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VSEM IMETNIKOM DOVOLJENJ ZA PROMET
Z ZAVIRALCI ANGIOTENZINSKE
KONVERTAZE (ZAVIRALCI ACE)

Zahteva za predložitev spremembe tipa II – dopolnitev povzetka glavnih značilnosti zdravila (SmPC) in navodila za uporabo (PIL) za celotno skupino zaviralcev ACE glede uporabe med nosečnostjo in dojenjem

Spoštovani,

Javna agencija RS za zdravila in medicinske pripomočke (JAZMP), v skladu s priporočilom Delovne skupine za farmakovigilanco (PhVWP) ter Koordinacijske skupine za zdravila za uporabo v humani medicini (CMD(h)) pri Evropski agenciji za zdravila (EMEA),

poziva vse imetnike dovoljenj za promet z zaviralci angiotenzinske konvertaze (C09AA) k predložitvi spremembe tipa II za zadevna zdravila.

JAZMP je februarja 2008 pozvala imetnike dovoljenj za promet z zadevnimi zdravili k predložitvi spremembe tipa II glede uporabe v nosečnosti. Zaradi kasnejših sprememb v besedilu za posamezne učinkovine ponovno objavljamo odobrena besedila.
Delovna skupina za farmakovigilanco (PhVWP) je ocenila tudi podatke o uporabi inhibitorjev ACE med dojenjem. V nadaljevanju glejte besedilo spremembe za dojenje.

Prosimo, da pri oddaji vloge za spremembo tipa II v zvezi z dojenjem vključite tudi spremembe že predloženih besedil za nosečnost.

Imetniki dovoljenj za promet z zadevnimi zdravili morajo Javni agenciji RS za zdravila in medicinske pripomočke predložiti spremembo tipa II v skladu s Pravilnikom o dovoljenju za promet z zdravilom za uporabo v humani medicini (Uradni list RS, št. 59/2006) čim prej, oz. najkasneje v 30 dneh po prejemu obvestila. Dodatne informacije in podporna dokumentacija v vlogi niso potrebne. Ta dopis je objavljen na spletni strani JAZMP www.jazmp.si .

S spoštovanjem,

JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA ZDRAVILA IN MEDICINSKE PRIPOMOČKE

dr. Martina Cvelbar, mag.farm., spec.
Direktorica

Lisinopril, fosinopril, trandopril, moexipril & perindopril

Annex I: Summary of Product Characteristics

Section 4.3 Contraindication
Second and third trimesters of pregnancy (see sections 4.4 and 4.6).
[Comment: No contraindication in Section 4.3 for lactation.]

Section 4.4 Special warnings and precautions for use
Pregnancy: ACE inhibitors should not be initiated during pregnancy. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Section 4.6 Pregnancy and lactation

The use of ACE inhibitors is not recommended during the first trimester of pregnancy (see section 4.4). The use of ACE inhibitors is contraindicated during the second and third trimester of pregnancy (see sections 4.3 and 4.4).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started. Exposure to ACE inhibitor therapy during the second and third trimesters is known to induce human foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3.) Should exposure to ACE inhibitor have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Infants whose mothers have taken ACE inhibitors should be closely observed for hypotension (see sections 4.3 and 4.4).

Lactation:
Because no information is available regarding the use of [Product] during breastfeeding, [Product] is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

Annex II: Package Leaftlet

Before you take [Product]

Do not take [Product]
If you are more than 3 months pregnant. (It is also better to avoid [Product] in early pregnancy – see pregnancy section.)

Take special care with [Product]
You must tell your doctor if you think you are (or might become) pregnant. [Product] is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Pregnancy and breast feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking [Product] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [Product]. [Product] is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. [Product] is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Ramipril

Annex I: Summary of Product Characteristics

Section 4.3 Contraindication
Second and third trimesters of pregnancy (see sections 4.4 and 4.6).
[Comment: No contraindication in section 4.3 for lactation.]

Section 4.4 Special warnings and precautions for use
Pregnancy: ACE inhibitors should not be initiated during pregnancy. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Section 4.6 Pregnancy and lactation

Pregnancy:

The use of ACE inhibitors is not recommended during the first trimester of pregnancy (see section 4.4). The use of ACE inhibitors is contraindicated during the second and third trimester of pregnancy (see sections 4.3 and 4.4).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started.
Exposure to ACE inhibitor therapy during the second and third trimesters is known to induce human foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3). Should exposure to ACE inhibitors have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Infants whose mothers have taken ACE inhibitors should be closely observed for hypotension (see sections 4.3 and 4.4).

Lactation:
Because insufficient information is available regarding the use of ramipril during breastfeeding (see section 5.2), [Product] is not recommended and alternative treatments
with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

Section 5.2 Pharmacokinetic properties
Lactation:
One single 10mg oral dose of ramipril produced an undetectable level in breast milk. However the effect of multiple doses is not known.

Annex II: Package Leaftlet

Before you take [Product]

Do not take [Product]
If you are more than 3 months pregnant. (It is also better to avoid [Product] in early pregnancy – see pregnancy section.)

Take special care with [Product]
You must tell your doctor if you think you are (or might become) pregnant. [Product] is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Pregnancy and breast feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking [Product] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [Product]. [Product] is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. [Product] is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Benazepril

Annex I: Summary of Product Characteristics

Section 4.3 Contraindication
Second and third trimesters of pregnancy (see sections 4.4 and 4.6).
[Comment: No contraindication in Section 4.3 for lactation.]

Section 4.4 Special warnings and precautions for use
Pregnancy: ACE inhibitors should not be initiated during pregnancy. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Section 4.6 Pregnancy and lactation
Pregnancy

The use of ACE inhibitors is not recommended during the first trimester of pregnancy (see section 4.4). The use of ACE inhibitors is contraindicated during the 2nd and 3rd trimesters of pregnancy (see sections 4.3 and 4.4).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started.
Exposure to ACE inhibitor therapy during the second and third trimesters is known to induce human foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3). Should exposure to ACE inhibitor have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Infants whose mothers have taken ACE inhibitors should be closely observed for hypotension (see section 4.3 and 4.4).

Lactation:
Limited pharmacokinetic data demonstrate very low concentrations in breast milk (see section 5.2). Although these concentrations seem to be clinically irrelevant, the use of [Product] in breastfeeding is not recommended for preterm infants and for the first few weeks after delivery, because of the hypothetical risk of cardiovascular and

renal effects and because there is not enough clinical experience.
In the case of an older infant, the use of [Product] in a breast-feeding mother may be considered if this treatment is necessary for the mother and the child is observed for any adverse effect.

Section 5.2 Pharmacokinetic properties
Lactation:
In nine women given an oral dose of 20 mg of benazepril daily for 3 days (time postpartum not stated), peak milk levels of 0.9 µg/L of benazepril at 1 hour after the dose and 2 µg/L of its active metabolite benazeprilat at 1.5 hours after the dose were detected. It is estimated that the breastfed infant would receive a daily dose less than 0.14% of the maternal weight-adjusted dose of benazepril.

Annex II: Package Leaftlet

Before you take [Product]

Do not take [Product]
If you are more than 3 months pregnant. (It is also better to avoid [Product] in early pregnancy – see pregnancy section.)

Take special care with [Product]
You must tell your doctor if you think you are (or might become) pregnant. [Product] is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Pregnancy and breast feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking [Product] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [Product]. [Product] is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking [Product].
In the case of an older baby your doctor should advise you on the benefits and risks of taking [Product] whilst breast-feeding, compared with other treatments.

Captopril

Annex I: Summary of Product Characteristics

Section 4.3 Contraindication
Second and third trimesters of pregnancy (see sections 4.4 and 4.6).
[Comment: No contraindication in Section 4.3 for lactation.]

Section 4.4 Special warnings and precautions for use
Pregnancy: ACE inhibitors should not be initiated during pregnancy. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Section 4.6 Pregnancy and lactation
Pregnancy:

The use of ACE inhibitors is not recommended during the first trimester of pregnancy (see section 4.4). The use of ACE inhibitors is contraindicated during the second and third trimesters of pregnancy (see sections 4.3 and 4.4).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started.
Exposure to ACE inhibitor therapy during the second and third trimesters is known to induce human foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3.) Should exposure to ACE inhibitors have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Infants whose mothers have taken ACE inhibitors should be closely observed for hypotension (see sections 4.3 and 4.4).

Lactation:
Limited pharmacokinetic data demonstrate very low concentrations in breast milk (see section 5.2). Although these concentrations seem to be clinically irrelevant, the use of [Product] in breastfeeding is not recommended for preterm infants and for the first few weeks after delivery, because of the hypothetical risk of cardiovascular and renal effects and because there is not enough clinical experience.
In the case of an older infant, the use of [Product] in a breast-feeding mother may be considered if this treatment is necessary for the mother and the child is observed for any adverse effect.

Section 5.2 Pharmacokinetic properties
Lactation:
In the report of twelve women taking oral captopril 100 mg 3 times daily, the average peak milk level was 4.7µg/L and occurred 3.8 hours after the dose. Based on these data, the maximum daily dosage that a nursing infant would receive is less than

0.002% of the maternal daily dosage.

Annex II: Package Leaftlet
Before you take [Product]

Do not take [Product]
If you are more than 3 months pregnant. (It is also better to avoid [Product] in early pregnancy – see pregnancy section.)

Take special care with [Product]
You must tell your doctor if you think you are (or might become) pregnant. [Product] is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Pregnancy and breast feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking [Product] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [Product]. [Product] is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking [Product].
In the case of an older baby your doctor should advise you on the benefits and risks of taking [Product] whilst breast-feeding, compared with other treatments.

Enalapril

Annex I: Summary of Product Characteristics

Section 4.3 Contraindication
Second and third trimesters of pregnancy (see sections 4.4 and 4.6).
[Comment: No contraindication in Section 4.3 for lactation.]

Section 4.4 Special warnings and precautions for use
Pregnancy: ACE inhibitors should not be initiated during pregnancy. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Section 4.6 Pregnancy and lactation

Pregnancy:

The use of ACE inhibitors is not recommended during the first trimester of pregnancy (see section 4.4). The use of ACE inhibitors is contraindicated during the second and third trimesters of pregnancy (see sections 4.3 and 4.4).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started. Exposure to ACE inhibitor therapy during the second and third trimesters is known to induce human foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3.) Should exposure to ACE inhibitor have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Infants whose mothers have taken ACE inhibitors should be closely observed for hypotension (see sections 4.3 and 4.4).

Lactation: Limited pharmacokinetic data demonstrate very low concentrations in breast milk (see section 5.2). Although these concentrations seem to be clinically irrelevant, the use of [Product] in breastfeeding is not recommended for preterm infants and for the first few weeks after delivery, because of the hypothetical risk of cardiovascular and renal effects and because there is not enough clinical experience. In the case of an older infant, the use of [Product] in a breast-feeding mother may be considered if this treatment is necessary for the mother and the child is observed for any adverse effect.

Section 5.2 Pharmacokinetic properties

Lactation: After a single 20 mg oral dose in five postpartum women, the average peak enalapril milk level was 1.7µg/L (range 0.54 to 5.9 µg/L) at 4 to 6 hours after the dose. The average peak enalaprilat level was 1.7µg/L (range 1.2 to 2.3µg/L); peaks occurred at various times over the 24-hour period. Using the peak milk level data, the estimated maximum intake of an exclusively breastfed infant would be about 0.16% of the maternal weight-adjusted dosage. A woman who had been taking oral enalapril 10 mg daily for 11 months had peak enalapril milk levels of 2 µg/L 4 hours after a dose and peak enalaprilat levels of 0.75 µg/L about 9 hours after the dose. The total amount of enalapril and enalaprilat measured in milk during the 24 hour period was 1.44µg/L and 0.63 µg/L of milk respectively. Enalaprilat milk levels were undetectable (<0.2µg/L) 4 hours after a single dose of enalapril 5 mg in one mother and 10mg in two mothers; enalapril levels were not determined.

Annex II: Package Leaftlet

Before you take [Product]

Do not take [Product]
If you are more than 3 months pregnant. (It is also better to avoid [Product] in early pregnancy – see pregnancy section.)

Take special care with [Product]
You must tell your doctor if you think you are (or might become) pregnant. [Product] is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Pregnancy and breast feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking [Product] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [Product]. [Product] is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Breastfeeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking [Product].
In the case of an older baby your doctor should advise you on the benefits and risks of taking [Product] whilst breast-feeding, compared with other treatments.

Quinapril

Annex I: Summary of Product Characteristics

Section 4.3 Contraindication
Second and third trimesters of pregnancy (see sections 4.4 and 4.6).
[Comment: No contraindication in Section 4.3 for lactation.]

Section 4.4 Special warnings and precautions for use
Pregnancy: ACE inhibitors should not be initiated during pregnancy. Unless continued ACE inhibitor therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Section 4.6 Pregnancy and lactation
Pregnancy:

The use of ACE inhibitors is not recommended during the first trimester of pregnancy (see section 4.4). The use of ACE inhibitors is contraindicated during the 2nd and 3rd trimester of pregnancy (see sections 4.3 and 4.4).

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Unless continued ACE inhibitor

therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started.
Exposure to ACE inhibitor therapy during the second and third trimesters is known to induce human foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3.) Should exposure to ACE inhibitor have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Infants whose mothers have taken ACE inhibitors should be closely observed for hypotension (see sections 4.3 and 4.4).

Lactation:
Limited pharmacokinetic data demonstrate very low concentrations in breast milk (see section 5.2). Although these concentrations seem to be clinically irrelevant, the use of [Product] in breastfeeding is not recommended for preterm infants and for the first few weeks after delivery, because of the hypothetical risk of cardiovascular and renal effects and because there is not enough clinical experience.
In the case of an older infant, the use of [Product] in a breast-feeding mother may be considered if this treatment is necessary for the mother and the child is observed for any adverse effect.

Section 5.2 Pharmacokinetic properties
Lactation:
After a single oral dose of 20 mg of quinapril in six breast-feeding women, the M/P (milk to plasma ratio) for quinapril was 0.12. Quinapril was not detected in milk after 4 hours after the dose. Quinalaprilat milk levels were undetectable (<5 µg/L) at all time points. It is estimated that a breastfed infant would receive about 1.6% of the maternal weight-adjusted dosage of quinapril.

Annex II: Package Leaftlet

Before you take [Product]

Do not take [Product]
If you are more than 3 months pregnant. (It is also better to avoid [Product] in early pregnancy – see pregnancy section.)

Take special care with [Product]
You must tell your doctor if you think you are (or might become) pregnant. [Product] is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Pregnancy and breast feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking [Product] before you become pregnant or as soon as you know you are pregnant and will advise you to take

another medicine instead of [Product]. [Product] is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Breastfeeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking [Product].
In the case of an older baby your doctor should advise you on the benefits and risks of taking [Product] whilst breast-feeding, compared with other treatments.