

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

## 2. BEFORE YOU USE PNEUMO 23

It is important that you tell your doctor or pharmacist if any of the points mentioned below applies to you or your child.

If there is anything that you do not understand, ask your doctor or pharmacist for advice.

### Do not use PNEUMO 23:

- If you or your child are allergic to the active substances or to any of the components in PNEUMO 23 (see Section 6, "Further Information") or if you or your child developed an allergic reaction following a previous injection of PNEUMO 23 or a vaccine with a similar composition,
- if you or your child have an infection with a high temperature. In this case, vaccination should be postponed until you or your child have recovered.

### Take special care with PNEUMO 23:

- This vaccine must not be injected into a blood vessel.
- If you or your child are going to have your spleen removed (splenectomy) or are going to start any treatment which reduces immunity (chemotherapy or other treatment), it is preferable to receive the vaccine at least two weeks beforehand.
- If you or your child are taking any treatment that reduces immunity, the immune response may be reduced by that treatment, and your doctor will decide whether vaccination should be postponed until you have finished the treatment.
- If you or your child suffer from permanently impaired immunity (chronic immunodeficiency), such as AIDS, your doctor may recommend vaccination, even with a limited immune response.
- If you or your child have had a confirmed or suspected pneumococcal infection, pneumococcal vaccination is not contraindicated and your doctor may decide to vaccinate you.
- If you or your child have been vaccinated within the last 3 years, PNEUMO 23 is not generally recommended. If there is a specific reason, your doctor may then decide that you should be revaccinated strictly in accordance with the indications set out in Section 3 "How to use PNEUMO 23".
- If you or your child have any blood disorders (such as haemophilia or an abnormally low platelet level (thrombocytopenia)), or if you or your child are taking a treatment to thin the blood (anticoagulant).
- Before vaccination, your doctor will ask you questions about yourself or your child: state of health, personal and family vaccination history and appearance of any side effects following previous vaccinations.

If you or your child have previously had any major allergic reactions (serious to severe) within 48 hours of the injection of a vaccine with a similar composition, your doctor will carefully reconsider vaccination.

### Using other medicines

- In adults, this vaccine may be administered simultaneously with an influenza vaccine using separate injection sites and different syringes.
- In children, the administration of PNEUMO 23 with other paediatric vaccines has not been documented.

Please tell your doctor or pharmacist if you or your child are taking or have recently taken any other medicines, including a medicine available without a prescription.

### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicines.

### Pregnancy

- In animals, there are no data concerning possible risks of malformations.
- In humans, there are no sufficiently relevant data enabling the assessment of possible risks of malformations or foetal toxicity related to the administration of the vaccine during pregnancy.

# PNEUMO 23

solution for injection in prefilled syringe

## POLYSACCHARIDE PNEUMOCOCCAL VACCINE

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions or if you have a doubt, ask your doctor or pharmacist, for more information.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if the symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

1. WHAT PNEUMO 23 IS AND WHAT IT IS USED FOR
2. BEFORE YOU USE PNEUMO 23
3. HOW TO USE PNEUMO 23
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE PNEUMO 23
6. FURTHER INFORMATION

### 1. WHAT PNEUMO 23 IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Purified polysaccharide pneumococcal antigens.

This product is a vaccine indicated for the prevention of pneumococcal pneumonia and any other serious pneumococcal infection (such as septicæmia or meningitis) caused by the types of pneumococci (*Streptococcus pneumoniae*) contained in the vaccine. PNEUMO 23 is particularly indicated in subjects over 2 years of age with an increased risk of pneumococcal infection or associated complications. People at risk who need to be vaccinated are determined in accordance with official recommendations.

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

### **Breastfeeding**

This vaccine can be used during breast-feeding.

### **Driving and using machines**

The effects on the ability to drive and use machines have not been studied.

## **3. HOW TO USE PNEUMO 23**

### **Dosage**

You or your child will receive a dose of 0.5 ml as an injection for the first vaccination (primary vaccination).

### **Method of administration**

Administration by the intramuscular (IM) route is preferable.

The subcutaneous (SC) route may also be used.

### **Frequency of administration**

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

If revaccination is necessary, you or your child will receive a dose of 0.5 ml per injection.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, PNEUMO 23 can cause side effects, although not everybody gets them.

### **Allergic reactions**

You should seek urgent medical assistance if you or your child develop any of the symptoms listed below, or any other serious symptoms following the vaccination:

- Difficulty in breathing, a blue tongue or blue lips,
- Low blood pressure (which causes dizziness) and fainting,
- Fever, feeling generally unwell with pain or even inflammation, swelling of the joints and muscular pain,
- Swelling of the face, lips, tongue and/or throat and neck,
- Swelling of the hands, feet or ankles,
- Urticaria (inflamed bumps on the skin) and a rash.
- If an allergic reaction appears, this generally happens very soon after the injection, while the patient is still in the doctor's surgery.

### **Side effects**

The following side effects have been reported with PNEUMO 23, based on spontaneous post-marketing reports. It is not possible to calculate exactly how frequently they occur.

These side effects have been reported in very rare cases (less than 1 person in every 10 000).

Of these side effects, fever and local reactions at the injection site are the most frequent.

- Swollen glands (lymphadenopathy).
- Headaches.
- Convulsions following a high fever (febrile convulsions), especially in children.
- Generalised skin eruption (rash), urticaria.
- Muscular pain (myalgia), joint pain (arthralgia).
- Inflammation of a deep layer of the skin (cellulitis) at the injection site.
- Reaction at the injection site such as: pain, redness, swelling and hardening.
- Swelling of the vaccinated limb.
- Fever.
- Feeling of tiredness.
- Feeling generally unwell.
- Local inflammatory reaction around the injection site (Arthus-type reaction): pain, swelling, hardening (induration), which may be intense. These reactions

are reversible, have no lasting effects and generally appear in people who have an initially high level of anti-pneumococcal antibodies.

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

## **5. HOW TO STORE PNEUMO 23**

Keep out of reach and sight of children.

Do not use after the expiry date shown on the label and on the box.

Store between +2°C and +8°C (in a refrigerator).

Do not freeze.

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

## **6. FURTHER INFORMATION**

**The active substances are:** 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 micrograms of each of the 23 serotypes, per 0.5 ml dose).

**The other ingredients are:** a phenolated buffer solution containing phenol, sodium chloride, dihydrated disodium phosphate, dihydrated monosodium phosphate, and water for injections.

### **What PNEUMO 23 looks like and content of the pack**

PNEUMO 23 is a solution for injection in pre-filled syringe (0.5 ml).

### **Marketing Authorization Holder**

**SANOFI PASTEUR SA** - 2 avenue Pont Pasteur - 69007 LYON - FRANCE

This leaflet was last approved in: 10/2011.

**The following information is intended for medical or healthcare professionals only:**

The vaccine must be left at room temperature for several minutes prior to use.

- Shake before use.
- Do not administer via the intravascular route.
- Anyone responsible for the injection of a biological product must take all the usual precautions in order to avoid any allergic or other reactions. As with any injectable vaccine, appropriate medical treatment and medical supervision should always be available in case of an anaphylactic reaction.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.