Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Inactivated Influenza Vaccine (Split Virion) for Paediatric use, suspension for injection in prefilled syringe.

Influenza vaccine (split virion, inactivated).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus (inactivated, split) of the following strains*:

- A/California/7/2009 (H1N1)pdm09-derived strain used (NYMC X-179A) 7.5 micrograms HA**
- A/Texas/50/2012 (H3N2)-derived strain used (NYMC X-223A)..... ...7.5 micrograms HA**
- B/Massachusetts/2/2012..... 7.5 micrograms HA**

Per 0.25 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2014/2015 season.

For a full list of excipients, see section 6.1.

Inactivated Influenza Vaccine (Split Virion) for Paediatric Use may contain traces of eggs, such as ovalbumin, and of neomycin, formaldehyde and octoxinol-9, which are used during the manufacturing process (see section 4.3).

3 PHARMACEUTICAL FORM

Suspension for injection in prefilled syringe.

The vaccine, after shaking gently, is a slightly whitish and opalescent liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prophylaxis of influenza, especially in those who run an increased risk of associated complications.

Inactivated Influenza Vaccine (Split Virion) For Paediatric Use is indicated in children from 6 to 35 months of age.

The use of Inactivated Influenza Vaccine (Split Virion) For Paediatric Use should be based on official recommendations.

4.2 Posology and method of administration

Posology

Children from 6 months to 35 months: clinical data are limited. Dosages of 0.25 ml or 0.5 ml may be given. The dose given should be in accordance with the existing national recommendations.

For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Children less than 6 months: the safety and efficacy of Inactivated Influenza Vaccine (Split Virion) BP For Paediatric Use in children less than 6 months have not been established. No data are available.

Method of administration

Immunisation should be carried out by intramuscular or deep subcutaneous injection.

Precautions to be taken before handling or administering the medicinal product

For instructions for preparation of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9.

Immunisation shall be postponed in children with febrile illness or acute infection.

4.4 Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Inactivated Influenza Vaccine (Split Virion) For Paediatric Use should under no circumstances be administered intravascularly.

Antibody response in children with endogenous or iatrogenic immunosuppression may be insufficient.

Interference with serological testing

See section 4.5.

4.5 Interaction with other medicinal products and other forms of interaction

Inactivated Influenza Vaccine (Split Virion) BP For Paediatric Use may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the child is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.6 Fertility, pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

ADVERSE REACTIONS OBSERVED FROM CLINICAL TRIALS:

The safety of trivalent inactivated influenza vaccines is assessed in open label, uncontrolled clinical trials performed as annual update requirement, including at least 50 adults aged 18 – 60 years of age and at least 50 elderly aged 61 years or older. Safety evaluation is performed during the first 3 days following vaccination.

The following undesirable effects have been observed during clinical trials with the following frequencies:

Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100).

Organ class	**Very common ≥1/10**	**Common ≥1/100, <1/10**	**Uncommon ≥1/1,000, <1/100**
Nervous system disorders		Headache*	
Skin and subcutaneous tissue disorders		Sweating*	
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia*	
General disorders and administration site conditions		Fever, malaise, shivering, fatigue. Local reactions: redness, swelling, pain, ecchymosis, induration*	

* These reactions usually disappear within 1−2 days without treatment.

ADVERSE REACTIONS REPORTED FROM POST MARKETING SURVEILLANCE:

Adverse reactions reported from post marketing surveillance are, next to the reactions which have also been observed during the clinical trials, the following:

Blood and lymphatic system disorders:

Transient thrombocytopenia, transient lymphadenopathy

Immune system disorders:

Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders:

Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome

Vascular disorders:

Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders:

Generalized skin reactions including pruritus, urticaria or non specific rash

4.9 Overdose

Overdosage is unlikely to have any untoward effect.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC code: J07BB02

Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologuous strains or to strains closely related to the vaccine strains varies but is usually 6−12 months.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Buffer solution:

- Sodium chloride
- Potassium chloride
- Disodium phosphate
- Potassium dihydrogen phosphate
- Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

1 year.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

6.5 Nature and contents of container

0.25 ml of suspension in prefilled syringe (type I glass) with attached needle, equipped with a plunger stopper (elastomer chlorobromobutyl or chlorobutyl or bromobutyl) – pack size of 1, 10 or 20.
0.25 ml of suspension in prefilled syringe (type I glass) without needle, equipped with a plunger stopper (elastomer chlorobromobutyl or chlorobutyl or bromobutyl) – pack size of 1, 10 or 20.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

The vaccine should be allowed to reach room temperature before use.
Shake before use. Inspect visually prior to administration.
The vaccine should not be used if foreign particles are present in the suspension.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi Pasteur MSD Limited

Block A, Second Floor
Cookstown Court, Old Belgard Road
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 544/034/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 April 1999

Date of last renewal: 30 December 2007

10 DATE OF REVISION OF THE TEXT

August 2014