

## **PNEUMO 23** *Sanofi-Pasteur*

### **Composition**

Polysaccharide 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 of each of the 23 serotypes for 0.5 ml

Phenol buffer solution (up to pH = 6.9) containing phenol, sodium chloride, disodium phosphate dihydrate, monosodium phosphate dihydrate and water for injections.

### **Pharmaceutical Dosage Form**

Solution for injection in a prefilled syringe (0,5 ml).

### **Indications**

This vaccine is indicated for the prevention of pneumococcal infections, in particular pneumonia, from the age of 2 years for: subjects older than 65 years of age, particularly elderly persons living in institutions, frail subjects who are immuno-competent, subjects who are likely to be frequently hospitalized (diabetes, chronic bronchitis, respiratory insufficiency, heart failure, tobacco/alcohol dependency...), immunocompromised subjects (splenectomized subjects, subjects with sickle cell disease, nephrotic syndrome), and subjects with a cerebrospinal fluid leak.

### **Contraindications**

This medicinal product **MUST NOT BE USED** in the following cases:

- in the case of fever, acute disease, or relapse of chronic disease, it is preferable to postpone vaccination.
- true allergy to one of the ingredients of the vaccine
- during the first three months of pregnancy, unless advised otherwise by your doctor.

Vaccination is not recommended for subjects who have been vaccinated within the previous 3 years unless indicated otherwise. A confirmed or suspected episode of pneumococcal infection is not a contraindication and vaccination should be considered according to the underlying risk status.

If there is any doubt, it is essential to consult the doctor or the pharmacist.

### **Side Effects**

Like any active product, this medicinal product may in certain persons cause effects which are disturbing to a greater or lesser extent:

- Local reactions at the injection site: pain, erythema (redness), induration and oedema (swelling); these reactions are mild and transient.
- Rare reactions such as the Arthus phenomenon (severe local reactions) are reversible without after-effects; they mainly occur in subjects with high initial levels of pneumococcal antibody.
- Moderate and transient fever, sometimes above 39°C. This fever generally occurs very soon after vaccination and disappears within 24 hours.
- Other systemic reactions such as adenopathy (inflammation of the lymph nodes), rashes, arthralgia (pain in the joints) and allergic reactions (urticaria, Quincke's oedema [type of urticaria with sudden swelling of the face and neck], anaphylactoid reactions) have exceptionally been reported. Report to the doctor or to the pharmacist any unwanted and disturbing effects which might not be mentioned in this medical reference book.

### **Precautions**

If there is any doubt, do not hesitate to consult the doctor or the pharmacist.

Keep out of the reach of children.

### **Pregnancy and Lactation**

This medicinal product should only be used during the last three months of pregnancy on medical advice.

Breast feeding is compatible with vaccination with this medicinal product.

As a general rule, during pregnancy and breast feeding, it is always recommended to ask your doctor's or pharmacist's advice before using a medicinal product.

## **Storage**

Do not exceed the expiry date stated on the external packaging.

This medicinal product should be stored at a temperature of between +2°C and +8°C (in a refrigerator).

Do not freeze.

## **Drug Interactions**

In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to the doctor or to the pharmacist

## **Dosage and Administration**

Primary vaccination: one 0.5 ml injection.

Revaccination: one 0.5 ml injection.

## **Mode and Route of Administration**

- Administer preferably by the intramuscular route or subcutaneous route.
- In all cases, follow the doctor's prescription strictly