**With Respect to “Pregnancy”**

**[1]**<Based on human experience *[specify]* {Active substance} causes <congenital malformations *[specify]* when administered during pregnancy.> *[or]* <harmful pharmacological effects during pregnancy and/or on the fetus/newborn child.>

{Invented name} is contraindicated <during pregnancy><during {trimester} of pregnancy> *[this case is a strict contraindication]* (see section 4.3).

<Women of childbearing potential have to use effective contraception <during <and up to {number} weeks after> treatment.>>

***[2]*** <Based on human experience *[specify]* {Active substance} is suggested / suspected to cause congenital malformations *[specify]* when administered during pregnancy.

A <Studies in animals have shown reproductive toxicity (see section 5.3).>

*[or]*

B <Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).>

{Invented name} should not be used <during pregnancy><during {trimester} of pregnancy> unless the clinical condition of the woman requires treatment with {Active substance}*.*

<Women of childbearing potential have to use effective contraception <during <and up to {number} weeks after> treatment.>>

***[3]*** <Based on human experience *[specify]* {Active substance} is suggested / suspected to cause congenital malformations *[specify]* when administered during pregnancy.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

{Invented name} should not be used<during pregnancy><during {trimester} of pregnancy> unless the clinical condition of the woman requires treatment with {Active substance}.

<Women of childbearing potential have to use effective contraception <during <and up to {number} weeks after)> treatment.>>

***[4]*** <There are no or limited amount of data from the use of {Active substance} in pregnant women.

A <Studies in animals have shown reproductive toxicity (see section 5.3).>

*[or]*

B <Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).>

{Invented name} is not recommended <during pregnancy><during {trimester} of pregnancy> and in women of childbearing potential not using contraception.>

***[5]*** <There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of {Active substance} in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

As a precautionary measure**,** it is preferable to avoid the use of {Invented name} <during pregnancy> <during {trimester} of pregnancy>. >

***[6]*** *<*A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or feto/ neonatal toxicity of {Active substance}.

A <Animal studies have shown reproductive toxicity (see section 5.3).>

 *[or]*

B <Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).>

As a precautionary measure**,** it is preferable to avoid the use of {invented name} <during pregnancy > <during {trimester} of pregnancy.>

***[7]*** *<*A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or feto/ neonatal toxicity of {Active substance}.>

Animal studies do not indicate reproductive toxicity (see section 5.3).

The use of {invented name} may be considered <during pregnancy><during {trimester} of pregnancy>, if necessary.

***[8]*** <A large amount of data on pregnant women (more than 1000 pregnancy outcomes) indicate no malformative nor feto/ neonatal toxicity of {Active substance}.>

{Invented name} can be used <during pregnancy><during {trimester} of pregnancy> if clinically needed.

***[9]*** <No effects during pregnancy are anticipated, since systemic exposure to {Active substance} is negligible.>

{Invented name} can be used during pregnancy. *[E.g. medicinal products for which negligible systemic exposure/negligible pharmacodynamic systemic activity has been demonstrated in clinical situation]*

**With Respect to “Lactation”**

**[1]** <{Active substance}/metabolites are excreted in human milk and effects have been shown in breastfed newborns/infants of treated women.>

*[or]*

<{Active substance}/metabolites have been identified in breastfed newborns/infants of treated women. <The effect of {Active substance} on newborns/infants is unknown.> *[or]* <There is insufficient information on the effects of {Active substance} in newborns/infants.>>

*[or]*

<{Active substance}/metabolites are excreted in human milk to such an extent that effects on the breastfed newborns/infants are likely.>

<{Invented name}<is contraindicated during breast-feeding (see section 4.3)> *[or]* <should not be used during breast-feeding>.>

 *[or]*

<Breast-feeding should be discontinued during treatment with {Invented name}.>

*[or]*

<A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from {Invented name} therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.>

**[2]** <It is unknown whether {Active substance}/metabolites are excreted in human milk.>

*[or]*

<There is insufficient information on the excretion of {Active substance}/metabolites in human milk.>

*[or]*

<There is insufficient information on the excretion of {Active substance}/metabolites in animal milk.>

*[or]*

<Available pharmacodynamic/toxicological data in animals have shown excretion of {Active substance}/metabolites in milk (for details see 5.3).>

*[or]*

<Physico-chemical data suggest excretion of {Active substance}/metabolites in human milk.>

A risk to the newborns/infants cannot be excluded.

<{Invented name} <is contraindicated during breast-feeding (see section 4.3)> *[or]* <should not be used during breast-feeding>.>

*[or]*

<Breast-feeding should be discontinued during treatment with {Invented name}.>

 *[or]*

<A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from {Invented name} therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.>

**[3]** <No effects of {Active substance} have been shown in breastfed newborns/infants of treated mothers.>

*[or]*

<No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to {Active substance} is negligible.>

*[or]*

<{Active substance}/metabolites have not been identified in plasma of breastfed newborns/infants of treated mothers.>

*[or]*

<{Active substance}/metabolites are not excreted in human milk.>

*[or]*

<{Active substance}/metabolites are excreted in human milk, but at therapeutic doses of {Invented name} no effects on the breastfed newborns/infants are anticipated.>

{Invented name} can be used during breast-feeding.