

Annex III

Amendments to relevant sections of the summaries of product characteristics and package leaflets

Amendments to be included in the relevant sections of the summary of product characteristics for monovalent measles containing vaccines

Section 4.3 Contraindications

The wording regarding pregnancy and immunocompromised patients should read as follows:

“[...]

Pregnancy. Furthermore, pregnancy should be avoided for 1 month following vaccination (see section 4.6).

Severe humoral or cellular (primary or acquired) immunodeficiency, e.g. severe combined immunodeficiency, agammaglobulinemia 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).

[...]”

Section 4.4 Special warnings and precautions for use

The wording on pregnancy and breastfeeding should be deleted.

The wording below should be inserted:

“[...]

Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (e.g. asymptomatic HIV subjects, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases).

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

[...]”

Section 4.6 Fertility, pregnancy and lactation

The wording regarding pregnancy should read as follows:

“[...]

Pregnant women should not be vaccinated with [PRODUCT NAME].

However, fetal damage has not been documented when measles vaccines have been given to pregnant women.

Therefore, inadvertent vaccination of unknowingly pregnant women with measles containing vaccines should not be a reason for termination of pregnancy.

Pregnancy should be avoided for 1 month following vaccination. Women who intend to become pregnant should be advised to delay.

[...]”

Amendments to be included in the relevant sections of the package leaflet for monovalent measles containing vaccines

2. What you need to know before you use [PRODUCT NAME]

Do not use [PRODUCT NAME]

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.*
- if you or your child has any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or takes any medicine that weakens the immune system. Whether you or your child receives the vaccine will depend upon the level of your immune defenses.*

[...]"

Warnings and precautions

The text of this section should be read as follows:

"[...]

Talk to your doctor or pharmacist before you or your child receives [PRODUCT NAME]:

- if you or your child has weakened immune system (e.g. such as 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 "Do not use [PRODUCT NAME]")*

[...]"

Pregnancy, breast-feeding and fertility

The wording regarding pregnancy should read as follows:

"[PRODUCT NAME] should not be administrated to pregnant women.

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 the vaccination is given. Also, it is important that you do not become pregnant within one month after having the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.

In case of inadvertent vaccination of pregnant women with [PRODUCT NAME], this should not be a reason for termination of pregnancy.

[...]"

Amendments to be included in the relevant sections of the summary of product characteristics for monovalent mumps containing vaccines

Section 4.3 Contraindications

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

Pregnancy. Furthermore, pregnancy should be avoided for 1 month following vaccination (see section 4.6).

Severe humoral or cellular (primary or acquired) immunodeficiency, e.g. severe combined immunodeficiency, agammaglobulinemia 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).

[...]"

Section 4.4 Special warnings and precautions for use

The wording on pregnancy and breastfeeding should be deleted.

The wording below should be inserted:

"[...]

Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (e.g. asymptomatic HIV subjects, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases).

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

[...]"

Section 4.6 Fertility, pregnancy and lactation

The wording regarding pregnancy should read as follows:

"[...]

Pregnant women should not be vaccinated with [PRODUCT NAME].

However, fetal damage has not been documented when mumps vaccines have been given to pregnant women.

Therefore, inadvertent vaccination of unknowingly pregnant women with mumps containing vaccines should not be a reason for termination of pregnancy.

Pregnancy should be avoided for 1 month following vaccination. Women who intend to become pregnant should be advised to delay.

[...]"

Amendments to be included in the relevant sections of the package leaflet for monovalent mumps containing vaccines

2. What you need to know before you use [PRODUCT NAME]

Do not use [PRODUCT NAME]

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.*
- if you or your child has any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or takes any medicine that weakens the immune system. Whether you or your child receives the vaccine will depend upon the level of your immune defenses.*

[...]"

Warnings and precautions

The text of this section should be read as follows:

"[...]

Talk to your doctor or pharmacist before you or your child receives [PRODUCT NAME]:

- if you or your child has weakened immune system (e.g. such as 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 "Do not use [PRODUCT NAME]")*

[...]"

Pregnancy, breast-feeding and fertility

The wording regarding pregnancy should read as follows:

"[PRODUCT NAME] should not be administered to pregnant women.

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 the vaccination is given. Also, it is important that you do not become pregnant within one month after having the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.

In case of inadvertent vaccination of pregnant women with [PRODUCT NAME], this should not be a reason for termination of pregnancy.

[...]"

Amendments to be included in the relevant sections of the summary of product characteristics for monovalent rubella containing vaccines

Section 4.3 Contraindications

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

Pregnancy. Furthermore, pregnancy should be avoided for 1 month following vaccination (see section 4.6).

Severe humoral or cellular (primary or acquired) immunodeficiency, e.g. severe combined immunodeficiency, agammaglobulinemia 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).

[...]"

Section 4.4 Special warnings and precautions for use

The wording on pregnancy and breastfeeding should be deleted.

The wording below should be inserted:

"[...]

Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (e.g. asymptomatic HIV subjects, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases).

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

[...]"

Section 4.6 Fertility, pregnancy and lactation

The wording regarding pregnancy should read as follows:

"[...]

Pregnant women should not be vaccinated with [PRODUCT NAME].

However, fetal damage has not been documented when rubella vaccines have been given to pregnant women.

Even if a theoretical risk cannot be excluded yet, no cases of congenital rubella syndrome have been reported in more than 3500 susceptible women who were unknowingly in early stages of pregnancy when vaccinated with rubella containing vaccines. Therefore, inadvertent vaccination of unknowingly pregnant women with rubella containing vaccines should not be a reason for termination of pregnancy.

Pregnancy should be avoided for 1 month following vaccination. Women who intend to become pregnant should be advised to delay.

[...]"

Amendments to be included in the relevant sections of the package leaflet for monovalent rubella containing vaccines

2. What you need to know before you use [PRODUCT NAME]

Do not use [PRODUCT NAME]

The wording regarding pregnancy and immunocompromised patients should read as follows:

The text of this section should be read as follows:

"[...]

- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.*
- if you or your child has any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or takes any medicine that weakens the immune system. Whether you or your child receives the vaccine will depend upon the level of your immune defenses.*

[...]"

Warnings and precautions

The text of this section should be read as follows:

"[...]

Talk to your doctor or pharmacist before you or your child receives [PRODUCT NAME]:

- if you or your child has weakened immune system (e.g. such as 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 "Do not use [PRODUCT NAME]")*

[...]"

Pregnancy, breast-feeding and fertility

The wording regarding pregnancy should read as follows:

"[PRODUCT NAME] should not be administered to pregnant women.

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 the vaccination is given. Also, it is important that you do not become pregnant within one month after having the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.

In case of inadvertent vaccination of pregnant women with [PRODUCT NAME], this should not be a reason for termination of pregnancy.

[...]"

Amendments to be included in the relevant sections of the summary of product characteristics for monovalent varicella containing vaccines

Section 4.3 Contraindications

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

Pregnancy. Furthermore, pregnancy should be avoided for 1 month following vaccination (see section 4.6).

Severe humoral or cellular (primary or acquired) immunodeficiency, e.g. severe combined immunodeficiency, agammaglobulinemia 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).

[...]"

Section 4.4 Special warnings and precautions for use

The wording on pregnancy and breastfeeding should be deleted.

The wording below should be inserted:

"[...]

Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (e.g. asymptomatic HIV subjects, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases).

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

[...]"

Section 4.6 Fertility, pregnancy and lactation

The wording regarding pregnancy should read as follows:

"[...]

Pregnant women should not be vaccinated with [PRODUCT NAME].

However, fetal damage has not been documented when varicella vaccines have been given to pregnant women.

Pregnancy should be avoided for 1 month following vaccination. Women who intend to become pregnant should be advised to delay.

[...]"

Amendments to be included in the relevant sections of the package leaflet for monovalent varicella containing vaccines

2. What you need to know before you use [PRODUCT NAME]

Do not use [PRODUCT NAME]

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.*
- if you or your child has any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or takes any medicine that weakens the immune system. Whether you or your child receives the vaccine will depend upon the level of your immune defenses.*

[...]"

Warnings and precautions

The text of this section should be read as follows:

"[...]

Talk to your doctor or pharmacist before you or your child receives [PRODUCT NAME]:

- if you or your child has weakened immune system (e.g. such as 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 "Do not use [PRODUCT NAME]")*

[...]"

Pregnancy, breast-feeding and fertility

The wording regarding pregnancy should read as follows:

"[PRODUCT NAME] should not be administered to pregnant women.

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 the vaccination is given. Also, it is important that you do not become pregnant within one month after having the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.

[...]"

Amendments to be included in the relevant sections of the summary of product characteristics for multivalent measles and rubella containing vaccines

Section 4.3 Contraindications

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

Pregnancy. Furthermore, pregnancy should be avoided for 1 month following vaccination (see section 4.6).

Severe humoral or cellular (primary or acquired) immunodeficiency, e.g. severe combined immunodeficiency, agammaglobulinemia 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).

[...]"

Section 4.4 Special warnings and precautions for use

The wording on pregnancy and breastfeeding should be deleted.

The wording below should be inserted:

"[...]

Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (e.g. asymptomatic HIV subjects, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases).

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

[...]"

Section 4.6 Fertility, pregnancy and lactation

The wording regarding pregnancy should read as follows:

"[...]

Pregnant women should not be vaccinated with [PRODUCT NAME].

However, fetal damage has not been documented when measles or rubella vaccines have been given to pregnant women.

Even if a theoretical risk cannot be excluded yet, no cases of congenital rubella syndrome have been reported in more than 3500 susceptible women who were unknowingly in early stages of pregnancy when vaccinated with rubella containing vaccines. Therefore, inadvertent vaccination of unknowingly pregnant women with measles and rubella containing vaccines should not be a reason for termination of pregnancy.

Pregnancy should be avoided for 1 month following vaccination. Women who intend to become pregnant should be advised to delay. [...]"

Amendments to be included in the relevant sections of the package leaflet for multivalent measles and rubella containing vaccines

2. What you need to know before you use [PRODUCT NAME]

Do not use [PRODUCT NAME]

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.*
- if you or your child has any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or takes any medicine that weakens the immune system. Whether you or your child receives the vaccine will depend upon the level of your immune defenses.*

[...]"

Warnings and precautions

The text of this section should be read as follows:

"[...]

Talk to your doctor or pharmacist before you or your child receives [PRODUCT NAME]:

- if you or your child has weakened immune system (e.g. such as 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 "Do not use [PRODUCT NAME]")*

[...]"

Pregnancy, breast-feeding and fertility

The wording regarding pregnancy should read as follows:

"[PRODUCT NAME] should not be administered to pregnant women.

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 the vaccination is given. Also, it is important that you do not become pregnant within one month after having the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.

In case of inadvertent vaccination of pregnant women with [PRODUCT NAME], this should not be a reason for termination of pregnancy.

[...]"

Amendments to be included in the relevant sections of the summary of product characteristics for multivalent measles, mumps and rubella containing vaccines

Section 4.3 Contraindications

The wording regarding pregnancy and immunocompromised patients should read as follows:

[...]

Pregnancy. Furthermore, pregnancy should be avoided for 1 month following vaccination (see section 4.6).

Severe humoral or cellular (primary or acquired) immunodeficiency, e.g. severe combined immunodeficiency, agammaglobulinemia 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).

[...]

Section 4.4 Special warnings and precautions for use

The wording on pregnancy and breastfeeding should be deleted.

The wording below should be inserted:

[...]

Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (e.g. asymptomatic HIV subjects, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases).

Immunocompromised patients who have no contraindication for this vaccination (see section 4.3) may not respond as well as immunocompetent subjects, 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.

[...]

Section 4.6 Fertility, pregnancy and lactation

The wording regarding pregnancy should read as follows:

[...]

Pregnant women should not be vaccinated with [PRODUCT NAME].

However, fetal damage has not been documented when measles, mumps or rubella vaccines have been given to pregnant women.

Even if a theoretical risk cannot be excluded yet, no cases of congenital rubella syndrome have been reported in more than 3500 susceptible women who were unknowingly in early stages of pregnancy when vaccinated with rubella containing vaccines. Therefore, inadvertent vaccination of unknowingly pregnant women with measles, mumps and rubella containing vaccines should not be a reason for termination of pregnancy.

Pregnancy should be avoided for 1 month following vaccination. Women who intend to become pregnant should be advised to delay.

[...]

Amendments to be included in the relevant sections of the package leaflet for multivalent measles, mumps and rubella containing vaccines

2. What you need to know before you use [PRODUCT NAME]

Do not use [PRODUCT NAME]

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.*
- if you or your child has any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or takes any medicine that weakens the immune system. Whether you or your child receives the vaccine will depend upon the level of your immune defenses.*

[...]"

Warnings and precautions

The text of this section should be read as follows:

"[...]

Talk to your doctor or pharmacist before you or your child receives [PRODUCT NAME]:

- if you or your child has weakened immune system (e.g. such as 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 "Do not use [PRODUCT NAME]")*

[...]"

Pregnancy, breast-feeding and fertility

The wording regarding pregnancy should read as follows:

"[PRODUCT NAME] should not be administered to pregnant women.

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 the vaccination is given. Also, it is important that you do not become pregnant within one month after having the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.

In case of inadvertent vaccination of pregnant women with [PRODUCT NAME], this should not be a reason for termination of pregnancy.

[...]"

Amendments to be included in the relevant sections of the summary of product characteristics for multivalent measles, mumps, rubella and varicella containing vaccines

Section 4.3 Contraindications

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

Pregnancy. Furthermore, pregnancy should be avoided for 1 month following vaccination (see section 4.6).

Severe humoral or cellular (primary or acquired) immunodeficiency, e.g. severe combined immunodeficiency, agammaglobulinemia 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).

[...]"

Section 4.4 Special warnings and precautions for use

The wording on pregnancy and breastfeeding should be deleted.

The wording below should be inserted:

"[...]

Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (e.g. asymptomatic HIV subjects, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases).

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

[...]"

Section 4.6 Fertility, pregnancy and lactation

The wording regarding pregnancy should read as follows:

"[...]

Pregnant women should not be vaccinated with [PRODUCT NAME].

However, fetal damage has not been documented when measles, mumps, rubella or varicella vaccines have been given to pregnant women.

Pregnancy should be avoided for 1 month following vaccination. Women who intend to become pregnant should be advised to delay.

[...]"

Amendments to be included in the relevant sections of the package leaflet for multivalent measles, mumps, rubella and varicella containing vaccines

2. What you need to know before you use [PRODUCT NAME]

Do not use [PRODUCT NAME]

The wording regarding pregnancy and immunocompromised patients should read as follows:

"[...]

- if you are pregnant. In addition, pregnancy should be avoided for 1 month following vaccination.*
- if you or your child has any illness (such as Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)) or takes any medicine that weakens the immune system. Whether you or your child receives the vaccine will depend upon the level of your immune defenses.*

[...]"

Warnings and precautions

The text of this section should be read as follows:

"[...]

Talk to your doctor or pharmacist before you or your child receives [PRODUCT NAME]:

- if you or your child has weakened immune system (e.g. such as 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 "Do not use [PRODUCT NAME]")*

[...]"

Pregnancy, breast-feeding and fertility

The wording regarding pregnancy should read as follows:

"[PRODUCT NAME] should not be administered to pregnant women.

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 the vaccination is given. Also, it is important that you do not become pregnant within one month after having the vaccine. During this time you should use an effective method of birth control to avoid pregnancy.

[...]"