Annex III

Summary of product characteristics, labelling and package leaflet

Note: This SmPC, labelling and packages leaflet is the version valid at the time of Commission decision.

After the Commission decision the Member State competent authorities, in liaison with the reference Member State, will update the product information as required. Therefore, this SmPC, labelling and package leaflet may not necessarily represent the current text.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

[See Annex I - To be completed nationally]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[To be completed nationally]

Excipients with known effect:
The vaccine contains 9 mg of sorbitol, see section 4.4.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

[To be completed nationally]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PRIORIX is indicated for the active immunisation of children from the age of 9 months or older, adolescents and adults against measles, mumps and rubella.

For use in children between 9 to 12 months of age see sections 4.2, 4.4 and 5.1.

4.2 Posology and method of administration

Posology

The use of PRIORIX should be based on official recommendations.

Individuals 12 months of age or older
The dose is 0.5 ml. A second dose should be given according to official recommendations.

PRIORIX may be used in individuals who have previously been vaccinated with another monovalent or combined measles, mumps and rubella vaccine.

Infants between 9 and 12 months of age
Infants in their first year of life may not respond sufficiently to the components of the vaccines. In case an epidemiological situation requires vaccinating infants in their first year of life (e.g. outbreak or travel to endemic regions), a second dose of PRIORIX should be given in the second year of life, preferably within three months after the first dose. Under no circumstances should the interval between doses be less than four weeks (see sections 4.4 and 5.1).

Infants less than 9 months of age
The safety and efficacy of PRIORIX in infants under 9 months of age has not been established.

Method of administration

PRIORIX is for subcutaneous injection, although it can also be given by intramuscular injection. (see sections 4.4 and 5.1).

The vaccine should preferably be administered subcutaneously in patients with thrombocytopenia or any coagulation disorder (see section 4.4).
For instructions on reconstitution of the medicinal product before administration see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 or neomycin. A history of contact dermatitis to neomycin is not a contraindication. For hypersensitivity reactions to egg proteins, see section 4.4.

Humoral or cellular immune deficiency (primary or acquired), including hypogammaglobulinaemia, dysgammaglobulinaemia and AIDS or symptomatic HIV infection or an age-specific CD4+ T-lymphocyte percentage in children below 12 months: CD4+ <25%; children between 12-35 months: CD4+ < 20%; children between 36-59 months: CD4+ < 15% (see section 4.4).

Pregnancy (see section 4.6).

As with other vaccines, the administration of PRIORIX should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

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 a rare anaphylactic event following the administration of the vaccine.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine.

Infants in their first year of life may not respond sufficiently to the components of the vaccine, due to the possible interference with maternal antibodies (see sections 4.2 and 5.1).

Due caution should be employed in administration of PRIORIX to individuals with Central Nervous System (CNS) disorder, susceptibility to febrile convulsions or family history of convulsions. Vaccinees with a history of febrile convulsions should be closely followed-up.

The measles and mumps components of the vaccine are produced in chick embryo cell culture and may therefore contain traces of egg protein. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g. generalised urticaria, swelling of the mouth and throat, difficulty in breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after vaccination, although these types of reactions have been shown to be very rare. Individuals who have experienced anaphylaxis after egg ingestion should be vaccinated with extreme caution, with adequate treatment for anaphylaxis on hand should such a reaction occur.

Patients with rare hereditary problems of fructose intolerance should not be vaccinated with PRIORIX since it contains sorbitol.

Limited protection against measles may be obtained by vaccination up to 72 hours after exposure to natural measles.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

PRIORIX SHOULD UNDER NO CIRCUMSTANCES BE ADMINISTERED INTRAVASCULARLY.

<u>Thrombocytopenia</u>

Cases of worsening of thrombocytopenia and cases of recurrence of thrombocytopenia in subjects who suffered thrombocytopenia after the first dose have been reported following vaccination with live measles, mumps and rubella vaccines. MMR-associated thrombocytopenia is rare and generally self-limited. In patients with existing thrombocytopenia or a history of thrombocytopenia after measles, mumps or rubella vaccination the risk-benefit of administering PRIORIX should be carefully evaluated. These patients should be vaccinated with caution and preferably using subcutaneous route.

Immunocompromised patients
Immunocompromised patients who have no contraindication for this vaccination (see section 4.3) may not respond as well as immunocompetent patients, therefore some of these patients may acquire measles, mumps or rubella in case of contact, despite appropriate vaccine administration. These patients should be monitored carefully for signs of measles, parotitis and rubella.

Transmission
Transmission of measles and mumps virus from vaccinees to susceptible contacts has never been documented. Pharyngeal excretion of the rubella and measles virus is known to occur about 7 to 28 days after vaccination with peak excretion around the 11th day. However there is no evidence of transmission of these excreted vaccine viruses to susceptible contacts. Transmission of the rubella vaccine virus to infants via breast milk as well as transplacental transmission has been documented without any evidence of clinical disease.

4.5 Interaction with other medicinal products and other forms of interaction

PRIORIX can be given simultaneously (but at separate injection sites) with any of the following monovalent or combination vaccines [including hexavalent vaccines (DTPa-HBV-IPV/Hib)]: diphtheria-tetanus-acellular pertussis vaccine (DTPa), *Haemophilus influenzae* type b vaccine (Hib), inactivated polio vaccine (IPV), hepatitis B vaccine (HBV), hepatitis A vaccine (HAV), Meningococcal serotype C conjugated vaccine (MenC), varicella zoster vaccine (VZV), oral polio vaccine (OPV) and 10-valent pneumococcal conjugate vaccine in accordance with local recommendations.

If not given at the same time, an interval of at least one month is recommended between administration of PRIORIX and other live attenuated vaccines.

There are no data to support the use of PRIORIX with any other vaccines.

If tuberculin testing has to be done it should be carried out before or simultaneously with vaccination since it has been reported that combined measles, mumps and rubella vaccines may cause a temporary depression of tuberculin skin sensitivity. As this anergy may last up to a maximum of 6 weeks, tuberculin testing should not be performed within that period after vaccination to avoid false negative results.

In subjects who have received human gammaglobulins or a blood transfusion, vaccination should be delayed for three months or longer (up to 11 months) depending on the dose of human globulins administered because of the likelihood of vaccine failure due to passively acquired measles, mumps and rubella antibodies.

4.6 Fertility, pregnancy and lactation

Fertility

PRIORIX has not been evaluated in fertility studies.

Pregnancy

PRIORIX is contraindicated during pregnancy (see section 4.3). However foetal damage has not been documented when measles, mumps and rubella vaccines have been given to women who were unknowingly in early stages of pregnancy.

Women of Childbearing Potential

Women who intend to become pregnant should be advised to delay for 1 month following PRIORIX vaccination. Although women should be asked about the possibility of early pregnancy prior to vaccination, screening tests to exclude pregnancy are not required. Inadvertent vaccination of unknowingly pregnant women with PRIORIX should not be a reason for termination of pregnancy.

Breast-feeding

There is limited experience with PRIORIX during breast-feeding. Studies have shown that breast-feeding postpartum women vaccinated with live attenuated rubella vaccines may secrete the virus in breast milk and transmit it to breast-fed infants without evidence of any symptomatic disease. Only in the event the child is confirmed or suspected to be immunodeficient, risks and benefits of vaccinating the mother should be evaluated (see section 4.3).

4.7 Effects on ability to drive and use machines

PRIORIX has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile
The safety profile presented below is based on a total of approximately 12,000 subjects administered PRIORIX in clinical trials.

Adverse reactions which might occur following the use of a combined mumps, measles, rubella vaccine correspond to those observed after administration of the monovalent vaccines alone or in combination.

In controlled clinical studies, signs and symptoms were actively monitored during a 42-day follow-up period. The vaccinees were also requested to report any clinical events during the study period.

The most common adverse reactions following PRIORIX administration were injection site redness and fever ≥38°C (rectal) or ≥37.5°C (axillary/oral).

List of adverse reactions
Adverse reactions reported are listed according to the following frequency:

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)

Clinical trial data

Infections and infestations:
Common: upper respiratory tract infection
Uncommon: otitis media

Blood and lymphatic system disorders:
Uncommon: lymphadenopathy

Immune system disorders:

Rare: allergic reactions

Metabolism and nutrition disorders:
Uncommon: anorexia

Psychiatric disorders:
Uncommon: nervousness, abnormal crying, insomnia

Nervous system disorders:
Rare: febrile convulsions

Eye disorders:
Uncommon: conjunctivitis

Respiratory, thoracic and mediastinal disorders:
Uncommon: bronchitis, cough

Gastrointestinal disorders:
Uncommon: parotid gland enlargement, diarrhoea, vomiting

Skin and subcutaneous tissue disorders:
Common: rash

General disorders and administration site conditions:
Very common: redness at the injection site, fever ≥38°C (rectal) or ≥37.5°C (axillary/oral)
Common: pain and swelling at the injection site, fever >39.5°C (rectal) or >39°C (axillary/oral)

In general, the frequency category for adverse reactions was similar for the first and second vaccine doses. The exception to this was pain at the injection site which was “Common” after the first vaccine dose and “Very common” after the second vaccine dose.

Post-marketing data

During post-marketing surveillance, the following adverse reactions have been reported additionally following PRIORIX vaccination.
Because these adverse reactions were reported spontaneously, it is not possible to reliably estimate their frequency.

Infections and infestations:
Meningitis, orchitis, epididymitis, atypical mild or attenuated measles, mumps-like syndrome

Blood and lymphatic system disorders:
Thrombocytopenia, thrombocytopenic purpura

Immune system disorders:
Anaphylactic reactions

Nervous system disorders:
Transverse myelitis, Guillain Barré syndrome, peripheral neuritis, encephalitis*

Skin and subcutaneous tissue disorders:
Erythema multiforme

Musculoskeletal and connective tissue disorders:
Arthralgia, arthritis

General disorders and administration site conditions:

Kawasaki syndrome

* Encephalitis has been reported with a frequency below 1 per 10 million doses. The risk of encephalitis following administration of the vaccine is far below the risk of encephalitis caused by natural diseases (measles: 1 in 1000 to 2000 cases; mumps: 2-4 in 1000 cases; rubella: approximately 1 in 6000 cases).

Accidental intravascular administration may give rise to severe reactions or even shock. Immediate measures depend on the severity of the reaction (see section 4.4).

4.9 Overdose

Cases of overdose (up to 2 times the recommended dose) have been reported during post-marketing surveillance. No adverse reactions have been associated to the overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Viral vaccine, ATC code J07BD52

Immune response in children 12 months and older
In clinical studies in children aged from 12 months to 2 years PRIORIX has been demonstrated to be highly immunogenic.

Vaccination with a single dose of PRIORIX induced antibodies against measles in 98. 1%, against mumps in 94.4% and against rubella in 100% of previously seronegative vaccinees.

Two years after primary vaccination seroconversion rates were 93.4% for measles, 94.4% for mumps and 100% for rubella.

Although there are no data available concerning the protective efficacy of PRIORIX, immunogenicity is accepted as an indication of protective efficacy. However, some field studies report that the effectiveness against mumps may be lower than the observed seroconversion rates to mumps.

Immune response in children aged 9 to 10 months
A clinical trial enrolled 300 healthy children 9 to 10 months of age at the time of first vaccine dose. Of these 147 subjects received PRIORIX and VARILRIX concomitantly. Seroconversion rates for measles, mumps and rubella were 92.6%, 91.5% and 100%, respectively. The seroconversion rates reported following the second dose given 3 months after the first dose were 100% for measles and 99.2% for mumps. Therefore a second dose of PRIORIX should be given within three months to provide optimal immune responses.

Adolescents and adults
The safety and immunogenicity of PRIORIX in adolescents and adults has not been specifically studied in clinical trials.

Intramuscular route of administration
A limited number of subjects received PRIORIX intramuscularly in clinical trials. The seroconversion rates to the three components were comparable to those seen after subcutaneous administration.

5.2 Pharmacokinetic properties

An evaluation of pharmacokinetics in vaccines is not necessary.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on general safety studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[To be completed nationally]

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.
[To be completed nationally]

6.3 Shelf-life

2 years.

The vaccine should be injected promptly after reconstitution. If this is not possible, it must be stored at 2°C – 8°C and used within 8 hours of reconstitution.
[To be completed nationally]

6.4 Special precautions for storage

[To be completed nationally]

For storage conditions after reconstitution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

[To be completed nationally]

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and handling

The solvent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the solvent or reconstituted vaccine.

The vaccine must be reconstituted by adding the entire contents of the supplied container of solvent to the vial containing the powder. After the addition of the solvent to the powder, the mixture should be well shaken until the powder is completely dissolved in the solvent.

Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuchsia pink without deterioration of the vaccine potency.

Inject the entire content of the vial.

Contacts with disinfectants should be avoided (see section 4.4).

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

7. MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

1. NAME OF THE MEDICINAL PRODUCT

[See Annex I - To be completed nationally]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[To be completed nationally]

Excipients with known effect:
The vaccine contains 9 mg of sorbitol, see section 4.4.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

[To be completed nationally]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PRIORIX is indicated for the active immunisation of children from the age of 9 months or older, adolescents and adults against measles, mumps and rubella.

For use in children between 9 to 12 months of age see sections 4.2, 4.4 and 5.1.

4.2 Posology and method of administration

Posology

The use of PRIORIX should be based on official recommendations.

Individuals 12 months of age or older
The dose is 0.5 ml. A second dose should be given according to official recommendations.

PRIORIX may be used in individuals who have previously been vaccinated with another monovalent or combined measles, mumps and rubella vaccine.

Infants between 9 and 12 months of age
Infants in their first year of life may not respond sufficiently to the components of the vaccines. In case an epidemiological situation requires vaccinating infants in their first year of life (e.g. outbreak or travel to endemic regions), a second dose of PRIORIX should be given in the second year of life, preferably within three months after the first dose. Under no circumstances should the interval between doses be less than four weeks (see sections 4.4 and 5.1).

Infants less than 9 months of age
The safety and efficacy of PRIORIX in infants under 9 months of age has not been established.

Method of administration

PRIORIX is for subcutaneous injection, although it can also be given by intramuscular injection. (see sections 4.4 and 5.1).

The vaccine should preferably be administered subcutaneously in patients with thrombocytopenia or any coagulation disorder (see section 4.4).

For instructions on reconstitution of the medicinal product before administration see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 or neomycin. A history of contact dermatitis to neomycin is not a contraindication. For hypersensitivity reactions to egg proteins, see section 4.4.

Humoral or cellular immune deficiency (primary or acquired), including hypogammaglobulinaemia, dysgammaglobulinaemia and AIDS or symptomatic HIV infection or an age-specific CD4+ T-lymphocyte percentage in children below 12 months: CD4+ <25%; children between 12-35 months: CD4+ < 20%; children between 36-59 months: CD4+ < 15% (see section 4.4).

Pregnancy (see section 4.6).

As with other vaccines, the administration of PRIORIX should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

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 a rare anaphylactic event following the administration of the vaccine.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine.

Infants in their first year of life may not respond sufficiently to the components of the vaccine, due to the possible interference with maternal antibodies (see sections 4.2 and 5.1).

Due caution should be employed in administration of PRIORIX to individuals with Central Nervous System (CNS) disorder, susceptibility to febrile convulsions or family history of convulsions. Vaccinees with a history of febrile convulsions should be closely followed-up.

The measles and mumps components of the vaccine are produced in chick embryo cell culture and may therefore contain traces of egg protein. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g. generalised urticaria, swelling of the mouth and throat, difficulty in breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after vaccination, although these types of reactions have been shown to be very rare. Individuals who have experienced anaphylaxis after egg ingestion should be vaccinated with extreme caution, with adequate treatment for anaphylaxis on hand should such a reaction occur.

Patients with rare hereditary problems of fructose intolerance should not be vaccinated with PRIORIX since it contains sorbitol.

Limited protection against measles may be obtained by vaccination up to 72 hours after exposure to natural measles.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

PRIORIX SHOULD UNDER NO CIRCUMSTANCES BE ADMINISTERED INTRAVASCULARLY.

Thrombocytopenia

Cases of worsening of thrombocytopenia and cases of recurrence of thrombocytopenia in subjects who suffered thrombocytopenia after the first dose have been reported following vaccination with live measles, mumps and rubella vaccines. MMR-associated thrombocytopenia is rare and generally self-limited. In patients with existing thrombocytopenia or a history of thrombocytopenia after measles,

mumps or rubella vaccination the risk-benefit of administering PRIORIX should be carefully evaluated. These patients should be vaccinated with caution and preferably using subcutaneous route.

Immunocompromised patients
Immunocompromised patients who have no contraindication for this vaccination (see section 4.3) may not respond as well as immunocompetent patients, therefore some of these patients may acquire measles, mumps or rubella in case of contact, despite appropriate vaccine administration. These patients should be monitored carefully for signs of measles, parotitis and rubella.

Transmission
Transmission of measles and mumps virus from vaccinees to susceptible contacts has never been documented. Pharyngeal excretion of the rubella and measles virus is known to occur about 7 to 28 days after vaccination with peak excretion around the 11th day. However there is no evidence of transmission of these excreted vaccine viruses to susceptible contacts. Transmission of the rubella vaccine virus to infants via breast milk as well as transplacental transmission has been documented without any evidence of clinical disease.

4.5 Interaction with other medicinal products and other forms of interaction

PRIORIX can be given simultaneously (but at separate injection sites) with any of the following monovalent or combination vaccines [including hexavalent vaccines (DTPa-HBV-IPV/Hib)]: diphtheria-tetanus-acellular pertussis vaccine (DTPa), *Haemophilus influenzae* type b vaccine (Hib), inactivated polio vaccine (IPV), hepatitis B vaccine (HBV), hepatitis A vaccine (HAV), Meningococcal serotype C conjugated vaccine (MenC), varicella zoster vaccine (VZV), oral polio vaccine (OPV) and 10-valent pneumococcal conjugate vaccine in accordance with local recommendations.

If not given at the same time, an interval of at least one month is recommended between administration of PRIORIX and other live attenuated vaccines.

There are no data to support the use of PRIORIX with any other vaccines.

If tuberculin testing has to be done it should be carried out before or simultaneously with vaccination since it has been reported that combined measles, mumps and rubella vaccines may cause a temporary depression of tuberculin skin sensitivity. As this anergy may last up to a maximum of 6 weeks, tuberculin testing should not be performed within that period after vaccination to avoid false negative results.

In subjects who have received human gammaglobulins or a blood transfusion, vaccination should be delayed for three months or longer (up to 11 months) depending on the dose of human globulins administered because of the likelihood of vaccine failure due to passively acquired measles, mumps and rubella antibodies.

4.6 Fertility, pregnancy and lactation

Fertility

PRIORIX has not been evaluated in fertility studies.

Pregnancy

PRIORIX is contraindicated during pregnancy (see section 4.3). However foetal damage has not been documented when measles, mumps and rubella vaccines have been given to women who were unknowingly in early stages of pregnancy.

Women of Childbearing Potential

Women who intend to become pregnant should be advised to delay for 1 month following PRIORIX vaccination. Although women should be asked about the possibility of early pregnancy prior to

vaccination, screening tests to exclude pregnancy are not required. Inadvertent vaccination of unknowingly pregnant women with PRIORIX should not be a reason for termination of pregnancy.

Breast-feeding

There is limited experience with PRIORIX during breast-feeding. Studies have shown that breast-feeding postpartum women vaccinated with live attenuated rubella vaccines may secrete the virus in breast milk and transmit it to breast-fed infants without evidence of any symptomatic disease. Only in the event the child is confirmed or suspected to be immunodeficient, risks and benefits of vaccinating the mother should be evaluated (see section 4.3).

4.7 Effects on ability to drive and use machines

PRIORIX has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile
The safety profile presented below is based on a total of approximately 12,000 subjects administered PRIORIX in clinical trials.

Adverse reactions which might occur following the use of a combined mumps, measles, rubella vaccine correspond to those observed after administration of the monovalent vaccines alone or in combination.

In controlled clinical studies, signs and symptoms were actively monitored during a 42-day follow-up period. The vaccinees were also requested to report any clinical events during the study period.

The most common adverse reactions following PRIORIX administration were injection site redness and fever ≥38°C (rectal) or ≥37.5°C (axillary/oral).

List of adverse reactions
Adverse reactions reported are listed according to the following frequency:

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)

Clinical trial data

Infections and infestations:
Common: upper respiratory tract infection
Uncommon: otitis media
Common: upper respiratory tract infection

Blood and lymphatic system disorders:
Uncommon: lymphadenopathy

Immune system disorders:
Rare: allergic reactions

Metabolism and nutrition disorders:
Uncommon: anorexia

Psychiatric disorders:
Uncommon: nervousness, abnormal crying, insomnia

Nervous system disorders:

Rare: febrile convulsions

Eye disorders:
Uncommon: conjunctivitis

Respiratory, thoracic and mediastinal disorders:
Uncommon: bronchitis, cough

Gastrointestinal disorders:
Uncommon: parotid gland enlargement, diarrhoea, vomiting

Skin and subcutaneous tissue disorders:
Common: rash

General disorders and administration site conditions:
Very common: redness at the injection site, fever ≥38°C (rectal) or ≥37.5°C (axillary/oral)
Common: pain and swelling at the injection site, fever >39.5°C (rectal) or >39°C (axillary/oral)

In general, the frequency category for adverse reactions was similar for the first and second vaccine doses. The exception to this was pain at the injection site which was “Common” after the first vaccine dose and “Very common” after the second vaccine dose.

Post-marketing data

During post-marketing surveillance, the following adverse reactions have been reported additionally following PRIORIX vaccination.
Because these adverse reactions were reported spontaneously, it is not possible to reliably estimate their frequency.

Infections and infestations:
Meningitis, orchitis, epididymitis, atypical mild or attenuated measles, mumps-like syndrome

Blood and lymphatic system disorders:
Thrombocytopenia, thrombocytopenic purpura

Immune system disorders:
Anaphylactic reactions

Nervous system disorders:
Transverse myelitis, Guillain Barré syndrome, peripheral neuritis, encephalitis*

Skin and subcutaneous tissue disorders:
Erythema multiforme

Musculoskeletal and connective tissue disorders:
Arthralgia, arthritis

General disorders and administration site conditions:
Kawasaki syndrome

* Encephalitis has been reported with a frequency below 1 per 10 million doses. The risk of encephalitis following administration of the vaccine is far below the risk of encephalitis caused by natural diseases (measles: 1 in 1000 to 2000 cases; mumps: 2-4 in 1000 cases; rubella: approximately 1 in 6000 cases).

Accidental intravascular administration may give rise to severe reactions or even shock. Immediate measures depend on the severity of the reaction (see section 4.4).

4.9 Overdose

Cases of overdose (up to 2 times the recommended dose) have been reported during post-marketing surveillance. No adverse reactions have been associated to the overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Viral vaccine, ATC code J07BD52

Immune response in children 12 months and older
In clinical studies in children aged from 12 months to 2 years PRIORIX has been demonstrated to be highly immunogenic.

Vaccination with a single dose of PRIORIX induced antibodies against measles in 98. 1%, against mumps in 94.4% and against rubella in 100% of previously seronegative vaccinees.

Two years after primary vaccination seroconversion rates were 93.4% for measles, 94.4% for mumps and 100% for rubella.

Although there are no data available concerning the protective efficacy of PRIORIX, immunogenicity is accepted as an indication of protective efficacy. However, some field studies report that the effectiveness against mumps may be lower than the observed seroconversion rates to mumps.

Immune response in children aged 9 to 10 months
A clinical trial enrolled 300 healthy children 9 to 10 months of age at the time of first vaccine dose. Of these 147 subjects received PRIORIX and VARILRIX concomitantly. Seroconversion rates for measles, mumps and rubella were 92.6%, 91.5% and 100%, respectively. The seroconversion rates reported following the second dose given 3 months after the first dose were 100% for measles and 99.2% for mumps. Therefore a second dose of PRIORIX should be given within three months to provide optimal immune responses.

Adolescents and adults
The safety and immunogenicity of PRIORIX in adolescents and adults has not been specifically studied in clinical trials.

Intramuscular route of administration
A limited number of subjects received PRIORIX intramuscularly in clinical trials. The seroconversion rates to the three components were comparable to those seen after subcutaneous administration.

5.2 Pharmacokinetic properties

An evaluation of pharmacokinetics in vaccines is not necessary.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on general safety studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[To be completed nationally]

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.
[To be completed nationally]

6.3 Shelf-life

2 years.

The vaccine should be injected promptly after reconstitution. If this is not possible, it must be stored at 2°C – 8°C and used within 8 hours of reconstitution.
[To be completed nationally]

6.4 Special precautions for storage

[To be completed nationally]

For storage conditions after reconstitution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

[To be completed nationally]

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and handling

The solvent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the solvent or reconstituted vaccine.

The vaccine must be reconstituted by adding the entire contents of the supplied container of solvent to the vial containing the powder. After the addition of the solvent to the powder, the mixture should be well shaken until the powder is completely dissolved in the solvent.

Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuchsia pink without deterioration of the vaccine potency.

Inject the entire content of the vial.

Contacts with disinfectants should be avoided (see section 4.4).

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

7. MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
VIAL + AMPOULE, PACK OF 1, 10, 20, 25, 40, 100

1. NAME OF THE MEDICINAL PRODUCT

[See Annex I - To be completed nationally]

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
Subcutaneous (SC) or intramuscular (IM) use
Powder and solvent to be reconstituted before use
Shake before use

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

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP:

After reconstitution, use promptly or within 8 hours if stored in a refrigerator

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

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

Dispose of in accordance with local regulations

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<See Annex I - To be completed nationally>

12. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription
[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

[To be completed nationally]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
VIAL + PRE-FILLED SYRINGE
WITH 1 SEPARATE NEEDLE: PACK OF 20, 40
WITH 2 SEPARATE NEEDLES: PACK OF 1, 10, 25, 100
WITHOUT NEEDLE: PACK OF 1, 10, 20, 25, 40, 100

1. NAME OF THE MEDICINAL PRODUCT

[See Annex I - To be completed nationally]

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
Subcutaneous (SC) or intramuscular (IM) use
Powder and solvent to be reconstituted before use
Shake before use

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

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP:

After reconstitution, use promptly or within 8 hours if stored in a refrigerator

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

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

Dispose of in accordance with local regulations

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<See Annex I - To be completed nationally>

12. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription
[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

[To be completed nationally]

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
VIAL WITH POWDER

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

SC or IM
[See Annex I - To be completed nationally]

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 dose
[To be completed nationally]

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS AMPOULE OR SYRINGE WITH SOLVENT

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

[See Annex I - To be completed nationally]

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)
[To be completed nationally]

6. OTHER

PACKAGE LEAFLET

Package leaflet: information for the user
[See Annex I - To be completed nationally]

Read all of this leaflet carefully before you or your child receives this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet..

What is in this leaflet:

1. What Priorix is and what it is used for

Priorix is a vaccine for use in children from 9 months up, adolescents and adults to protect them against illnesses caused by measles, mumps and rubella viruses.

How Priorix works
When a person is vaccinated with Priorix, the immune system (the body's natural defence system) will make antibodies to protect the person from being infected by measles, mumps and rubella viruses.

Although Priorix contains live viruses, they are too weak to cause measles, mumps or rubella in healthy people.

2. What you need to know before you or your child receive(s) Priorix

Priorix should not be given

- if you or your child is allergic against any of the components of this vaccine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue;
- if you or your child is known to be allergic to neomycin (an antibiotic agent). A known contact dermatitis (skin rash when the skin is in direct contact with allergens such as neomycin) should not be a problem but talk to your doctor first;
- if you or your child has a severe infection with a high temperature. In these cases, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first;
- if you or your child has any illness or takes any medicine that weakens the immune system such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS). Whether you or your child receives the vaccine will depend upon the level of your immune defenses.
- Priorix must not be administered to pregnant women. Pregnancy must be avoided for one month after vaccination. In case of inadvertent vaccination of pregnant woman with Priorix, this should not be a reason for termination of pregnancy.

Warnings and precautions

Talk to the doctor or pharmacist before you or your child receives Priorix :

- if you or your child has disorders of the central nervous system, a history of convulsion accompanying high fever or family history of convulsions. In case of high fever following vaccination please consult your doctor promptly;
- if you or your child has ever had a severe allergic reaction to egg protein.
- if you or your child has had a side effect after vaccination against measles, mumps or rubella that involved easy bruising or bleeding for longer than usual (see section 4).
- if you or your child has a weakened immune defenses (e.g. because of an HIV infection. You or your child should be closely monitored as the responses to the vaccines may not be sufficient to ensure a protection against the illness (see section 2).

If you or your child is vaccinated within 72 hours after contact with someone with measles, Priorix will to some extent protect you against the disease.

Children below 12 months of age
Children vaccinated in their first year of life may not be fully protected. Your doctor will advise if additional doses of vaccine are needed.

As with all vaccines, Priorix may not fully protect all people who are vaccinated.

Other medicines and Priorix

Tell your doctor if you or your child is taking, has recently taken or might take any other medicines (or other vaccines).

Priorix may be given at the same time you or your child receives other recommended vaccinations such as diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b, oral or inactivated polio, hepatitis A and B, meningococcal serogroup C conjugate vaccines, varicella as well as 10-valent pneumococcal conjugate vaccine.
The injections should be given at separate injection sites. Your doctor will advise you.

If not given at the same time, an interval of at least one month is recommended between administration of Priorix and other live attenuated vaccines.

Your doctor may delay vaccination for at least 3 months if you or your child has received a blood transfusion or human antibodies (immunoglobulins).

If a tuberculin test is to be performed, it should be done either any time before, simultaneously with, or 6 weeks after vaccination with Priorix.

Pregnancy, breast-feeding and fertility

Priorix must not be administered to pregnant women. Pregnancy must be avoided for one month after vaccination. In case of inadvertent vaccination of pregnant woman with Priorix, this should not be a reason for termination of pregnancy.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this vaccine.

Priorix contains sorbitol.
If you have been told by your doctor that you or your child has an intolerance to some sugars, contact your doctor before receiving this vaccine.
[To be completed nationally]

3. How Priorix is given

Priorix is injected under the skinor into the muscle.

Priorix is intended for children from 9 months up, adolescents and adults. The appropriate time and number of injections that will be given to you or your child will be determined by your doctor on the basis of appropriate official recommendations.

The vaccine should never be given into a vein.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.
The following side effects may happen with this medicine:

Side effects that occurred during clinical trials with Priorix were as follows:

- Very common (these may occur with more than 1 in 10 doses of the vaccine):
  - redness at the injection site
  - fever of 38°C or higher

- Common (these may occur with up to 1 in 10 doses of the vaccine):
  - pain and swelling at the injection site
  - fever higher than 39.5°C
  - rash (spots)
  - upper respiratory tract infection

- Uncommon (these may occur with up to 1 in 100 doses of the vaccine):
  - infection of the middle ear
  - swollen lymph glands (glands in the neck, armpit or groin)
  - loss of appetite
  - nervousness
  - abnormal crying
  - inability to sleep (insomnia)
  - redness, irritation and watering of the eyes (conjunctivitis)
  - bronchitis
  - cough
  - swollen parotid glands (glands in the cheek)
  - diarrhoea
  - vomiting

- Rare (these may occur with up to 1 in 1,000 doses of the vaccine):
  - convulsions accompanying high fever
  - allergic reactions

After the marketing of Priorix, the following additional side effects have been reported on a few occasions:

- joint pain and inflammation
- punctual or small spotted bleeding or bruising more easily than normal due to a drop in platelets
- sudden life-threatening allergic reaction
- inflammation of the meninges, brain, spinal cord and peripheral nerves, Guillain-Barré syndrome (ascending paralysis up to respiratory paralysis)
- Kawasaki syndrome (major signs of the illness are for instance: fever, skin rash, swollen lymph glands, inflammation and rash of the mucous membranes of the mouth and throat)

- erythema multiforme (symptoms are red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body)
- measles and mumps like symptoms
- reduced measles
- transient, painful swelling of the testicles

If you or your child get(s) any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Priorix

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton after EXP.

After reconstitution, the vaccine should be administered promptly. If this is not possible, it must be stored in the refrigerator (2°C – 8°C) and used within 8 hours of reconstitution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you or your child no longer use(s). These measures will help protect the environment.

[To be completed nationally]

6. Contents of the pack and other information

What Priorix contains

[To be completed nationally]

What Priorix looks like and contents of the pack

[To be completed nationally]

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<See Annex I - To be completed nationally>

This leaflet was last revised in {MM/YYYY}
[To be completed nationally]

The following information is intended for healthcare professionals only:

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.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine.

Priorix should under no circumstances be administered intravascularly.

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

The solvent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the solvent or reconstituted vaccine.

The vaccine must be reconstituted by adding the entire contents of the supplied container of solvent to the vial containing the powder. After the addition of the solvent to the powder, the mixture should be well shaken until the powder is completely dissolved in the solvent.

Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuchsia pink without deterioration of the vaccine potency.

Inject the entire content of the vial.

After reconstitution, the vaccine should be administered promptly. If this is not possible, it must be stored in the refrigerator (2°C – 8°C) and used within 8 hours of reconstitution.

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

Package leaflet: information for the user
[See Annex I - To be completed nationally]

Read all of this leaflet carefully before you or your child receives this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Priorix is and what it is used for

Priorix is a vaccine for use in children from 9 months up, adolescents and adults to protect them against illnesses caused by measles, mumps and rubella viruses.

How Priorix works

When a person is vaccinated with Priorix, the immune system (the body's natural defence system) will make antibodies to protect the person from being infected by measles, mumps and rubella viruses.

Although Priorix contains live viruses, they are too weak to cause measles, mumps or rubella in healthy people.

2. What you need to know before you or your child receive(s) Priorix

Priorix should not be given

- if you or your child is allergic against any of the components of this vaccine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue;
- if you or your child is known to be allergic to neomycin (an antibiotic agent). A known contact dermatitis (skin rash when the skin is in direct contact with allergens such as neomycin) should not be a problem but talk to your doctor first;
- if you or your child has a severe infection with a high temperature. In these cases, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first;
- if you or your child has any illness or takes any medicine that weakens the immune system such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS). Whether you or your child receives the vaccine will depend upon the level of your immune defenses.
- Priorix must not be administered to pregnant women. Pregnancy must be avoided for one month after vaccination. In case of inadvertent vaccination of pregnant woman with Priorix, this should not be a reason for termination of pregnancy.

Warnings and precautions

Talk to the doctor or pharmacist before you or your child receives Priorix :

- if you or your child has disorders of the central nervous system, a history of convulsion accompanying high fever or family history of convulsions. In case of high fever following vaccination please consult your doctor promptly;
- if you or your child has ever had a severe allergic reaction to egg protein.
- if you or your child has had a side effect after vaccination against measles, mumps or rubella that involved easy bruising or bleeding for longer than usual (see section 4).
- if you or your child has a weakened immune defenses (e.g. because of an HIV infection. You or your child should be closely monitored as the responses to the vaccines may not be sufficient to ensure a protection against the illness (see section 2).

If you or your child is vaccinated within 72 hours after contact with someone with measles, Priorix will to some extent protect you against the disease.

Children below 12 months of age
Children vaccinated in their first year of life may not be fully protected. Your doctor will advise if additional doses of vaccine are needed.

As with all vaccines, Priorix may not fully protect all people who are vaccinated.

Other medicines and Priorix

Tell your doctor if you or your child is taking, has recently taken or might take any other medicines (or other vaccines).

Priorix may be given at the same time you or your child receives other recommended vaccinations such as diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b, oral or inactivated polio, hepatitis A and B, meningococcal serogroup C conjugate vaccines, varicella as well as 10-valent pneumococcal conjugate vaccine.
The injections should be given at separate injection sites. Your doctor will advise you.

If not given at the same time, an interval of at least one month is recommended between administration of PRIORIX and other live attenuated vaccines.

Your doctor may delay vaccination for at least 3 months if you or your child has received a blood transfusion or human antibodies (immunoglobulins).

If a tuberculin test is to be performed, it should be done either any time before, simultaneously with, or 6 weeks after vaccination with Priorix.

Pregnancy, breast-feeding and fertility

Priorix must not be administered to pregnant women. Pregnancy must be avoided for one month after vaccination. In case of inadvertent vaccination of pregnant woman with Priorix, this should not be a reason for termination of pregnancy.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this vaccine.

Priorix contains sorbitol.
If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before your child receives this vaccine.
[To be completed nationally]

3. How Priorix is given

Priorix is injected under the skinor into the muscle.

Priorix is intended for children from 9 months up, adolescents and adults.
The appropriate time and number of injections that will be given to you or your child will be determined by your doctor on the basis of appropriate official recommendations.

The vaccine should never be given into a vein.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.
The following side effects may happen with this medicine:

Side effects that occurred during clinical trials with Priorix were as follows:

♦ Very common (these may occur with more than 1 in 10 doses of the vaccine):
- redness at the injection site
- fever of 38°C or higher

♦ Common (these may occur with up to 1 in 10 doses of the vaccine):
- pain and swelling at the injection site
- fever higher than 39.5°C
- rash (spots)
- upper respiratory tract infection

♦ Uncommon (these may occur with up to 1 in 100 doses of the vaccine):
- infection of the middle ear
- swollen lymph glands (glands in the neck, armpit or groin)
- loss of appetite
- nervousness
- abnormal crying
- inability to sleep (insomnia)
- redness, irritation and watering of the eyes (conjunctivitis)
- bronchitis
- cough
- swollen parotid glands (glands in the cheek)
- diarrhoea
- vomiting

♦ Rare (these may occur with up to 1 in 1,000 doses of the vaccine):
- convulsions accompanying high fever
- allergic reactions

After the marketing of Priorix, the following additional side effects have been reported on a few occasions:
- joint pain and inflammation
- punctual or small spotted bleeding or bruising more easily than normal due to a drop in platelets
- sudden life-threatening allergic reaction
- inflammation of the meninges, brain, spinal cord and peripheral nerves, Guillain-Barré syndrome (ascending paralysis up to respiratory paralysis)
- Kawasaki syndrome (major signs of the illness are for instance: fever, skin rash, swollen lymph glands, inflammation and rash of the mucous membranes of the mouth and throat)

- erythema multiforme (symptoms are red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body)
- measles and mumps like symptoms
- reduced measles
- transient, painful swelling of the testicles

If you or your child get(s) any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Priorix

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton after EXP.

After reconstitution, the vaccine should be administered promptly. If this is not possible, it must be stored in the refrigerator (2°C – 8°C) and used within 8 hours of reconstitution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you or your child no longer use(s). These measures will help protect the environment.

[To be completed nationally]

6. Contents of the pack and other information

What Priorix contains

[To be completed nationally]

What Priorix looks like and contents of the pack

[To be completed nationally]

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<See Annex I - To be completed nationally>

This leaflet was last revised in {MM/YYYY}
[To be completed nationally]

The following information is intended for healthcare professionals only:

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.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine.

Priorix should under no circumstances be administered intravascularly.

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

The solvent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the solvent or reconstituted vaccine.

The vaccine must be reconstituted by adding the entire contents of the supplied container of solvent to the vial containing the powder. After the addition of the solvent to the powder, the mixture should be well shaken until the powder is completely dissolved in the solvent.

Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuchsia pink without deterioration of the vaccine potency.

Inject the entire content of the vial.

After reconstitution, the vaccine should be administered promptly. If this is not possible, it must be stored in the refrigerator (2°C – 8°C) and used within 8 hours of reconstitution.

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