

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE MEDICINAL PRODUCT

Infanrix penta – Suspension for injection

Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 ml) contains:

|  |                     |
|--|---------------------|
| Diphtheria toxoid <sup>1</sup>             | not less than 30 IU |
| Tetanus toxoid <sup>1</sup>                | not less than 40 IU |
| <i>Bordetella pertussis</i> antigens       |                     |
| Pertussis toxoid <sup>1</sup>              | 25 micrograms       |
| Filamentous Haemagglutinin <sup>1</sup>    | 25 micrograms       |
| Pertactin <sup>1</sup>                     | 8 micrograms        |
| Hepatitis B surface antigen <sup>2,3</sup> | 10 micrograms       |
| Poliovirus (inactivated)                   |                     |
| type 1 (Mahoney strain)                    | 40 D-antigen unit   |
| type 2 (MEF-1 strain)                      | 8 D-antigen unit    |
| type 3 (Saukett strain)                    | 32 D-antigen unit   |

<sup>1</sup>adsorbed on aluminium hydroxide, hydrated (Al(OH)<sub>3</sub>) 0.95 milligrams Al<sup>3+</sup>

<sup>2</sup>produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology

<sup>3</sup>adsorbed on aluminium phosphate (AlPO<sub>4</sub>) 0.90 milligrams Al<sup>3+</sup>

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Suspension for injection

Infanrix penta is a turbid white suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Infanrix penta is indicated for primary and booster vaccination of infants against diphtheria, tetanus, pertussis, hepatitis B and poliomyelitis.

Infanrix penta is not intended for use in children over 36 months of age.

### 4.2 Posology and method of administration

#### Posology

##### Primary vaccination:

The primary vaccination schedule (such as 2, 3, 4 months; 3, 4, 5 months; 2, 4, 6 months; 3, 5 and 11 or 12 months) consists of three doses of 0.5 ml. There should be an interval of at least 1 month between doses.

The Expanded Program on Immunisation schedule (at 6, 10, 14 weeks of age) may only be used if a dose of hepatitis B vaccine has been given at birth.

Locally established immunoprophylactic measures against hepatitis B should be maintained.

Where a dose of hepatitis B vaccine is given at birth, Infanrix penta can be used for the second dose from the age of six weeks. If a second dose of hepatitis B vaccine is required before this age, monovalent hepatitis B vaccine should be used.

#### Booster vaccination:

The administration of the booster dose should be based on official recommendations. Infanrix penta can be used for the booster dose provided that the infant has received a full primary vaccination course of each of the antigens contained in Infanrix penta regardless of whether these were administered as monovalent or combination vaccines.

Other combinations of antigens have been studied in clinical trials following primary vaccination with Infanrix penta and may be used for a booster dose: diphtheria, tetanus, acellular pertussis (DTPa), diphtheria, tetanus, acellular pertussis, *Haemophilus influenzae* type b (DTPa/Hib), diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, *Haemophilus influenzae* type b (DTPa-IPV/Hib) and diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliomyelitis, *Haemophilus influenzae* type b (DTPa-HBV-IPV/Hib). In these clinical trials, infants received Hib vaccine simultaneously with Infanrix penta as primary vaccination.

#### **Method of administration**

Infanrix penta is for deep intramuscular injection, preferably at alternating sites for subsequent injections.

#### **4.3 Contraindications**

Hypersensitivity to the active substances or to any of the excipients or neomycin and polymyxin.

Hypersensitivity after previous administration of diphtheria, tetanus, pertussis, hepatitis B or polio vaccines.

Infanrix penta is contra-indicated if the infant has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis containing vaccine. In these circumstances pertussis vaccination should be discontinued and the vaccination should be continued with diphtheria-tetanus, hepatitis B and polio vaccines.

As with other vaccines, administration of Infanrix penta should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection is not a contra-indication.

#### **4.4 Special warnings and precautions for use**

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable events) and a clinical examination.

If any of the following events are known to have occurred in temporal relation to receipt of pertussis-containing vaccine, the decision to give further doses of pertussis-containing vaccines should be carefully considered:

Temperature of  $\geq 40.0$  C within 48 hours, not due to another identifiable cause.

Collapse or shock-like state (hypotonic-hyporesponsiveness episode) within 48 hours of vaccination.

Persistent, inconsolable crying lasting  $\geq 3$  hours, occurring within 48 hours of vaccination.

Convulsions with or without fever, occurring within 3 days of vaccination.

There may be circumstances, such as a high incidence of pertussis, when the potential benefits outweigh possible risks.

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

Infanrix penta should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Infanrix penta should under no circumstances be administered intravascularly.

The hepatitis B component of the vaccine will not prevent infection caused by other agents such as hepatitis A, hepatitis C and hepatitis E viruses and other pathogens known to infect the liver.

A history of febrile convulsions requires special attention. A family history of convulsions or a family history of Sudden Infant Death Syndrome (SIDS) does not constitute a contra-indication.

HIV infection is not considered as a contra-indication. The expected immunological response may not be obtained after vaccination of immunosuppressed patients.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Clinical studies have demonstrated that Infanrix penta can be administered simultaneously with *Haemophilus influenzae* type b vaccines. In these clinical studies, the injectable vaccines were given at different injection sites.

There are no data with regard to the efficacy and safety of simultaneous administration of Infanrix penta and Measles- Mumps-Rubella vaccine.

As with other vaccines it may be expected that in patients receiving immunosuppressive therapy or patients with immunodeficiency, an adequate response may not be achieved.

#### **4.6 Pregnancy and lactation**

As Infanrix penta is not intended for use in adults, adequate human data on use during pregnancy or lactation and adequate animal reproduction studies are not available.

#### **4.7 Effects on ability to drive and use machines**

Not relevant.

#### **4.8 Undesirable effects**

- Clinical trials

Clinical trials involved the administration of over 22,400 doses of Infanrix penta to more than 7,500 healthy infants from 6 weeks of age as primary vaccination. More than 1,000 infants 12 to 24 months of age received a booster dose of Infanrix penta. In virtually all instances, Infanrix penta was administered at the same time as a HIB vaccine.

No increase in the incidence or severity of undesirable events was seen with subsequent doses of the primary vaccination series.

As has been observed for DTPa and DTPa-containing combinations, an increase in reactogenicity was reported after booster vaccination with Infanrix penta with respect to the primary course; however, the incidence of symptoms graded as severe was low.

Undesirable effects reported in two pivotal clinical trials (one primary immunisation and one booster trial) or reported during post marketing surveillance are listed here below per system organ class. For those symptoms reported both during clinical trials and during PMS, invariably the highest frequencies were under controlled clinical trial conditions.

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Frequencies are defined as follows:

Very common:  $\geq 10\%$   
Common:  $\geq 1\%$  and  $< 10\%$   
Uncommon:  $\geq 0.1\%$  and  $< 1\%$   
Rare:  $\geq 0.01\%$  and  $< 0.1\%$   
Very rare:  $< 0.01\%$

#### Infections and infestations

Common: infection, viral infection, moniliasis, otitis media, upper respiratory tract infection, pharyngitis  
Uncommon: sinusitis

#### Metabolism and nutrition disorders

Very common: loss of appetite

#### Psychiatric disorders:

Very common: restlessness, unusual crying

#### Nervous system disorders:

Common: sleepiness  
Uncommon: somnolence  
Very rare: convulsions

#### Eye disorders

Uncommon: conjunctivitis

#### Respiratory, thoracic and mediastinal disorders

Common: bronchitis, coughing, rhinitis, stridor  
Uncommon: respiratory disorder

#### Gastrointestinal disorders:

Very common: diarrhoea  
Common: vomiting, enteritis, gastro-enteritis

#### Skin and subcutaneous tissue disorders

Common: rash, dermatitis, eczema

#### General disorders and administration site conditions:

Very common: pain, redness, local swelling at the injection site ( $\leq 50$  mm), fever  $\geq 38^{\circ}\text{C}$   
Common: local swelling at the injection site ( $> 50$  mm)\*, influenza-like symptoms, fever  $>39^{\circ}\text{C}$   
Uncommon: diffuse swelling of the injected limb, sometimes involving the adjacent joint\*

- Post-marketing surveillance

#### Immune system disorders

Allergic reactions, anaphylactoid reactions (including urticaria)

#### Nervous system disorders:

Convulsions (with or without fever), collapse or shock-like state (hypotonic-hyporesponsiveness episode)

General disorders and administration site conditions:

Swelling of the entire injected limb\*

- Experience with hepatitis B vaccine:

Nearly 100 million doses of Engerix B 10 µg, GlaxoSmithKline Biologicals' hepatitis B vaccine, have been distributed for infants < 2 years old. In extremely rare cases, paralysis, neuropathy, Guillain-Barré syndrome, encephalopathy, encephalitis and meningitis have been reported. The causal relationship to the vaccine has not been established.

\* Children primed with acellular pertussis vaccines are more likely to experience swelling reactions after booster administration in comparison with children primed with whole cell vaccines. These reactions resolve over an average of 4 days.

#### **4.9 Overdose**

No case of overdose has been reported.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmaco-therapeutic group: Bacterial and viral vaccines combined, ATC code JO7CA

The tetanus and diphtheria toxoids are obtained by formaldehyde treatment of purified *Corynebacterium diphtheriae* and *Clostridium tetani* toxins. The acellular pertussis vaccine components are obtained by extraction and purification from phase I *Bordetella pertussis* cultures, followed by irreversible detoxification of the pertussis toxin by glutaraldehyde and formaldehyde treatment, and formaldehyde treatment of filamentous haemagglutinin and pertactin. The surface antigen of the HBV is produced by culture of genetically-engineered yeast cells (*Saccharomyces cerevisiae*) which carry the gene coding for the major surface antigen of the HBV and is highly purified. The diphtheria toxoid, tetanus toxoid, acellular pertussis and hepatitis B components are adsorbed onto aluminium salts.

The three polioviruses are cultivated on a continuous VERO cell line, purified and inactivated with formaldehyde.

The diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliomyelitis (DTPa-HBV-IPV) components are formulated in saline and contain phenoxyethanol.

Infanrix penta meets the World Health Organisation (WHO) requirements for manufacture of biological substances, of diphtheria, tetanus, pertussis and combined vaccines, of hepatitis B vaccines made by recombinant DNA techniques and of inactivated poliomyelitis vaccines.

Surveillance studies are ongoing and will provide additional information with regard to the duration of protection.

Results obtained in the clinical studies for each of the components are summarised below:

. DTPa component:

Immunological data:

One month after the 3-dose primary vaccination course, 98.4 to 100% of infants vaccinated with Infanrix penta had antibody titres of  $\geq 0.1$  IU/ml for both tetanus and diphtheria.

Following administration of a 4th dose of Infanrix penta in the second year of life, 98.8 to 100% of infants had antibody titres of  $\geq 0.1$  IU/ml for both tetanus and diphtheria.

One month after the 3-dose primary vaccination course, the overall response rate for each of the three individual pertussis antigens (pertussis toxoid, filamentous haemagglutinin, pertactin) was between 97.0-100%, 86.4-100% and 89.0-100%, respectively.

Following administration of a 4th dose of Infanrix penta in the second year of life, a booster response was seen in 95.3-100%, 93.2-100% and 91.9-100% of vaccinated infants against the respective pertussis antigens.

Since the serological correlation for protection against pertussis disease does not exist, the efficacy of the pertussis component presently relies on efficacy trials described just hereafter.

Protective efficacy data:

The clinical protection of the DTPa component, against WHO-defined typical pertussis ( $\geq 21$  days of paroxysmal cough) was demonstrated in:

- a prospective blinded household contact study performed in Germany (3, 4, 5 months schedule). Based on data collected from secondary contacts in households where there was an index case with typical pertussis, the protective efficacy of the vaccine was 88.7%.
- a NIH sponsored efficacy study performed in Italy (2, 4, 6 months schedule). The vaccine efficacy was found to be 84%. In a follow-up of the same cohort, the efficacy was confirmed up to 60 months after completion of primary vaccination without administration of a booster dose of pertussis.

Hepatitis B component:

After the primary vaccination course with Infanrix penta, 95.7 to 100% of infants developed protective antibody titres of  $\geq 10$  mIU/ml.

At one month after the booster dose, 96.5 to 100% of these subjects had protective titres of  $\geq 10$  mIU/ml.

Inactivated poliovirus (IPV) component:

One month after the primary vaccination, the seroprotection rates for each of the three serotypes (types 1, 2 and 3) were between 96.0-100%, 94.8-100% and 96.0-100% respectively.

Following administration of the booster dose, 94.4 to 100%, 100% and 100% of infants were seroprotected for the three serotypes, respectively.

## **5.2 Pharmacokinetic properties**

Evaluation of pharmacokinetic properties is not required for vaccines.

## **5.3 Preclinical safety data**

Non-clinical data reveal no special hazard for humans based on conventional studies of safety, specific toxicity, repeated dose toxicity and compatibility of ingredients.

## **6. PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Sodium chloride (NaCl)  
Phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

For adjuvants, see section 2.

## **6.2 Incompatibilities**

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

## **6.3 Shelf-life**

3 years.

Upon removal from the refrigerator, the vaccine is stable for 8 hours at 21°C.

## **6.4 Special precautions for storage**

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

Store in the original package, in order to protect from light.

## **6.5 Nature and contents of container**

0.5 ml of suspension in a prefilled syringe (type I glass) with plunger stoppers (butyl).

Pack sizes of 1, 10, 20 and 50 with or without needles.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal**

Upon storage, a white deposit and clear supernatant may be observed. This does not constitute a sign of deterioration.

The syringe should be well shaken in order to obtain a homogeneous turbid white suspension.

The DTPa-HBV-IPV suspension should be inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine.

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

## **7. MARKETING AUTHORISATION HOLDER**

GlaxoSmithKline Biologicals s.a.  
rue de l'Institut 89  
B-1330 Rixensart, Belgium

## **8. MARKETING AUTHORISATION NUMBER(S)**



EU/1/00/153/001  
EU/1/00/153/002  
EU/1/00/153/003  
EU/1/00/153/004  
EU/1/00/153/005  
EU/1/00/153/006  
EU/1/00/153/007  
EU/1/00/153/008

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

23/10/2000

**10. DATE OF REVISION OF THE TEXT**

**ANNEX II**

- A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCES  
AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE  
FOR BATCH RELEASE**
  
- B. CONDITIONS OF THE MARKETING AUTHORISATION**

**A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer(s) of the biological active substances

GlaxoSmithKline Biologicals s.a.  
Rue de l'Institut 89,  
1330 Rixensart  
Belgium

Chiron-Behring  
Postfach 1140  
3550 Marburg  
Germany

Name and address of the manufacturer responsible for batch release

GlaxoSmithKline Biologicals s.a.  
Rue de l'Institut 89,  
1330 Rixensart  
Belgium

**B. CONDITIONS OF THE MARKETING AUTHORISATION**

• **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription.

• **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable.

• **OTHER CONDITIONS**

The holder of the marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

Official batch release: in accordance with Article 114 of Directive 2001/83/EC as amended, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

The holder of marketing authorisation will continue to submit annual PSURs.

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 1  
PREFILLED SYRINGE WITHOUT NEEDLE**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta – Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
| Diphtheria toxoid <sup>1</sup>  | ≥ 30 IU                  |
| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
| <i>Bordetella pertussis</i> antigens<br>(Pertussis toxoid <sup>1</sup> , Filamentous haemagglutinin <sup>1</sup> , Pertactin <sup>1</sup> ) | 25, 25, 8 µg             |
| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) type 1, 2, 3   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

GlaxoSmithKline Biologicals s.a.  
Rue de l'Institut 89  
B-1330 Rixensart, Belgium

**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/001

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 10  
PREFILLED SYRINGES WITHOUT NEEDLE**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta – Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
| Diphtheria toxoid <sup>1</sup>  | ≥ 30 IU                  |
| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
| <i>Bordetella pertussis</i> antigens<br>(Pertussis toxoid <sup>1</sup> , Filamentous haemagglutinin <sup>1</sup> , Pertactin <sup>1</sup> ) | 25, 25, 8 µg             |
| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) type 1, 2, 3   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe  
10 x 1 dose  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children



**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

GlaxoSmithKline Biologicals s.a.  
Rue de l'Institut 89  
B-1330 Rixensart, Belgium

**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/002

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 20  
PREFILLED SYRINGES WITHOUT NEEDLE**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta – Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
| Diphtheria toxoid <sup>1</sup>  | ≥ 30 IU                  |
| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
| <i>Bordetella pertussis</i> antigens<br>(Pertussis toxoid <sup>1</sup> , Filamentous haemagglutinin <sup>1</sup> , Pertactin <sup>1</sup> ) | 25, 25, 8 µg             |
| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) (type 1, 2, 3)   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe  
20 x 1 dose  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

GlaxoSmithKline Biologicals s.a.  
Rue de l'Institut 89  
B-1330 Rixensart, Belgium

**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/003

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 50  
PREFILLED SYRINGES WITHOUT NEEDLE**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta – Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
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| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
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| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) type 1, 2, 3   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe  
50 x 1 dose  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

GlaxoSmithKline Biologicals s.a.  
Rue de l'Institut 89  
B-1330 Rixensart, Belgium

**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/004

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 1  
PREFILLED SYRINGE WITH NEEDLE**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta - Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
| Diphtheria toxoid <sup>1</sup>  | ≥ 30 IU                  |
| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
| <i>Bordetella pertussis</i> antigens<br>(Pertussis toxoid <sup>1</sup> , Filamentous haemagglutinin <sup>1</sup> , Pertactin <sup>1</sup> ) | 25, 25, 8 µg             |
| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) type 1, 2, 3   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe, needle  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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Rue de l'Institut 89  
B-1330 Rixensart, Belgium

**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/005

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 10  
PREFILLED SYRINGES WITH NEEDLE**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta – Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
| Diphtheria toxoid <sup>1</sup>  | ≥ 30 IU                  |
| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
| <i>Bordetella pertussis</i> antigens<br>(Pertussis toxoid <sup>1</sup> , Filamentous haemagglutinin <sup>1</sup> , Pertactin <sup>1</sup> ) | 25, 25, 8 µg             |
| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) type 1, 2, 3   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe, needle  
10 x 1 dose  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children



**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

GlaxoSmithKline Biologicals s.a.  
Rue de l'Institut 89  
B-1330 Rixensart, Belgium

**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/006

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 20  
PREFILLED SYRINGES WITH NEEDLE**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta – Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
| Diphtheria toxoid <sup>1</sup>  | ≥ 30 IU                  |
| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
| <i>Bordetella pertussis</i> antigens<br>(Pertussis toxoid <sup>1</sup> , Filamentous haemagglutinin <sup>1</sup> , Pertactin <sup>1</sup> ) | 25, 25, 8 µg             |
| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) type 1, 2, 3   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe, needle  
20 x 1 dose  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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Rue de l'Institut 89  
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**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/007

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 50  
PREFILLED SYRINGES WITH NEEDLE**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta – Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
| Diphtheria toxoid <sup>1</sup>  | ≥ 30 IU                  |
| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
| <i>Bordetella pertussis</i> antigens<br>(Pertussis toxoid <sup>1</sup> , Filamentous haemagglutinin <sup>1</sup> , Pertactin <sup>1</sup> ) | 25, 25, 8 µg             |
| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) type 1, 2, 3   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe, needle  
50 x 1 dose  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/008

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 1  
PREFILLED SYRINGE WITH 2 NEEDLES**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta - Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
| Diphtheria toxoid <sup>1</sup>  | ≥ 30 IU                  |
| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
| <i>Bordetella pertussis</i> antigens<br>(Pertussis toxoid <sup>1</sup> , Filamentous haemagglutinin <sup>1</sup> , Pertactin <sup>1</sup> ) | 25, 25, 8 µg             |
| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) type 1, 2, 3   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe, needles  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/009

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING PACK SIZE OF 10  
PREFILLED SYRINGES WITH 2 NEEDLES**

**1. NAME OF THE MEDICINAL PRODUCT**

Infanrix penta - Suspension for injection  
Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV),  
poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

|   |                          |
|---|--------------------------|
| 1 dose (0.5 ml):  |                          |
| Diphtheria toxoid <sup>1</sup>  | ≥ 30 IU                  |
| Tetanus toxoid <sup>1</sup>   | ≥ 40 IU                  |
| <i>Bordetella pertussis</i> antigens<br>(Pertussis toxoid <sup>1</sup> , Filamentous haemagglutinin <sup>1</sup> , Pertactin <sup>1</sup> ) | 25, 25, 8 µg             |
| Hepatitis B surface antigen <sup>2,3</sup>  | 10 µg                    |
| Poliovirus (inactivated) type 1, 2, 3   | 40, 8, 32 DU             |
| <sup>1</sup> adsorbed on Al(OH) <sub>3</sub>  | 0.95 mg Al <sup>3+</sup> |
| <sup>2</sup> produced in yeast cells ( <i>Saccharomyces cerevisiae</i> ) by recombinant DNA technology                                      |                          |
| <sup>3</sup> adsorbed on AlPO <sub>4</sub>  | 0.90 mg Al <sup>3+</sup> |

**3. LIST OF EXCIPIENTS**

NaCl  
phenoxyethanol (2.5 mg)  
Medium 199 containing principally amino acids, mineral salts, vitamins  
Water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection  
Syringe  
Needles  
10 x 1 dose  
1 dose (0.5 ml)

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

intramuscular use  
Shake before use

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT  
OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children



**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator  
Do not freeze  
Store in the original package in order to protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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Rue de l'Institut 89  
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**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/00/153/010

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

Infanrix penta  
Suspension for injection  
DTPa-HBV-IPV  
IM

**2. METHOD OF ADMINISTRATION**

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Lot

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

1 dose (0.5 ml)

**6. OTHER**

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Infanrix penta, Suspension for injection**

Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) vaccine (adsorbed)

#### **Read all of this leaflet carefully before your child starts receiving this vaccine.**

- Keep this leaflet until your child has finished the complete vaccination course. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This vaccine has been prescribed for your child. Do not pass it on to others.
- 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 Infanrix penta is and what it is used for
2. Before your child receives Infanrix penta
3. How Infanrix penta is given
4. Possible side effects
5. How to store Infanrix penta
6. Further information

### **1. WHAT Infanrix penta IS AND WHAT IT IS USED FOR**

Pharmaco-therapeutic group: Bacterial and viral vaccines combined, ATC code J07CA

Infanrix penta is a vaccine used in children to prevent five diseases: diphtheria, tetanus (lockjaw), pertussis (whooping cough), hepatitis B and poliomyelitis (Polio). The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

- **Diphtheria:** Diphtheria mainly affects the airways and sometimes the skin. Generally the airways become inflamed (swollen) causing severe breathing difficulties and sometimes suffocation. The bacteria also release a toxin (poison), which can cause nerve damage, heart problems, and even death.
- **Tetanus (Lockjaw):** Tetanus bacteria enter the body through cuts, scratches or wounds in the skin. Wounds that are especially prone to infection are burns, fractures, deep wounds or wounds contaminated with soil, dust, horse manure/dung or wood splinters. The bacteria release a toxin (poison), which can cause muscle stiffness, painful muscle spasms, fits and even death. The muscle spasms can be strong enough to cause bone fractures of the spine.
- **Pertussis (Whooping cough):** Pertussis is a highly infectious illness. The disease affects the airways causing severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a “whooping” sound, hence the common name “whooping cough”. The cough may last for 1-2 months or longer. Pertussis can also cause ear infections, bronchitis which may last a long time, pneumonia, fits, brain damage and even death.
- **Hepatitis B:** Hepatitis B is caused by the hepatitis B virus. It causes the liver to become swollen (inflamed). The virus is found in body fluids such as blood, semen, vaginal secretions, or saliva (spit) of infected people.
- **Poliomyelitis (Polio):** Poliomyelitis, sometimes called simply “polio” is a viral infection that can have variable effects. Often it causes only a mild illness but in some people it causes permanent damage or even death. In its severest form, polio infection causes paralysis of the muscles

(muscles cannot move), including those muscles needed for breathing and walking. The limbs affected by the disease may be painfully deformed.

Vaccination is the best way to protect against these diseases. None of the components in the vaccine are infectious.

## **2. BEFORE YOUR CHILD RECEIVES Infanrix penta**

### **Infanrix penta should not be given:**

- if your child has previously had any allergic reaction to Infanrix penta, or any ingredient contained in this vaccine. The active substances and other ingredients in Infanrix penta are listed at the end of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- if your child has previously had an allergic reaction to any vaccine against diphtheria, tetanus, pertussis (whooping cough), hepatitis B or poliomyelitis diseases.
- if your child experienced problems of the nervous system within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease.
- if your child has a severe infection with a high temperature (over 38°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.

### **Take special care with Infanrix penta**

- if after previously having Infanrix penta or another vaccine against pertussis (whooping cough) disease, your child had any problems, especially:
  - ◆ A high temperature (over 40°C) within 48 hours of vaccination
  - ◆ A collapse or shock-like state within 48 hours of vaccination
  - ◆ Persistent crying lasting 3 hours or more within 48 hours of vaccination
  - ◆ Seizures/fits with or without a high temperature within 3 days of vaccination
- if your child has a bleeding problem or bruises easily
- if your child has a tendency to seizures/fits due to a fever, or if there is a history in the family of this

### **Using other medicines or vaccines**

Please tell your doctor if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription or has recently received any other vaccine.

### **Important information about some of the ingredients of Infanrix penta**

Please tell your doctor if your child has had an allergic reaction to neomycin and polymyxin (antibiotics).

## **3. HOW Infanrix penta IS GIVEN**

Your child will receive a total of three injections with an interval of at least one month between each one. Each injection is given on a separate visit. You will be informed by the doctor or nurse when you should come back for subsequent injections.

If additional injections or “booster” are necessary, the doctor will tell you.

If your child misses a scheduled injection, talk to your doctor and arrange another visit.

Make sure your child finishes the complete vaccination course of three injections. If not, your child may not be fully protected against the diseases.

The doctor will give Infanrix penta as an injection into the muscle.

The vaccine should never be given into a vein.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Infanrix penta can cause side effects, although not everybody gets them.

Your child may feel:

- ◆ pain or discomfort at the injection site

or you may see some:

- ◆ redness or swelling at the injection site.

However, these effects usually clear up within a few days.

Other side effects which can occur are:

- ◆ Diarrhoea, loss of appetite, vomiting
- ◆ Fever (more than 38°C)
- ◆ Restlessness, unusual crying

If these events continue or become severe, tell your doctor.

As with all injectable vaccines, there is an extremely small risk of allergic reactions. These can be recognised by:

- ◆ Itchy rash of the hands and feet
  - ◆ Swelling of the eyes and face
  - ◆ Difficulty in breathing or swallowing
- Such reactions will usually occur before leaving the doctor's surgery. However, you should seek immediate treatment in any event.

The following side effects have occurred with other vaccines against pertussis (whooping cough) disease. They usually occur within 2 to 3 days after vaccination:

- ◆ Collapse or periods of unconsciousness or lack of awareness
- ◆ Seizures or fits

Diffuse swelling of the entire injected limb has been reported very rarely (less than 1 per 10,000 doses of vaccine)

Do not be alarmed by this list of possible side effects. It is possible that your child has no side effects from vaccination.

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 Infanrix penta**

Keep out of the reach and sight of children.

Do not use Infanrix penta after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Store in the original package in order to protect from light.

Do not freeze. Freezing destroys the vaccine.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.





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**This leaflet was last approved in**

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.ema.eu.int/>.

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

Upon storage, a white deposit and clear supernatant can be observed. This does not constitute a sign of deterioration.

The syringe should be well shaken in order to obtain a homogeneous turbid white suspension.

The diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliomyelitis (DTPa-HBV-IPV) suspension should be inspected visually for any foreign particulate matter and/or variation of physical aspect. In the event of either being observed, discard the container.