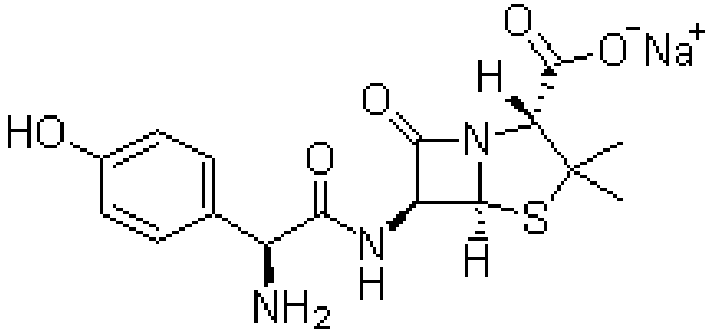
KIT DAP AMOXICILLIN

Description

Main allergenic determinants implicated in type I or immediate hypersensitivity to Amoxicillin and related antibiotics (amino penicillins), dosed and stabilized by means of freeze-drying. To be exclusively used for the diagnosis of type I or immediate hypersensitivity to amino penicillins and akin antibiotics (beta-lactams) by skin testing (skin prick test and intradermal reaction).

Composition

Sodium Amoxicillin



Quali-quantitatively AMOXICILIN KIT DAP composition is the following:

Vial with:	Sodium Amoxicillin	20 mg
	Manitol	20 mg
Vial with solvent:	Saline solution	
	Sodium chloride	9 mg
	Water for injection	q.s. 1 mL

Pharmaceutical presentation and packing content

Vials with freeze-dried powder and solvent for injectable solution.

- 3 or 6 vials with freeze-dried powder of Amoxicillin.
- 6 or 12 vials with solvent, each one of them containing 1 mL of saline solution.

Activity

For diagnostic use in type I hypersensitivity to amoxicillin and akin antibiotics (beta-lactams).

Proprietary and manufacturer

Diater Laboratorio de Diagnóstico y Aplicaciones Terapéuticas S. A. Calle Gregorio Peces Barba nº 2; Parque Tecnológico de Leganés 28918 Leganés. (Madrid) Spain.
Telephone: +34 91 496 60 13
Fax: +34 91 496 60 12
E-mail: diater@diater.com

Indications

Diagnostic assessment by skin testing (skin prick test and intradermal reaction), of allergic, sensitization, or type I hypersensitivity conditions in which allergy to beta-lactam antibiotics is suspected.

Contraindications

Any pathologic dermal condition of the area chosen to perform skin testing, as well as any other pathologic condition affecting the general well-being of the patient constitute a contraindication for carrying out skin testing.

An ongoing acute allergic reaction due to any kind of allergenic substance is a contraindication for carrying out skin testing.

Antihistamines, corticosteroids, cromones, and in general any other medication having a secondary anti-allergic activity have to be discontinued for at least 1 week before skin testing.

Therapeutic use of beta-blockers and ACE inhibitors is also a contraindication for carrying out skin testing, so for in agreement with the prescribing physician and adequate blood pressure control, these medications have to be discontinued 48 hours before skin testing.

Pregnancy, breastfeeding and in general a patient's age younger than 6 years represent a contraindication for carrying out skin testing, although they are left to the specialist's criterion who will determine the convenience and the timing for diagnostic skin evaluation according to the risk-benefit ratio of any given situation.

Contraindications derived from adrenalin administration have to be considered before the potential occurrence of a secondary allergic reaction.

Precautions

Skin testing with Amoxicillin should be started by assessing the skin reactivity by the skin prick test technique. The use of intradermal testing should only be started when skin prick tests have yielded negative results.

Skin testing should always be started with skin prick test with Amoxicillin. Preventively, it is recommended to start with the application of a dilution panel, 1:100 and 1:10, before performing intradermal testing.

In high-risk patients or patients with symptoms suggestive of a severe reaction, dilutions for skin testing should be started with the 1:1000 dilution.

The following algorithm for assessing the sensitivity to penicillin determinants is recommended when using skin testing:

Amoxicillin skin prick test ===➔Positive

(Recommended dilution 1:10)

⇓

Negative

⇓

Amoxicillin skin prick test ===➔Positive

(Without dilution)

⇓

Negative

⇓

Amoxicillin intradermal testing===➔ Positive

(Recommended dilution 1:100)

⇓

Negative

⇓

Amoxicillin intradermal testing ===➔ Positive

(Recommended dilution 1:10)

⇓

Negative

⇓

Amoxicillin intradermal testing ===➔ Positive

(Without dilution)

⇓

Negative

Dilutions must be carried out observing the required appropriate aseptic conditions and using the solvents that may be ordered for this purpose.

Interactions

Antihistamines, corticosteroids, cromones, and in general any other medication having a secondary anti-allergic activity present an interacting capacity that may alter the results obtained from skin testing. In the particular case of oral antihistamines, it is required to discontinue their use 1 week before the skin assessment.

The use of beta-blockers or ACE inhibitors should be discontinued 48 hours before skin testing, always in agreement with the prescribing physician and adequate blood pressure control.

Warnings

Performance of skin testing during pregnancy is not recommended given the additional risk that the potential induction of an anaphylactic reaction may represent.

After carrying out the skin tests, the patient must remain under close supervision for at least 30 minutes. Besides, the patient should be advised to avoid alcohol consumption, hard physical exercising, and receiving hot baths or showers within several hours before and after skin testing.

Given the case that a patient may be under allergen immunotherapy treatment, it is recommended that skin testing be performed with at least a 1-week interval since the administration of the last allergen vaccine shot. Similarly, the time interval between skin testing and the administration of an allergen vaccine shot should be of 2-3 days.

Instructions for use

Preparation of diagnostic solutions for skin testing

Select and check the sell-by dates and the state of the vials that will be reconstituted. Under sterility conditions and with sterile syringe and needle, 1 mL of solvent will be drawn and transferred to the vial with Amoxicillin freeze-dried powder that will be reconstituted, being thus prepared for immediate use.

Skin testing by the skin prick test technique

The skin prick test is one of the most common tests used to assess most of the allergic conditions with the lowest risk for anaphylaxis. This skin test, virtually free from an irritant effect, is carried out by applying one drop of the allergenic determinant on the volar aspect of the patient's forearm skin and the epidermis is punctured perpendicularly with a special 1-mm long pointed lancet allowing in this way the solution to penetrate the skin, the excess of fluid being cleared immediately after.
In no case, the result of the skin test should be read if blood springs. The occurrence of a small erythematous area around the puncture site is common.

Skin testing by the intradermal technique

Intradermal testing consists in the administration of a dose of about 0.02-0.05 mL of the allergenic determinant into the dermis. For this purpose, a tuberculin syringe with a 4/10 gauge needle is used applying it onto the

volar aspect of the patient's forearm at a 10-15 degrees angle, thus creating a small blister which diameter must be delineated at the beginning of the test.

Care should be applied not to damage a blood vessel when performing the test; should this occur, the result would not be assessed.

Patient's conditions during skin testing

Although no special skin care is necessary before skin testing, the presence of dermographism should be assessed and the puncture site must be cleaned, preferably with water without hard rubbing.

Before skin testing, the patient should adjust to ambient conditions for 10 minutes.

Reading and interpreting the skin test results

Definitive skin test results must be read within 15-20 minutes from their puncture, being regularly observed.

The interpretation of skin prick test results is based on the wheal size induced, being considered as positive those tests with a wheal diameter of 3 mm or higher, or the appearance of pseudopodia around the wheal; the following assessment key may be applied:

Major wheal diameter	Skin test interpretation
≤ 3 mm	Negative
> 3 mm	Positive

For intradermal testing, the test is considered positive when the difference between the initial diameter and the induced diameter is greater than 3 mm.

Supervision and control of the patient are paramount during the development of the skin responses and until their reading in order to be able to immediately intervene provided that any kind of adverse reaction, either local or systemic, may occur.

Overdosing

In case of accidental overdosing, or incorrect skin test performance, usually damage of a blood vessel with subsequent endovenous administration, an adverse reaction of varying severity, including anaphylaxis, may develop, which treatment is detailed under "adverse reactions".

Adverse reactions

Adverse reactions may be immediate or delayed in nature, depending on the time of symptoms occurrence, seconds or minutes and hours, respectively, after skin testing, and they may classified as:

Local reactions

From a symptomatic viewpoint, they consist in the development and persistence of erythema, oedema, or inflammation, with or without itching, at the site of skin testing; they usually occur within 10-60 minutes and persist for several hours.

They usually do not require pharmacological treatment, although the use of oral antihistamines and/or topical corticosteroid-based creams may be recommended when the induration persists and is greater than 5 cm in diameter. The use of a tourniquet above the skin test site and adjacent adrenaline injection (1:1000 at a 0.01-mL/Kg of body weight dose S.C.) are recommended in the case of severe local reactions.

Moderate systemic reactions

From a symptomatic viewpoint, they consist in the development of big sized wheals, erythema, and itching, which may progress to generalized urticarial or exanthematous reaction together with ocular-nasal symptoms and Quincke's oedema. The symptoms usually occur within few minutes to 4-6 hours after skin testing.

A tourniquet must be applied above the puncture site and basic pharmacological therapy must be immediately implemented. In the case of occurrence of urticaria or Quincke's oedema, the management consists in the administration of I.V. antihistamines and additionally I.V. corticosteroids (100 mg of prednisolone or equivalent doses of other glucocorticoids). In case of necessary, adrenaline (1:1.000; at a 0.01-mL/Kg of body weight dose, S.C.) may be administered adjacent to the skin test puncture site, which may be repeated every 15 minutes; as well as the use of bronchodilating aerosols and slow theophylline I.V. infusion.

The patient's arterial blood pressure and pulse must be constantly monitored.

Severe systemic reactions: anaphylaxis

The main presentations of severe systemic reactions, which may develop within few minutes after skin testing, are bronchospasm, breathlessness, laryngeal oedema, and generalized urticaria.

Their management comprises applying a tourniquet above the site of skin test puncture and immediate adrenaline administration (1:1.000; at a 0.01-mL/kg of body weight dose, subcutaneously or intramuscularly) adjacent to the puncture site, which may be repeated every 15 minutes in case of necessary. Also required is the administration of oral or I.M. antihistamines

as well as high-dose corticosteroids (250-1000 mg of I.V. prednisolone) if marked malaise or oedema develop. If respiratory compromise, such as severe or refractory bronchospasm, onsets or coexists, beta-agonists bronchodilators and I.V. aminophylline (250-500 mg in adults and 5-7 mg/Kg of body weight in children, q.d.) must be administered.

The patient's arterial blood pressure and pulse must be constantly monitored.

Anaphylaxis may develop immediately and sequentially few minutes after having performed skin testing. It usually presents with prodromal symptoms such as itching on the palms of the hands and feet, as well as above and under the tongue, also affecting the throat and leading to intense and rapid collapse that involves several organ systems: Vascular collapse with marked hypotension; nasal congestion, laryngeal oedema and bronchospasm; generalized itching, urticaria and angioedema; abdominal cramps, nausea, vomiting and loose stools; metrorrhagia; tinnitus, dizziness; loss of sphincter control; seizures, and loss of consciousness.

The management comprises applying a tourniquet above the site of skin test puncture, positioning the patient in lateral recumbent position, and administering adrenaline (1:1.000; at a 0.01-mL/kg of body weight dose, subcutaneously or intramuscularly) that may repeated every 10-15 minutes up to three times. If cardiac monitoring of the patient is available, adrenaline 1:1000 may be administered I.V. in a 1:10 dilution, which can be repeated every 10-15 minutes up to three times, depending on the patient's clinical course. Oxygen and endovenous fluids with electrolytic solutions may be considered depending on the patient's clinical course, as well as I.V. antihistamines and high-dose corticosteroids (250-1000 mg of prednisolone). If asthma develops, beta-agonists bronchodilators and I.V. aminophylline (250-500 mg in adults and 5-7 mg/Kg of body weight in children, q.d.) must be administered. Under certain circumstances and for reanimating purposes in case of circulatory failure, intubation or tracheotomy must be foreseen and be ready for immediate use.

The patient's arterial blood pressure and pulse must be constantly monitored.

Preservation

The vials with Amoxicillin freeze-dried powder must be stored at a temperature below 25º C.

Once reconstituted or diluted, they must be cold stored at 5 ± 3º C.

Medications should be stored away from children's reach and sight.

Sell-by date

Do not use the vials with freeze-dried powder or solvent after the sell-by date indicated on the label.

After the vials have been reconstituted or diluted, they must be used within the next 24 hours, maximum.

Text revised in: Juny of 2009