been prescribed for you by your doctor, these will already be mixed and given in a single injection. But the doctor may need to give more than one injection if you are being treated for more than one allergy.

Treatment or maintenance should continue for 3 to 5 years depending on the severity of the allergy and response to treatment.

It is essential that you remain under medical supervision for at least 30 minutes after each injection of House Dust Mites Extract.

In the hours following the administration of this product, contact a doctor immediately if you get any symptoms like:

- severe itching of the palms of the hands or soles of the feet,
- hives,
- swelling of the mouth and/or mucous membranes, a choking sensation, breathing discomfort, difficulty swallowing or a change in your voice

Do not stop taking ALUSTAL HDM unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor.

Use in children

Allergen immunotherapy is not recommended before the age of 5 years old.

### **If you forget to use ALUSTAL House Dust Mites Extract**

If you miss a dose, talk to your doctor and arrange another visit as soon as possible.

### **If you use too much ALUSTAL House Dust Mites Extract**

Overdose is unlikely because your doctor will give you this medicine by injection.

If you think that you have used too much Alustal House Dust Mites Extract, you may need urgent medical attention. Symptoms such as:

- generalized rash,
- itching,
- swelling of lips, face, tongue or other parts of the body,
- shortness of breath, respiratory or cardiac distress (including asthma),

- seizure

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using ALUSTAL House Dust Mites Extract?

### Things you should do

**Call your doctor straight away if:**

- you had allergic symptoms that affect the whole body following previous allergen immunotherapy treatment.
- your asthma has worsened or if you experienced a recent asthma attack that is confirmed clinically and/or by expiratory peak flow measurement. Your doctor will reconsider the continuation of ALUSTAL House Dust Mites Extract. If you have asthma you should continue to use your regular asthma medication according to the instructions of your doctor
- you have a cardiovascular disease
- you are taking a beta blocker (i.e., a class of drugs often prescribed for heart conditions and high blood pressure but also present in some eye drops and ointments), as this drug may decrease the effectiveness of adrenaline used to treat serious systemic reactions.
- you are taking certain medicines against depression (tricyclic antidepressants or monoamine oxidase inhibitors (MAOIs) or parkinson's disease (COMT inhibitors)). Risk of undesirable effects of adrenaline (used in case of severe allergic reactions) could be increased with possible fatal consequences
- you experience large local reactions at the injection site such as: itching, redness and/or swelling

Remind any doctor, dentist or pharmacist you visit that you are using ALUSTAL House Dust Mites Extract.

### Things you should not do

It is recommended to avoid any activity that may increase blood flow through the injection site such as strenuous exercise, hot baths, sauna, application of local heat or rubbing, for the remainder of the day.

### Tell your doctor if you feel the treatment is not helping your condition.

Keep all of your appointments with your doctor so that your progress can be checked. It is important to have your follow-up doses of Alustal House Dust Mites Extract at the

appropriate times to make sure the immunotherapy has the best chance of working.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how ALUSTAL House Dust Mites Extract affects you.**

ALUSTAL House Dust Mites Extract is presumed to have no or negligible influence on the ability to drive and use machines.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

As Alustal House Dust Mites Extract contains aluminium, heavy meals and drinking alcohol are not recommended on the day of the injection.

### Looking after your medicine

Alustal House Dust Mites Extract is usually stored in the doctor's surgery. However, if you need to store it:

- Keep it in the original pack
- Keep it in the refrigerator (between 2° to 8°C). Do not freeze.

**Keep it where young children cannot reach it.**

### When to discard your medicine

**Your doctor will dispose of any unfinished medicine if the vials have passed their expiry date.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

Alustal allergen extracts helps most people with allergies but they may have unwanted side effects in a few people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

During treatment with ALUSTAL House Dust Mites Extract you will be exposed to substances that may cause allergic reactions at the application site and/or symptoms which may affect the whole body.

These reactions can occur at the beginning of therapy, or later during treatment.

Stop taking ALUSTAL House Dust Mites Extract and contact your doctor immediately if you develop or notice:

- severe allergic reaction or anaphylactic shock. Anaphylactic shock is a severe allergic reaction with rapid onset of symptoms which affect the whole body such as intensive itching, or rash, abdominal pain, or symptoms related to drop in blood pressure such as feeling dizzy, malaise, vertigo, loss of consciousness, rapid and irregular heartbeat, pallor.

Tolerance may vary over time depending on your condition and environment.  
Your doctor can prescribe you with pre-treatment with allergy medicines reducing frequency and severity of the adverse reaction

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Eye</b></p> <ul style="list-style-type: none"> <li>conjunctivitis (redness and irritation of the eyes)</li> <li>eye disorders (swelling, watery eyes, periorbital swelling, redness, eyelid swelling)</li> </ul> <p><b>Respiratory</b></p> <ul style="list-style-type: none"> <li>rhinitis (stuffy nose, runny nose, sneezing, itchy nose)</li> <li>asthma</li> <li>cough</li> <li>bronchitis</li> <li>sinusitis</li> <li>throat irritation</li> </ul> <p><b>Gastrointestinal</b></p> <ul style="list-style-type: none"> <li>abdominal pain</li> <li>diarrhoea</li> <li>nausea</li> <li>vomiting</li> </ul> <p><b>Nervous system</b></p> <ul style="list-style-type: none"> <li>headache</li> <li>sensitivity</li> <li>anxiety</li> <li>prickling (paraesthesia)</li> <li>somnolence (drowsiness)</li> <li>tremor</li> </ul> <p><b>Musculoskeletal System</b></p> <ul style="list-style-type: none"> <li>joint pain</li> <li>joint swelling</li> <li>muscle pain</li> <li>pain in extremities</li> </ul> <p><b>Skin and Injection Site Reactions</b></p> <ul style="list-style-type: none"> <li>Hives</li> <li>Redness of the skin</li> <li>Pruritus (itchiness)</li> <li>Ear pruritus</li> <li>Eczema</li> <li>Flushing</li> <li>Injection site reactions (bruising, discoloration, blood bump, bleeding, mass, small lump, papule, rash, hives, vesicles)</li> <li>Skin swelling</li> <li>Injection site inflammation (swelling, redness, pain)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>Injection site hardening</li> </ul> <p><b>General body organs</b></p> <ul style="list-style-type: none"> <li>feeling of weakness</li> <li>malaise</li> <li>fever</li> <li>chest pain</li> <li>sensation of foreign body</li> <li>swelling in extremities</li> <li>general swelling</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>Immune System</b></p> <ul style="list-style-type: none"> <li>Severe allergic reaction or anaphylactic shock</li> </ul> <p><b>Throat</b></p> <ul style="list-style-type: none"> <li>swelling in the back of the throat</li> <li>throat swelling</li> <li>throat tightening</li> </ul> <p><b>Respiratory</b></p> <ul style="list-style-type: none"> <li>difficulty breathing or shortness of breath</li> <li>breathing difficulty due to narrowed airways (bronchospasm)</li> <li>wheezing</li> <li>bronchial obstruction</li> <li>hoarse voice</li> </ul> <p><b>Nervous system</b></p> <ul style="list-style-type: none"> <li>loss of consciousness</li> </ul> <p><b>Gastrointestinal</b></p> <ul style="list-style-type: none"> <li>difficulty swallowing</li> </ul> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>rapid swelling under the skin (angioedema)</li> <li>face swelling</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

## What House Dust Mites Extract contains

<b>Active ingredient (main ingredient)</b>	<i>Dermatophagoides pteronyssinus</i> and <i>Dermatophagoides farinae</i> body extracts
<b>Other ingredients (inactive ingredients)</b>	Aluminum hydroxide hydrate, sodium chloride, phenol, mannitol and water for injections.
<b>Potential allergens</b>	

**Do not take this medicine if you are allergic to any of these ingredients.**

## What ALUSTAL House Dust Mites Extract looks like

Initial treatment set: 3 vials, each vial containing either 0.1, 1.0 and 10.0 IR/mL

Maintenance: a single vial containing 10.0 IR/mL

Available Concentrations: Vial containing 5 mL of suspension.

Yellow cap: 0.1 IR/mL

Green cap: 1.0 IR/mL

Blue cap: 10.0 IR/mL

The ARTG details for the Alustal HDM are:

ALUSTAL HOUSE DUST MITES EXTRACT INITIAL TREATMENT european house dust mite and american house dust mite injection suspension vial composite pack – AUST R 132725

ALUSTAL HOUSE DUST MITES EXTRACT MAINTENANCE european house dust mite and american house dust mite 10.0 IR/mL injection suspension vial – AUST R 132680

## Who distributes ALUSTAL House Dust Mites Extract

Sponsor in Australia:

Stallergenes Australia Pty Ltd

Suite 2408

4 Daydream St.,

Warriewood, NSW 2102

Ph: 1800 824 166

Sponsor in New Zealand:

Stallergenes Greer New Zealand Limited

Level 1, 24 Manukau Road,

Epsom, Auckland 1023

New Zealand

Ph: 0800 824 166

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