Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet about:
1. What Pharmalgen is and what it is used for
2. What you need to know before you use Pharmalgen
3. How to use Pharmalgen
4. Possible side effects
5. How to store Pharmalgen
6. Contents of the pack and other information

1. What Pharmalgen is and what it is used for

Pharmalgen Bee Venom and Pharmalgen Wasp Venom can be used in two ways:

For treatment
- Pharmalgen Bee Venom and Pharmalgen Wasp Venom are treatments to reduce your body’s reaction to bee or wasp stings. In the rest of this leaflet, these medicines will be called Pharmalgen.

For diagnosis
- Pharmalgen is also used to test if a person will react too strongly to bee or wasp stings.
- No specific indication for children can be made.

2. What you need to know before you use Pharmalgen

Do not use Pharmalgen if:
- If you are allergic to any of the ingredients of this medicine apart from the active substance (listed in section 6)
- You have a disease of, or a problem with, your immune system
- You have a chronic heart or lung disease or severe arterial hypertension or are being treated with β-blockers
- You are being treated with tricyclic antidepressants or monoamine oxidase inhibitors (MAOIs)
- You currently have cancer
- You have severe asthma (seasonal or chronic)
- You are being treated with ACE inhibitors (medicines for heart or blood pressure)
Warnings and precautions
Talk to your doctor or nurse before using Pharmalgen if:
• You have had a test for a reaction to bee or wasp venom
• You have ever had a bad reaction to this injection or any medicines containing bee or wasp venom
• You suffer from asthma
• You have recurrent or frequent infections

Other medicines and Pharmalgen
Tell your doctor if you are using, have recently used or might use any other medicines.

In particular tell your doctor if you are taking:
• Antihistamines to reduce allergic reactions
• Medicines to help you breathe (bronchodilators)
• Medicines for travel sickness
• Medicines for heart or blood pressure (β-blockers and ACE inhibitors)
• Antidepressants (tricyclics and monoamine oxidase inhibitors (MAOIs))
• Or if you are being treated with other allergens
• Or if you have recently received any vaccines

Pregnancy and breast-feeding
Treatment with Pharmalgen should not be started if you are already pregnant. If you are likely to become pregnant or you get pregnant during your treatment, talk to your doctor for advice.
If you are breast-feeding, ask your doctor for advice.

Take special care with Pharmalgen
Avoid alcohol, hot baths, and strenuous physical exercise on the days you receive your injection.

Special care should be given if children younger than 5 years of age are treated with Pharmalgen. Your doctor will carefully weight the risk-benefit for the individual child. For children ≥ 5 years of age clinical data of efficacy are sparse, however data on safety do not reveal a higher risk as for adults.

If levels of tryptase in your blood are increased and/or you are suffering from mastocytosis, the risk of side effects may be increased.

If you are suffering from mastocytosis you may expect less efficacy compared with the general insect venom allergic population.

Driving and using machines
Pharmalgen is not expected to affect your ability to drive or operate machinery.

3. How to use Pharmalgen

• Your diagnosis and treatment will be carried out by an experienced doctor.
• There are no fixed doses. All patients are treated individually. The doctor will work out which dose is correct for you.
• You will be looked after in hospital or clinic for at least 60 minutes after the injections.

Diagnosis
Pharmalgen is dissolved in Albumin Diluent by the healthcare professional before the product is ready to be used. Healthcare professionals should see section at the end of the technical information leaflet for detailed instruction on how to dissolve and dilute Pharmalgen.

Before treatment starts, you will have a test using Pharmalgen to make sure that it is bee venom or wasp venom that is responsible for producing your allergy. This is the diagnosis. This test will probably be a skin prick test but may be an injection under the skin. Alternatively, your allergy may be confirmed by testing your blood.

**Treatment**

Treatment of your bee or wasp venom allergy is in two phases, the initial phase and the maintenance phase. Pharmalgen will be given to you as an injection under the skin. It will not be injected into a vein.

- **Initial Phase**
  
  In the initial phase, the dose of Pharmalgen is increased by small amounts until the maximum dose suitable for you (maintenance dose) has been reached.

  The injections in the initial phase will usually be 3–7 days apart. If necessary, your doctor may decide to give you 2–4 injections, 30 minutes apart, once a week until the maximum dose is reached. If you are already in hospital, your doctor may decide to give you up to 4 injections a day, 2 hours apart.

- **Maintenance Phase**
  
  You will be given an injection containing the maintenance dose each month for at least three years.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects although not everybody gets them. If symptoms of side effects occur they usually occur within the first 30 minutes after the injection, but they may occur up to 24 hours after the injection.

**Very common side effects (affecting more than 1 person out of 10):**

- A continuously spreading weal may be formed at the site during the first 10-20 minutes after application of the allergen.
- Local widespread swelling and redness may happen 6-24 hours after the application of the allergen.
- Swelling, redness, pain, itching and local nettle rash where the injection needle entered the skin may appear within 30 minutes and may last for up to 6 hours.

**Common side effects (affecting more than 1 person out of 100): please tell your doctor if long or severe**

- Nettle rash, tiredness wheezing, chest tightness and flushing
- Headache, sneezing, coughing, itching, stuffy and runny nose, itchy eyes, asthma and general discomfort

Most local side effects are mild in nature and can be treated with medication if needed. Please talk to your doctor for advice.

**Rare side effects (affecting more than 1 person out of 10,000): please get doctor’s help straight away**
**Anaphylactic reaction**

**In very rare cases (less than 1 in 10,000 patients)** an anaphylactic reaction (a severe allergic reaction) may occur after skin-prick test with active allergens, within the first minutes after treatment.

An anaphylactic reaction is a severe reaction throughout the body and the onset is characterised by flushing, intense itching of the skin (like palms of hands and soles of feet or other areas of the body), raised rash (like a nettle rash). In addition, symptoms of an anaphylactic reaction may include swelling of the lips, throat and tongue; shortness of breath; wheezing; hoarseness, nausea; diarrhoea; vomiting; stomach cramp, low blood pressure; fast heart beat; disturbances of the heart rhythm and loss of consciousness.

If this happens your doctor or healthcare professional will have an emergency kit available with a ‘ready for use’ adrenaline syringe.

This is the reason why you are kept in hospital or clinic for at least one hour after having had your injection.

**TELL YOUR DOCTOR/NURSE IMMEDIATELY IF YOU FEEL ANY OF THESE CHANGES.** He or she will be able to give you the right treatment at once to make you feel well.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

**Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the MHRA Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

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### 5. How to store Pharmalgen

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

<table>
<thead>
<tr>
<th>Concentration (µg venom / ml)</th>
<th>Shelf life</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>6 months</td>
</tr>
<tr>
<td>All dilutions &lt;100 µg/ml</td>
<td>A maximum of 24 hours after first dilution</td>
</tr>
</tbody>
</table>

The hospital or clinic will store Pharmalgen for you in the refrigerator (2°C - 8°C) in the outer carton.

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### 6. Contents of the pack and other information

**What Pharmalgen contains**
Pharmalgen contains an extract of specific allergen. Pharmalgen Bee Venom contains bee venom and Pharmalgen Wasp Venom contains wasp venom. The allergen is the active substance that causes the allergic reaction to either bee or wasp stings. Pharmalgen is dissolved in Albumin Diluent before being injected into you. The Albumin Diluent contains only inactive ingredients: human serum albumin, phenol, sodium chloride and water for injections.

**What Pharmalgen looks like and contents of the pack**
Pharmalgen is available in a Treatment Set containing: four glass bottles, which when diluted with Albumin Diluent give a 100 µg/ml solution and four glass bottles of 5.0 ml sterile Albumin Diluent.

**Marketing Authorisation Holder and Manufacturer:**
ALK-Abelló A/S
Bøge Allé 6-8
DK-2970 Hørsholm
Denmark

**Distributor:**
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