

1011281 a **Patient information leaflet**

**Pharmalgen® Bee Venom**  
**Pharmalgen® Wasp Venom**

**What you should know about Pharmalgen® Bee and Wasp Venom**

Please read this leaflet carefully before these injections are given to you. It provides important information about your injections. If you have any questions or are in any doubt about anything, please ask your doctor.

The names of your injections are Pharmalgen® Bee Venom and Pharmalgen® Wasp Venom. They are part of either an "Initial Treatment Set" or a "Maintenance Set".

The Initial Treatment Set is to prevent you getting an unusual reaction to bee and wasp stings. It contains four small glass bottles of venom, each labelled with a different colour coded number – 1, 2, 3 and 4. It also contains four small glass bottles each containing 5 ml Albumin Diluent.

The Maintenance Set is to keep your ability to react to bee and wasp stings at a low level. It contains four small glass bottles labelled with number 4 and four small glass bottles each containing 5 ml Albumin Diluent.

**What is in your medicine?**

Each small bottle of venom contains a different amount of the active ingredient, either bee venom or wasp venom. Both venoms have been specially treated, by freeze drying, to make them pure and suitable for dissolving in Albumin Diluent before injecting into you. The powder for reconstitution also contains the inactive ingredients, mannitol and human albumin. The coloured number on the bottle label tells you how much venom is in the bottle after 1.2 ml of Albumin Diluent has been added:

1 (grey):	0.1 microgram venom in 1 ml
2 (green):	1 microgram venom in 1 ml
3 (orange):	10 microgram venom in 1 ml
4 (red):	100 microgram venom in 1 ml

Each small bottle of Albumin Diluent contains 5.0 ml of a sterile solution. This solution contains only inactive ingredients, human albumin, sodium chloride (salt), phenol and water for injections.

Pharmalgen® Venom will be given to you as an injection under the skin by your doctor at the hospital.

**Manufacturer and product licence holder:**

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**What is your injection for?**

Pharmalgen® Venoms are used to stop abnormal responses, or allergic reactions, to bee and wasp stings. These reactions may cause rashes, itching, sneezing, wheezing, runny nose and sometimes shortness of breath.

These venoms are also used to test people to see if they will have an abnormal reaction to bee and wasp venom.

**Before you are given your injection**

- Have you had a test for reaction to Honey Bee or Wasp Venom?
- Have you ever had a bad reaction to this injection or any medicines containing bee or wasp venom or any other ingredient of this injection?
- Have you ever had asthma?

- *Is your ability to fight infections reduced?*
- *Are you taking medicines (antihistamines) to reduce bad allergic reactions or for travel sickness or medicines (bronchodilators) to help you breathe?*
- *Are you being treated with other allergens or have you received any vaccines?*
- *Have you ever been treated with Whole Body Extracts?*
- *Are you pregnant?*

If the answer to any or all of the above questions is **yes**, tell your doctor before he gives you **Pharmalgen® Bee or Wasp Venom**.

### **How will you be given the injection?**

Avoid alcohol, heavy meals and strenuous physical exercise on the days you receive your injection.

Your diagnosis and treatment will only be carried out by experienced practitioners in hospitals with resuscitation facilities immediately available. You will be looked after in hospital for at least one hour after treatment.

One of the healthcare professionals will make up your injection by adding 1.2 ml of Albumin Diluent to the freeze-dried venom and shaking gently. Your doctor will give you the injection under the skin.

Before treatment starts, the substance responsible for producing your allergy will be confirmed. This is the diagnosis. This test will probably be by a skin prick but may involve an injection into the skin.

Treatment of your allergy is in two stages, "Initial Treatment" and "Maintenance Treatment".

### **Initial Treatment**

This is by one of three schedules, the "Modified Rush or Cluster Technique", the "Conventional (Ambulant) Schedule" or the "Rush Schedule":

### **"Modified Rush or Cluster Technique"**

If your doctor decides the "Modified Rush or Cluster Technique" is right for you, you will be given two to four doses at 30-minute intervals at each weekly session. Your doctor will decide your starting dose, usually 0.1 ml of a solution containing 0.1 micrograms venom in 1 ml. When your dose reaches 100 micrograms venom in 1 ml, it will be given to you again one, then two, three and four weeks later so that a monthly maintenance dose is reached.

### **"Conventional (Ambulant) Schedule"**

If your doctor decides the "Conventional (Ambulant) Schedule" should be used, you will be given one injection once or twice a week, usually starting at a dose of 0.1 ml of a solution containing 0.1 micrograms venom in 1 ml.

### **"Rush Schedule"**

If your doctor decides the "Rush Schedule" should be used, you will stay in hospital for the length of the injection treatment. On the first day you will be given 0.1 ml of a solution the strength of which has been calculated for you. Then at two hourly intervals you will be given 0.2, 0.4 and 0.8 ml. The next day the solution will be made 10 times stronger and you will be given injections of 0.1, 0.2, 0.4 and 0.8 ml. The daily increases in strength of the solution continue until you are given a dose of 100 micrograms. At this stage you will be allowed to go home. You will be given 100 microgram doses after one week, two weeks, three weeks, four weeks and then every month.

These dosage schedules are for guidance only. Your doctor will give you the dose that is right for you.

### **Maintenance Treatment**

You will be given an injection containing 100 micrograms of venom in 1ml each month for at least three years and your doctor may wish you to have treatment for longer.

If you get stung whilst you are on Maintenance Treatment, tell your doctor.

### Children and Elderly Persons

There are no special dosage instructions if you are a child or elderly patient. All patients are treated individually and the doctor works out which dose is right for you.

### After you have been given your injection

Normally this injection does not upset people but very occasionally some people may get side effects such as:

- *Hard, raised colourless patches on the surface of the skin, like nettle rash, or a sudden reddening of the surface of the skin;*
- *Swelling where the injection needle entered the skin may occur immediately after the injection or up to 48 hours after injection;*
- *Itchy red or whitish raised patches on the skin or reddening of the skin;*
- *Inflammation of the mucous membranes that line the nose;*
- *Mild or moderate difficulty in breathing;*
- *Swelling of the eyes, lips and tongue;*

If you experience any of these side effects, and they stay or become troublesome, tell your doctor or pharmacist.

If you get any other unusual or unexpected side effect, you should tell your doctor or pharmacist at once.

### Anaphylactic reaction

You will be kept in hospital for at least one hour after your injection because occasionally a severe reaction may occur within a few minutes of having the injection. This is called an anaphylactic reaction. If this happens, you will feel sick and might vomit, your chest will feel tight, you will have difficulty in breathing and be wheezing and gasping for air, you may be sneezing and your face may swell, especially around the eyes. You will also have a faster pulse than normal.

**Tell your doctor immediately if you feel any of these changes.** He will be able to give you the right treatment to make you feel well.

### How should your injection be stored?

- *The hospital will look after your injection.*
- *This and all medicines should be kept in a cool, safe place (between 2°C and 8°C) where children cannot get them. Your medicine could harm them.*
- *Do not freeze this injection.*
- *Keep away from light.*
- *Do not use this injection after the expiry date or expiry date after reconstitution, which are printed on the label.*

### Product licence numbers:

Bee Venom	PL 10085/0003
Wasp Venom	PL 10085/0004
Albumin Diluent	PL 10085/0005

### Date:

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ATLAS QUICK A.S. (KBH.S.)



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