1 PRODUCT NAME

Albey Venom Powder for Injection

Albey Bee Venom 550 µg (*Apis mellifera*)

Albey Yellow Jacket Venom 550 µg (*Vespula spp. venom*)

Albey paper Wasp Venom 550 µg (*Polistes spp.venom*)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The freeze dried honey bee venom consists of 550 µg protein
The freeze dried wasp venom consists of 550 µg protein / vial
The freeze dried yellow jacket consists of 550 µg protein / vial

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Hymenoptera venom allergenic extracts. Freeze dried venom of honey bees (*Apis mellifera*), venom protein of wasps (*Polistes sp.)* and venom protein of yellow jacket (*Vespula sp.),* commonly known as the European Wasp. Final containers of freeze dried venom products are sealed under vacuum. This will result in the diluting fluid being forcibly drawn into the sealed vial when the syringe needle penetrates the seal during reconstitution (see 4.4 Special warnings and precautions for use).

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Albey Honey Bee Venom, Wasp Venom and Yellow Jacket Venom are indicated for the diagnosis and treatment of hypersensitivity to honey bee venom, wasp venom and yellow jacket venom respectively.

4.2 Dose and method of administration

These freeze dried products should be dissolved in Albumin-Saline to a concentration of 100 µg/mL. Dilutions of this concentration should be made only with Albumin-Saline (see 4.4 Special warnings and precautions for use and 4.2 Dosage and method of administration for details of dilutions for diagnosis and treatment).

Skin testing

Prick testing should be done before intradermal testing. In both the prick and intradermal tests, a negative control test with diluent alone must be performed.

The flexor surface of the forearm is the usual location for skin testing. It is important that a separate sterile syringe and needle be used for each extract and each patient.

Prick tests are accomplished using a solution of 1 µg/mL venom protein. See instructions on reconstituting and diluting the venom in section 6.6 Special precautions for handling.

One drop of the 1 µg/mL venom protein solution is applied to the forearm, and the skin is pricked through the surface of the drop with a sterile 27 gauge needle. The prick is superficial and should not draw blood.

For prick tests, a positive reaction (reaction greater than diluent control) at the 1 µg/mL concentration indicates a high level of sensitivity to the test venom. Patients showing a positive reaction to the prick test at this concentration should begin intradermal tests at concentrations of not more than 0.0001 to 0.001µg/mL. Patients with negative prick tests may begin intradermal tests at a concentration of 0.001 µg/mL.

Intradermal test dilutions must be made in Albumin-Saline, following instructions for reconstitution and dilution of venom in section 6.6 Special precautions for handling.

A volume of 0.05 mL should be used for intradermal testing. Introduce the needle into the superficial skin layers until the bevel is completely buried, then slowly inject 0.05 mL aliquot of the venom dilution, making a small bleb.

Start intradermal tests with the most dilute solution. If after 20 minutes no skin reaction is obtained, continue the intradermal testing using tenfold increments in the concentration until a reaction of 5 to 10 mm weal and 11 to 20 mm erythema is obtained, or until a concentration of 1 µg/mL has been tested, whichever occurs first.

A patient should be considered sensitive to the test venom when a skin response of 5 to 10 mm weal, 11 to 20 mm erythema (or greater) occurs at a concentration of 1 µg/mL or less, providing that this reaction is greater than that of the diluent control.

Since the level of insect venom specific IgE may fall to low levels briefly after a reaction to a sting, patients should not be tested until two to four weeks after any sting.

The patient should not take drugs such as antihistamines in the 72 hour period prior to skin testing since such drugs may interfere with the skin test response (see 4.4 Special warnings and precautions for use).

Patients should be kept under medical observation for 60 minutes after each injection, and should be advised not to take any strenuous physical exercise for some hours.

Hyposensitisation

Patients who have multiple venom sensitivities should be given each specific venom injection in a separate site. Note which venom preparation is injected at a specific site, so that dosage of that venom preparation can be adjusted if an excessive local reaction occurs.

In patients receiving more than one venom, there is theoretically a greater risk of systemic reactions.

Reconstitute and dilute the freeze dried venom as directed previously.

Caution

Sensitivity to venom differs from patient to patient. Thus it is not possible to provide a dosage schedule suitable for all patients. The suggested dose schedule shown below gives an injection once per week and was used in clinical trials and should be suitable for a majority of patients.

The following alternative methods can also be used.

a) Rush hyposensitisation with injections every two hours (in this case the patient must be hospitalised).

b) Modified rush hyposensitisation with 2 to 3 injections per day once per week (given on an outpatient basis).

In extremely sensitive patients, however, an individualised dose schedule must be employed which will be dictated by the patient's sensitivity. This individualised schedule will probably include weaker dilutions and smaller increments between doses in progressing to the maintenance level (100 µg/venom).

In identifying those patients to be classified as extremely sensitive, individuals reacting with significant skin test (weal greater than 5 mm and erythema greater than 20 mm) at intradermal skin test concentrations of 0.01 µg/mL or less, or those patients experiencing a systemic reaction to any venom skin test concentration, should be considered highly sensitive. The suggested dose schedule for hyposensitisation with a single venom is shown in Table 1.

Table 1

Suggested dose schedule for hyposensitisation with a single venom*

Dose number	Volume of 1 µg/mL	Dose number	Volume of 10 µg/mL	Dose Number	Volume of 100 µg/mL
1	0.05 mL	5	0.05 mL	9	0.05 mL
2	0.10 mL	6	0.10 mL	10	0.10 mL
3	0.20 mL	7	0.20 mL	11	0.20 mL
4	0.40 mL	8	0.40 mL	12	0.40 mL
				13	0.60 mL
				14	0.80 mL
				15	1.00 mL

Albumin-Saline must be used to make treatment dilutions.

Rush hyposensitisation. The patients must be hospitalised. Subcutaneous injections with gradually increasing doses are given at two hourly intervals, the suggested schedule is shown in Table 2.

Table 2

Rush hyposensitisation schedule

1. 0.0001 µ/mL	2. 0.001 µ/mL	3. 0.01 µ/mL	4. 0.1 µ/mL	5. 1 µ/mL	6. 10 µ/mL	7. 100 µ/mL	8. 100 µ/mL	9. 100 µ/mL
0.1 mL	0.1 mL	0.1 mL	0.1 mL	0.1 mL	0.1 mL	0.1 mL		
0.2 mL	0.2 mL	0.2 mL	0.2 mL	0.2 mL	0.2 mL	0.2 mL	0.6 mL	0.9 mL
0.4 mL	0.4 mL	0.4 mL	0.4 mL	0.4 mL	0.4 mL	0.4 mL		
0.8 mL	0.8 mL	0.8 mL	0.8 mL	0.8 mL	0.8 mL	0.5 mL	0.8 mL	1.0 mL

Modified rush hyposensitisation
Treatment is given once a week on an outpatient basis and includes 2 to 3 injections per visit. Injections are given at intervals of one to two hours. A suitable starting dose is 0.1 mL of the concentration 0.00001 µg/mL. Initially dosage is stepped up by tenfold increments until a dose of 0.1 mL of the concentration 1 µg/mL has been given. Further increases should be made at a slower pace. Three doses per day are given when the total daily dose is below 10 µg. Thereafter, two doses per day are given.

In both rush and modified rush treatment, a maintenance dose of 100 µg/mL is desirable. This dose is given on an outpatient basis at intervals which are gradually increased to four weeks. Injections thereafter are given once per month.

In a previous clinical study with venom products, injections (using this suggested dose schedule) were given once per week at one study centre and twice or more per week at another centre. (For further discussions, see below.) It must be considered important to achieve the 100 µg per venom maintenance dose, since there is no data on effectiveness of maintenance levels below 100 µg per venom.

In deciding the criteria for proceeding from dose to dose of the suggested dose schedule (see above), the results of a 1978-79 clinical study should be considered. A study centre 'A' reporting the least number of systemic reactions during pre-maintenance treatment held the dose constant in most of the cases where significant local reactions occurred. With the systemic reactions reported, this centre held the dose the same in approximately 80% of the incidences. The treatment injections were given at this centre usually once per week, and if a patient missed an appointment, the next dose was often the same as the preceding dose (depending on the previous reactivity of the patient). Patients treated at this centre reached maintenance in an average of 17 to 19 visits.

Another study centre 'B' reporting a higher incidence of systemic reactions, was more regimented in following the suggested dose schedule. This centre reduced or held the dose the same in less than 10% of the cases reporting significant local reactions. With the systemic reactions reported, this centre held the dose the same or reduced the dosage in approximately 20% of the cases. This centre gave more than one injection per week at the outset as circumstances and sensitivity allowed. Patients treated at this centre reached maintenance in an average of 14 visits.

Therefore, in proceeding with the suggested dose schedule, or modified schedules (for highly sensitive patients), it is suggested that if a systemic, extremely large local (10 cm or more induration, or other severe local symptoms), or persistent and severe delayed local reaction occurs, the dose at the next visit should be held constant (or reduced, depending on judgment on severity of the reaction) as was done at study centre 'A' which reported the least number of systemic reactions during the course of therapy.

Following the achievement of maintenance level (100 µg per venom), approximately 80% or more patients were given a second maintenance injection at a one week interval. The third maintenance injection was usually (in approximately 60% of the patients) at a two week interval. The next injection was usually within three weeks, and the patients were then injected for ongoing maintenance at approximately monthly intervals. It is suggested that if a systemic, extremely large local (10 cm or more induration, or other severe local symptoms), or persistent and severe delayed

local reaction occurs following a maintenance injection, the dose at the next visit should still remain constant.
The optimum duration for hyposensitisation therapy is not known, so current recommendations are that maintenance injections be continued indefinitely, year around, particularly in patients experiencing life-threatening anaphylaxis after insect stings.
The dose schedule for children is the same as for adults, and 100 µg per venom should still be considered the maintenance dose. Because of the smaller size of the child, the larger volumes of solution may produce excessive discomfort. Therefore, in order to achieve the total dose required, the volume of the dose may need to be divided into more than one injection per visit.

Paediatric population
No data are available

Method of administration
Precautions to be taken before handling or administering the medicine
For instructions on reconstitution and dilution of the medicine before administration, see section 6.6

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

Rarely, severe reactions to insect stings have been reported. These include serum sickness, haematological abnormalities, and neurological disorders commencing sometime after a sting, and not associated with anaphylactoid reactions. These patients are not candidates for hyposensitisation using insect venoms as administration of venoms to such patients is contraindicated.

4.4 Special warnings and precautions for use

Hypersensitivity to insect stings may be extremely severe. Since the potential for severe systemic reactions exists in the use of these products, the Hymenoptera venom preparations should be used only by doctors experienced in administering hyposensitisation therapy to the maximum tolerated dose and/or under the guidance of an allergist, and only where adequate means for treating systemic reactions are immediately available. The patient should be fully informed of possible risks and should be closely observed.

In patients who are extremely sensitive to Hymenoptera venoms, small doses used for skin test purposes may potentially elicit a severe systemic reaction. Therefore, emergency equipment and personnel trained in its use should be available immediately in the event of such a reaction.

All patients should have available an emergency anaphylaxis kit containing adrenaline and be instructed in its use for emergency treatment of possible systemic reactions occurring at times after the patient has departed the testing or treatment premises. Patients on beta-blockers may be more reactive to the allergenic extracts given for testing or treatment and may be unresponsive to the usual doses of adrenaline used to treat allergic reactions.

Hyposensitisation for insect sting allergy should be given to those patients who have experienced significant systemic reactions (for detailed description of symptoms see 4.1 Therapeutic Indications and 4.8 Undesirable effects) from insect stings and who demonstrate hypersensitivity by skin testing with these products.

Patients currently on whole body Hymenoptera insect immunotherapy should be completely reevaluated by both history and venom skin testing before treatment with these venom products is initiated.

Before testing or treatment of patients with these products the doctor should be thoroughly familiar with all aspects of use of these products including indications, risks, contraindications and treatment of adverse reactions.

Hyposensitisation injections should never be given intravenously. Subcutaneous injection is recommended. Intracutaneous or intramuscular injections may produce large local reactions or be excessively painful. After inserting needle, but before injecting, always withdraw the plunger slightly; if blood appears in the syringe, re-insert the needle in another site. Proper selection of the dose and careful injection should prevent most systemic reactions.

Patients should be instructed to avoid medications such as antihistamines for a period of 72 hours or more prior to skin testing, since such drugs may interfere with the skin response.

Severe local or systemic reactions to venom administration can occur immediately (within one hour) or as delayed reactions (see 4.4 Special warnings and precautions for use). Patients should be kept under direct observation for at least one hour following skin testing and/or therapeutic injections, and should be instructed to contact the doctor promptly if symptoms of an allergic reaction or shock occur. For measures to be taken if the patient exhibits an anaphylactic reaction, see 4.8 Undesirable effects. Patients should be instructed in the use of, and have available, an emergency anaphylaxis kit for self-administration of adrenaline. Patients showing negative intradermal skin tests to specific venoms at 1 µg/mL are not recommended for venom treatment.

Any injections, including hyposensitisation, should be avoided in patients with a bleeding tendency.

Since routine immunisations have been suspected of exacerbating autoimmune diseases, hyposensitisation should be given cautiously to patients with other immunological diseases and only if the risk from insect stings is greater than the risk of exacerbating the underlying disorder.

Venom sensitivity differs for individual patients, thus it is not possible to provide a dosage schedule that is universally suited to all patients. The dosage schedule shown under Dosage and Administration is a summary of the schedule used in clinical trials of this product and found suitable for the majority of patients. In highly sensitive patients, the doctor may be required to use a modified dose schedule, based on the patient's sensitivity to and tolerance of the injections. Lower initial doses and smaller dosage increments than shown under Dosage and Administration may be necessary.

Reconstitute the freeze dried venoms by adding 5.5 mL sterile diluent (Albumin-Saline) to the vial using a sterile syringe. Swirl or rock the container to dissolve the venom completely. Do not shake, since foaming leads to denaturation (inactivation) of protein.

Diluting fluid should be forcibly drawn into the sealed vial when the syringe needle penetrates the seal during reconstitution. Failure of this to occur for a particular vial indicates possible loss of vacuum. Discard vials without vacuum. In the event that an anaphylactic reaction occurs from overdose or inadvertent injection into the bloodstream, treat with adrenaline as directed under Adverse Reactions. Each vial is for single patient use only.

DILUTION

Dilutions must be made in Albumin-Saline, see Table 4. They should be made accurately and aseptically, using sterile solution, vials, syringes, etc., and thoroughly mixed by rocking or swirling. Do not shake. Maintain stock solutions and dilutions constantly at 2 to 8°C. Do not freeze.

A sterile tuberculin syringe, with a needle at least 16 mm long and graduated in 0.01 mL units, should be used to measure each dose from the prescribed dilution.

Table 4

Dilution table

Extract volume	of	Extract concentration	+	Diluent volume	=	Dilution concentration
1 part	of	100 µg/mL	+	9 parts	=	10 µg/mL
1 part	of	10 µg/mL	+	9 parts	=	1 µg/mL
1 part	of	1 µg/mL	+	9 parts	=	0.1 µg/mL
1 part	of	0.1 µg/mL	+	9 parts	=	0.01 µg/mL
1 part	of	0.01 µg/mL	+	9 parts	=	0.001 µg/mL
1 part	of	0.001 µg/mL	+	9 parts	=	0.0001 µg/mL

Examples of the preceding dilution table are shown in Table 5.

Table 5

Dilution examples

Extract volume	of	Extract concentration	+	Diluent volume	=	Dilution concentration
0.2 mL	of	100 µg/mL	+	1.8 mL	=	10 µg/mL
0.2 mL	of	10 µg/mL	+	1.8 mL	=	1 µg/mL
0.2 mL	of	1 µg/mL	+	1.8 mL	=	0.1 µg/mL
0.2 mL	of	0.1 µg/mL	+	1.8 mL	=	0.01 µg/mL
0.2 mL	of	0.01 µg/mL	+	1.8 mL	=	0.001 µg/mL
0.2 mL	of	0.001 µg/mL	+	1.8 mL	=	0.0001 µg/mL

A separate autoclave sterilised or disposable needle and syringe should be used for each patient to prevent transmission of homologous serum hepatitis and other infectious agents from one person to another.

Do not reinsert a needle into a diluent or into a vial containing a different venom, which has been previously inserted into a venom vial. Aseptic techniques should always be employed when administering skin tests and/or treatment injections.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed

4.6 Fertility, pregnancy and lactation

Pregnancy

Specific studies addressing risk to mother and fetus have not been done with venom products. Animal reproduction studies have not been conducted with Hymenoptera venom products. It is also not known whether Hymenoptera venom products can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

Hymenoptera venom products should be given to a pregnant woman only if clearly needed. On the basis of histamine's known ability to contract uterine muscle, theoretically, a systemic reaction, whether occurring from allergen exposure or hyposensitisation overdose, should be avoided. Therefore, the doctor must carefully consider the benefit to risk ratio, to both patient and fetus, of continuing a treatment program during pregnancy, and especially the initiation of such a program where there is a possibility that the patient may not be able to reach the recommended maintenance dose without significant risk of a systemic reaction.

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

Doctors administering venom testing or treatment materials should be experienced in the treatment of severe systemic reactions (see 4.4 Special warnings and precautions for use).

Patients should have available an emergency anaphylaxis kit containing adrenaline and be instructed in its use for emergency treatment of possible systemic reactions, occurring at times after the patient has departed the treatment premises.

Excessively large, painful or persistent local reactions can occur from skin tests or hyposensitisation. Large local reactions occurred in approximately 60% of patients given hyposensitisation. None of the local reactions required specific treatment, however subsequent injections in many instances were held to the previous dose or a reduced dose. Some patients had repeated large local reactions that slowed the increase in the hyposensitisation dose.

Systemic reactions may occur at any time after skin tests or hyposensitisation. Symptoms may range from mild to life-threatening anaphylaxis. In a clinical study some form of systemic response occurred, often repeatedly, in one third of the patients treated. Only one systemic response occurred on the first dose given. The rest occurred at various times in the course of hyposensitisation. Some systemic manifestations may have occurred because of the patient's apprehension and did not require treatment. Approximately one-quarter of the patients experiencing systemic responses were given some form of specific therapy, some on several occasions.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Local reactions at the site of injection in the form of a weal or swelling occur frequently and are not cause for alarm, but if they persist, are indication that dosage may need adjustment.
Prolonged pain or pain radiating up the arm usually means the injection has been given intramuscularly. The increased pain from this route of injection is undesirable. For best results, be sure to inject subcutaneously.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: allergen extracts, ATC Code: V01AA07

The mechanism by which hyposensitisation is achieved is not known completely. IgG antibodies (blocking antibodies) appear in the serum of patients treated with injected venom. No direct relationship has been identified between the level of blocking antibody (or the ratio of blocking antibody to IgE antibody directed to the same venom antigens) and the degree of hyposensitisation. However, patients who show protection from symptoms after stings, have been found to have raised levels of specific blocking antibody.

Initially, after a period of immunotherapy with specific venom antigens, levels of IgE antibody may increase. However, from studies carried out with other venom preparations, these levels are reported to decline after a time. After maintenance level has been reached and maintained, symptoms after stings have been shown to decrease considerably. It is not known if skin sensitising antibody can be eradicated or if the patient can be entirely cured, nor is it known how long immunotherapy must be continued.

Skin testing with insect venoms is useful to demonstrate the presence of IgE antibodies which account for the patient's hypersensitivity symptoms. Patients are seldom able to identify the insect which stung them, so skin testing is used to determine the insect which stung them. Dilutions of these venom products will help judge the sensitivity of the patient and whether the patient should be treated.

It is not absolutely known what levels of venom that elicit positive skin tests are diagnostic of clinical sensitivity. However, patients with a history of reactions (any of three types: generalised urticaria or angioedema; respiratory difficulty due either to laryngeal oedema or to bronchospasm; or vascular collapse, with or without loss of consciousness) to previous stings and a positive skin test to a venom intradermal injection of approximately 1 µg/mL had about a 60% chance of reacting again when stung by the same insect. These patients should receive venom hyposensitisation.

Patients with a history of reaction (any of the three reaction types described above) to previous stings, but who did not demonstrate a positive skin test reaction to venom, are not recommended for hyposensitisation treatment. There is no data to determine whether a patient who might react to a higher concentration, e.g. 2 to 10 µg/mL, is at risk from subsequent stings. Since it is not known if sting sensitive patients who subsequently lose their IgE antivenom antibody can be resensitised by further stings, it is advisable to retest these patients after any subsequent stings. However, since the level of venom specific IgE may fall to low levels briefly. After a sting, patients should not be retested until 2 to 4 weeks after any sting.

Hyposensitisation is indicated for those patients diagnosed as sensitive (see Diagnosis) and is accomplished by using graded dilutions of the appropriate insect venom or venoms to control the severity of the patient's symptoms from subsequent stings.

Increasing doses of venom are given at intervals, dependent on the patient's ability to tolerate the venoms, until a maintenance dosage (100 µg per venom is recommended) is reached and maintained. It is considered important that the patient be able to reach this dosage since the efficacy of lower maintenance dosages has not been established.

ACTIONS
This product may be used for both diagnosis and hyposensitisation.

Diagnosis
Diluted solutions of stinging insect venoms injected intradermally will produce weal and erythema reactions in patients who have significant IgE-mediated, type I immediate hypersensitivity to stings of these insects.

Treatment
Repeated injections of increasing doses of insect venom extracts have been shown to ameliorate the intensity of allergic symptoms upon subsequent insect stings.

Clinical Trials
In a clinical trial, three patients at the maintenance dosage of bee venom (100 µg per venom) showed no systemic reaction following an insect sting challenge. The remaining ten patients were not challenged. The patients in this study reached maintenance (100 µg per venom) usually within 21/2 to 31/2 months after beginning therapy. Whether efficacy of therapy is influenced by the time required to reach maintenance has not yet been determined

5.2 Pharmacokinetic properties
No Data available

5.3 Preclinical safety data
No Data Available

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The freeze dried honey bee venom consists of mannitol 42.3 mg / vial and sodium chloride 1.72 mg / vial. The freeze dried wasp venom consists of mannitol 42.3 mg / vial. The freeze dried yellow jacket consists of mannitol 42.3 mg / vial.

Albumin-Saline contains sodium chloride 0.9%, phenol 0.4% and normal human serum albumin 0.03% (Refer to Section 2- Qualitative and Quantitative composition)

6.2 Incompatibilities

This medicine must not be mixed with other medicines except those mentioned in section 6.6 Special precautions for handling.

6.3 Shelf life

36 months from date of manufacture
6 months reconstituted at 100 µg/mL.

6.4 Special precautions for storage

Maintain stock solutions and dilutions constantly at 2 to 8°C. Do not freeze

At the time of reconstitution, record date of reconstitution and expiration date of reconstituted product in the space provided (day, month, year) on the product label. Expiration date of the reconstituted venom depends on the type of reconstituting fluid used. Products reconstituted in Albumin-Saline have an expiration date of 6 months from date of reconstitution. Date of expiration after reconstitution must not exceed Final Expiration Date indicated on the container label (see Table 3 for expiration dates, including dilutions).

Table 3

Recommended expiry dates following reconstitution with Albumin-Saline

Venom concentration	Recommended expiry date*
100 µg /mL	6 months
10 µg/mL	1 month
1 µg/mL	1 month
0.1 µg/mL	14 days
<0.1 µg/mL	Prepare fresh daily

*But not to exceed final expiration date indicated on container label

Recommended expiry dates following reconstitution with Albumin-Saline

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Vacuum sealed vial (10 mL capacity), 550 microgram: 1's (plus diluent).

6.6 Special precautions for handling.

Any unused medicine or waste material should be disposed of in accordance with local requirements

7 MEDICINE SCHEDULE

Prescription

8 SPONSOR

Stallergenes Greer New Zealand Limited
Level 1, 24 Manukau Road,
Epsom, Auckland 1023
New Zealand
Ph: 0800 824 166

9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:
1 July 2005

10 DATE OF REVISION OF THE TEXT

30 May 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
8 SPONSOR	The Sponsor in NZ has been changed from EBOS to Stallergenes Greer New Zealand. Hence the details have been updated.
NA	Reformat to the new Medsafe form (updating headings and/or subheadings, updating numbering and cross-references of tables and figures, and inclusion of standard text)