1. NAME OF THE MEDICINAL PRODUCT

PNEUMO 23, solution for injection in prefilled syringe

Polysaccharide pneumococcal vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Single dose presentation

Polysaccharides of Streptococcus pneumoniae serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F 25 µg for each of the 23 serotypes,

Per 0.5 ml

Cf. 6.1 for the excipients.

3. PHARMACEUTICAL FORM

Solution for injection in a pre-filled syringe.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

The vaccine is indicated for the prevention of pneumococcal infections, in particular pneumonia, caused by the serotypes contained in the vaccine, for subjects at risk, from the age of 2 years People at risk who should be vaccinated are determined in accordance with official recommendations.

The safety and efficacy of the vaccine have not been established in children under 2 years of age in whom the antibody response may be limited.

This vaccine is not efficacious in the prevention of acute otitis media, sinusitis and other common infections of the upper respiratory tract.

4.2. Posology and method of administration

Posology

Adult population

Primary vaccination: injection of a dose of 0.5 ml.

Revaccination: injection of a dose of 0.5 ml.

Paediatric population

The posology used for the paediatric population is the same as that used for the adult population.

Revaccination

On the basis of current knowledge, the systematic revaccination of subjects who have received primary vaccination is not recommended. The timescale and need for revaccination should be determined in accordance with official recommendations.

Method of administration

Administration by the intramuscular (IM) route is preferable. The subcutaneous (SC) route may also be used.

4.3. Contraindications

Known hypersensitivity to any of the components of the vaccine or previous hypersensitivity following the injection of the same vaccine or a vaccine with a similar composition.

As with other vaccines, the administration of this vaccine should be postponed in subjects with severe acute infections. The presence of a benign infection is not a contraindication.

4.4. Special warnings and special precautions for use

Administration of the pneumococcal vaccine is recommended at least 2 weeks prior to splenectomy or the start of immunosuppressive treatment (chemotherapy or other treatment).

The immunogenicity of the vaccine may be reduced by immunosuppressive treatment. In this case, vaccination should be postponed until immunosuppressive treatment has finished.

In subjects with chronic immunodeficiency, such as infection with the AIDS virus, vaccination is however recommended although the antibody response may be limited.

A previous pneumococcal infection, whether confirmed or suspected, is not a contraindication to vaccination and this should be considered.

PNEUMO 23 is not generally recommended for people who have been vaccinated within the last 3 years, unless there are specific reasons for considering revaccination.
Do not administer this vaccine by the intravascular route.

The vaccine must be administered gradually and with caution, in order to limit any risk of haematoma in patients receiving anticoagulant treatment or with blood disorders such as haemophilia or thrombocytopenia.

Vaccination must be carefully reconsidered in patients in whom serious to severe reactions have previously occurred, within 48 hours following the injection of a vaccine with a similar composition.

As with any vaccine, appropriate treatment and medical supervision should always be available in case of an unexpected anaphylactic reaction or a serious allergic reaction.

4.5. Interaction with other medicinal products and other forms of interaction

Adult population

This vaccine may be administered simultaneously with an influenza vaccine using separate injection sites and different syringes.

Paediatric population

Concomitant administration of PNEUMO 23 with other paediatric vaccines has not been documented.

4.6. Pregnancy and breast-feeding

Fertility

No fertility studies were performed.

Pregnancy

No reliable data on teratogenesis in animal species are available.

In clinical use, there are currently no sufficiently relevant data to evaluate a possible effect associated with malformations or foetal toxicity if this vaccine is administered during pregnancy.

As a precautionary measure, avoid prescribing this vaccine to pregnant women except in high-risk situations.

Lactation

This vaccine may be used during lactation.

4.7. Effects on ability to drive and use machines

No studies of the effects on the ability to drive and use machines have been performed.

4.8. Undesirable effects

The following undesirable effects have been reported with PNEUMO 23, based on spontaneous post-marketing reports.

These effects, the exact incidence of which cannot be calculated exactly, have been reported in very rare cases (<1/10 000).

The most frequent undesirable effects reported are fever and local reactions at the injection site.

Blood and lymphatic system disorders

- Lymphadenopathy

Nervous system disorders

- Headaches
- Febrile convulsions, particularly in the paediatric population

Skin and subcutaneous tissue disorders

- Rash, urticaria

Musculoskeletal and connective tissue disorders

- Myalgia, arthralgia

Infections and infestations

- Cellulitis at the injection site

General disorders and administration site conditions

- Injection site reactions such as pain, erythema, induration and oedema: these local reactions are generally mild and transient. Peripheral oedemas of the vaccinated limb have also been reported.
- Pirexia. Febrile episodes of moderate intensity generally occur soon after vaccination. They resolve within 24 hours. Fever above 39°C has also been reported.
- Asthenia, fatigue, malaise.

Immune system disorders

- Arthus-type reaction: these reversible reactions, without sequelae, are more likely to appear in patients with an initially high level of anti-pneumococcal antibodies.
- Acute hypersensitivity reactions, including anaphylactic shock.

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Purified polysaccharide pneumococcal antigens,

ATC Code: J07A L01

PNEUMO 23 contains 23 serotypes of Streptococcus pneumoniae, responsible for at least 90% of invasive pneumococcal infections.

The immune response is thymo-independent. It is characterised by low immunogenicity in young children under 2 years of age and by the absence of a booster effect after repeated injections.

Immunity appears 2 to 3 weeks after the injection.

5.2. Pharmacokinetic properties

No pharmacokinetic studies have been performed.

5.3. Preclinical safety data

Toxicity studies in animals (acute, sub-acute and chronic toxicity) indicate that there is no toxic effect and no target organ toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipient(s)

Phenolated buffer solution containing phenol, sodium chloride, dihydrated disodium hydrogen phosphate, dihydrated monosodium dihydrogen phosphate and water for injectable preparations.

6.2 Incompatibilities

In the absence of compatibility studies, the vaccine should not be mixed with other medicinal products or vaccines.

6.3 Shelf-life

2 years.

6.4. Special precautions for storage

Store in a refrigerator (2°C - 8°C). Do not freeze.

6.5. Nature and contents of container

Single dose presentation

0.5 ml of solution in a prefilled syringe, (glass) equipped with a plunger stopper (bromobutyl or chlorobutyl or bromochlorobutyl), box of 1 or 20.

6.6 Instructions for use and handling

Before use, the vaccine should be kept at room temperature for a few minutes.

Shake before use.

Any unused product or waste material should be disposed of in accordance with local requirements.

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69007 Lyon

License Holder:
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