Pharmalgen® Dilution Chart

Before use the product must be reconstituted with Albumin Diluent as described below.

Reconstitution of powder:

1. Extract 1.2 ml Albumin Diluent in a disposable syringe.
2. Carefully inject 1.2 ml Albumin Diluent into the vial with the freeze-dried extract.
3. Carefully turn the vial over 10-20 times; check that all the extract has dissolved. It is now ready for use.

   After reconstitution the solution contains 100 µg/ml of insect venom. The date of the reconstitution and the expiry date must be noted on the label of the vial.

   Lower concentrations should be obtained by diluting the solution. Use Albumin Diluent for dilution. To avoid confusion, the vials must be labelled before dilution (minimum information: allergen, concentration, date of dilution and expiry date).

Dilution series:

10 µg/ml (1:10):
(0.55 ml of the 100 µg/ml + 5 ml Albumin Diluent)

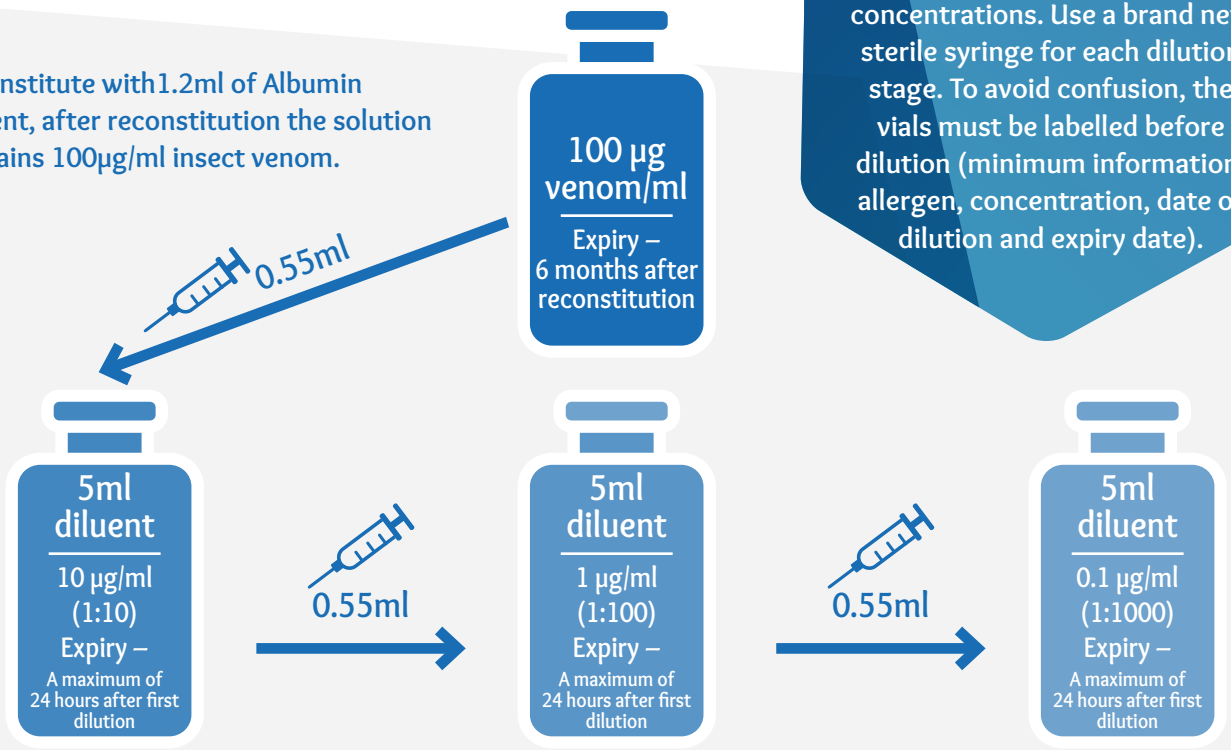
1 µg/ml (1:100):
(0.55 ml of the 10 µg/ml + 5 ml Albumin Diluent)

0.1 µg/ml (1:1000):
(0.55 ml of the 1 µg/ml + 5 ml Albumin Diluent)

Further dilutions can be prepared using the same method.

Please note!
Do not use the same sterile syringe to transfer different concentrations. Use a brand new sterile syringe for each dilution stage. To avoid confusion, the vials must be labelled before dilution (minimum information: allergen, concentration, date of dilution and expiry date).

Reconstitute with1.2ml of Albumin Diluent, after reconstitution the solution contains 100µg/ml insect venom.



Expiry: All dilutions < 100 µg/ml - A maximum of 24 hours after first dilution.

Pharmalgen®
Wasp & Bee Venom

Abbreviated Prescribing Information

Product name: Pharmalgen® Wasp Venom or Pharmalgen® Bee Venom Abbreviated Prescribing Information. Please refer to the Summary of Product Characteristics before prescribing.

Pharmaceutical form and composition: Powder and solvent for solution for injection containing freeze-dried venom extracts from wasp (*Vespula spp.*) or honey bee (*A. mellifera*).

Therapeutic indications: Diagnosis and treatment of IgE-mediated allergy to wasp or bee venom

Posology and method of administration: Treatment with Pharmalgen® must be performed using subcutaneous injections. Venom extracts must not be mixed. The dosage of Pharmalgen® must be individually adjusted. The dosage should depend on the patient's general condition, the allergic anamnesis and the patient's sensitivity to the specific allergen used. The initial dose is defined on the end point concentration obtained in the skin prick test. Further doses are increased in a stepwise fashion until a concentration of 0.01mcg venom/ml is reached. The follow up dosing steps, until maintenance dose is reached, are described in the SmPC. Alternative schedules are available in the SmPC, as well as details on dosing for maintenance phase. If a severe, systemic reaction occurs after injection treatment should only be continued after careful consideration.

Contraindications: Hypersensitivity to excipients, malignancy or systemic diseases affecting the immune system. Diseases preventing the treatment of possible anaphylactic reactions, including use of beta blockers. Treatment with tricyclic antidepressants, monoamine oxidase inhibitors and ACE inhibitors. Uncontrolled or severe asthma (FEV1 < 70% of predicted value, after adequate pharmacologic treatment).

Special warnings and precautions for use: Treatment with Pharmalgen® should be administered under supervision of a doctor experienced in specific immunotherapy. Special care should be given to the risk-benefit assessment with regard to treatment of children younger than 5 years. Due to the risk of potentially fatal anaphylactic reactions, treatment with Pharmalgen® must be carried out in clinics or hospitals where facilities for cardiopulmonary resuscitation are immediately available for use by adequately trained personnel. Patients must be observed for 60 minutes after each injection. In patients with increased baseline serum tryptase levels and/or mastocytosis, the risk of systemic allergic reactions and the severity of these may be increased. If the rushed dosage schedule is used the patient must be hospitalised.

Interaction with other medicinal products and other forms of interaction: ACE inhibitors may exacerbate the response to insect venom, resulting in potentially life threatening allergic reactions to insect stings or venom immunotherapy. Antihistamines and bronchodilators may increase tolerance. Concomitant use of venom immunotherapy and tricyclic antidepressants, MAOIs and beta blockers are contraindicated. No data exists on possible risks of simultaneous immunotherapy with other allergens.

Pregnancy and lactation: The risk to the mother and the foetus of an anaphylactic reaction must be considered. Treatment should not be initiated during pregnancy. No clinical data is available on the use of Pharmalgen® during lactation.

Undesirable effects: Generally reactions in connection with the treatment with Pharmalgen® are due to an immunological reaction (local and/or systemic). Very commonly reported adverse reactions in patients treated with Pharmalgen® were local reactions at the injection site. Systemic reactions can vary from allergic rhinitis to anaphylactic shock. Treatment of a severe systemic reaction must be initiated immediately. Prescribers should consult the summary of product characteristics for a list of adverse reactions.

Excipients: Mannitol, human serum albumin, sodium chloride, phenol, water for injection.

Legal Category: POM.

Marketing authorisation holder: ALK-Abelló A/S, Bøge Alle 6–8, DK-2970 Hørsholm, Denmark. UK Office: ALK-Abelló Ltd, 1 Manor Park, Manor Farm Road, Reading, Berkshire, RG2 0NA Telephone 01189 037940.

Marketing authorisation number: PL10085/0003 and PL10085/0004. **Price:** 4 x 120µg venom + 4 vials 5ml albumin diluent pack £150.

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Item code 920V.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to ALK-Abelló Ltd

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