

ALBEY VENOM

Pronounced (al-b-ay ve-n-om)

Contains the active ingredient (Allergen Extracts - there are three types of venom - Paper Wasp Venom (Pollistes sp); Vespula sp (commonly known as European Wasp or Yellow Jacket) and Honey Bee Venom (Apis Millefera) Mannitol and Sodium chloride are included as an inactive component in Honey Bee Venom Mannitol is included as an inactive component in Paper Wasp and Yellow Jacket Venom

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ALBEY VENOM.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ALBEY VENOM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is ALBEY VENOM used for

Up to 3% of the population in Australia may have an immediate allergic reaction to an insect sting. This can lead to death in some cases. An average of three deaths per year have been recorded in Australia. Venom immunotherapy or desensitisation can reduce the risk of severe reactions in adults from 30% -70% down to less than 2%. ALBEY VENOM is one type of immunotherapy your doctor may choose to administer to reduce the risk of a severe allergic reaction.

ALBEY VENOM contains freeze dried extracts of venom protein known as allergens.

ALBEY VENOM belongs to a group of medicines called Antiallergy preparations.

Antiallergy preparations can be used for both diagnosis and desensitisation of insect stings.

The exact mechanism by which ALBEY VENOM does this is not completely understood.

Your doctor, however, may have prescribed ALBEY VENOM for another purpose.

Ask your doctor if you have any questions why ALBEY VENOM has been prescribed for you.

ALBEY VENOM is not addictive.

This medicine is available only with a doctor's prescription and is usually administered under a doctor's supervision.

Before you take ALBEY VENOM

Do not take ALBEY VENOM if:

- 1. You have previously had severe reactions to insect stings. These include serum sickness, hematological abnormalities, and neurological disorders commencing some time after a sting, and not associated with anaphylactic reactions.**

- 2. You are currently receiving treatment with beta-blockers as you may be more reactive to the allergenic extracts given for testing or treatment and you may be unresponsive to the usual doses of adrenaline used to treat allergic reactions.**
- 3. You have shown a negative intradermal skin test to specific venom at 1 microgram/mL.**
- 4. the package is torn or shows signs of tampering.**
- 5. the expiry date (EXP) printed on the pack has passed.**
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking ALBEY VENOM, talk to your doctor.

Before you start to take it:

Severe local or systemic reactions to venom administration can occur immediately (within one hour) or as delayed reactions. 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. Patients should be instructed in the use of, and have available, an emergency anaphylaxis kit for self-administration of adrenaline.

Tell your doctor if:

- 1. You are pregnant or plan to become pregnant**

It is not known whether ALBEY VENOM is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take ALBEY VENOM when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

2. You are breastfeeding or plan to breastfeed

It is not known whether ALBEY VENOM passes into breast milk. Your doctor will discuss the risks and benefits of using ALBEY VENOM if you are breast-feeding.

3. You have any other health problems, especially the following:

- You have a known hypersensitivity to insect stings.
- You are currently receiving beta-blocker therapy.

4. You are allergic to any other medicines, foods, dyes or preservatives

5. You have a bleeding tendency.

6. You have or have experienced in the past any immunological diseases

If you have not told your doctor about any of the above, tell them before you start taking ALBEY VENOM.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you bought from a pharmacy, supermarket or health food shop.

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.

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.

Patients should also avoid strenuous exercise for several hours after taking medication.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ALBEY VENOM.

How to take ALBEY VENOM

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Desensitisation injections should never be given intravenously.

How much to take

Your doctor will administer the correct dose as appropriate. Patients are advised to remain in their doctor's surgery for at least 60 min after injection.

The dose administered will depend on the type of therapy decided upon by your doctor.

The dose schedule for children is the same as for adults, and 100 microgram 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.

How to take it

Your doctor will prepare the venom by reconstituting the freeze-dried venom by adding 5.5 mL sterile diluent (Albumin-Saline) to the vial using a sterile syringe. The vial should swirled or rocked gently until all of the powder is dissolved.

The vial should not be shaken, since foaming leads to denaturation (inactivation) of protein.

The doctor will administer ALBEY VENOM via a subcutaneous injection (under the skin). The treatment will generally last over several weeks, with the doctor increasing the dose until a maintenance dose is reached.

When to take it

Your doctor will advise you on when it is appropriate to be given ALBEY VENOM.

How long to take it

Your doctor will decide the length of treatment. The longer the course of treatment the better the therapeutic effect of the drug. Therefore the course of treatment may last from three to five years. Once a maintenance dose is reached the frequency of administration should decrease.

While you are taking ALBEY VENOM

Tell all doctors, dentists and pharmacists who are treating you that you are taking ALBEY VENOM.

Tell your doctor if you become pregnant while taking ALBEY VENOM.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.

Things to be careful of

ALBEY VENOM is not expected to affect your ability to drive a car or operate machinery

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ALBEY VENOM.

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.

ALBEY VENOM generally causes few side effects and helps most people with hypersensitivity to insect stings, however it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of these side effects.

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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- itching, redness, local irritation
- cramps
- nausea and vomiting
- large local reaction
- Some reactions can occur later on during therapy

These are the more common side effects of ALBEY VENOM.

Tell you doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- loss or blurring of vision
- loss of consciousness
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of face, lips, tongue or other parts of the body

- seizures
- shortness of breath, wheezing, respiratory or cardiac distress

These are serious side effects. You may need urgent medical attention. Serious side effects are rare. Very rarely some of these side effects can lead to death, that is why it is very important that you tell your doctor about any serious discomfort that you are experiencing.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell you doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask you doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storage

Your medicine will generally be stored by your doctor. It should be kept refrigerated between 2 to 8 deg. C. It should not be frozen.

At the time of reconstitution, your doctor will record the date of reconstitution and expiration date of reconstituted product in the space provided (day, month, year) on the product label and store the reconstituted vial in the refrigerator at between 2 to 8 deg. C

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

Syringes and vials should be disposed of appropriately.

Product Description

Availability

These freeze dried products should be dissolved in Albumin-Saline (which contains sodium chloride 0.9%, phenol 0.4% and normal human serum albumin 0.03%) to a concentration of 100 microgram/mL. Dilutions of this concentration should be made only with Albumin-Saline.

Mannitol and Sodium chloride are included as an inactive component in BeeVenom.

Mannitol is included as an inactive component in Paper Wasp and Yellow Jacket Venom.

ALBEY VENOM is available as:

Albey Honey Bee Venom Injection (Injection)

Honey bee (*Apis mellifera*) venom; freeze dried powder for reconstitution. To be diluted with Albumin Saline.

Pack - 550 micrograms per vial

Albey Wasp Venom Injection (Injection)

Wasp venom (*Polistes* sp.); freeze dried powder for reconstitution. To be diluted with Albumin Saline.

Pack - 550 micrograms per vial

Albey Yellow Jacket Venom Injection (Injection)

Vespa sp. freeze dried powder for reconstitution. To be diluted with Albumin Saline.

Pack - 550 micrograms per vial

Albey Saline Diluent (Diluent)

A carton consisting of 20 units of 9.0 mL of Albumin Saline Diluent. To be used only for the dilution of above Albey Venoms

Date: - 20/12/2013

AUST R: 161298 (Bee Venom)

AUST R: 18770 (Yellow Jacket Venom)

AUST R: 18695 (Paper Wasp Venom)

AUST R: 32486 (Albumin Saline Diluent)

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DISTRIBUTOR:*

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