

Annex III

Amendments to relevant sections of the summary of product characteristics and package leaflet

Note:

This Summary of Product Characteristics, labelling and package leaflet is the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the Reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

[The existing product information shall be amended (insertion, replacement or deletion of the text as appropriate) to reflect the agreed wording as provided below]

A. Summary of Product Characteristics

4.1 Therapeutic indications

[A. For products of 1 mg and 2.5 mg strengths, the current indication related to lactation inhibition in post-partum, including the examples of mastitis and painful breast engorgement, should be deleted and the below wording should be included in its place]

[...]

Prevention or suppression of post-partum physiological lactation only where medically indicated (such as in case of intrapartum loss, neonatal death, HIV infection of the mother...).

Bromocriptine is not recommended for the routine suppression of lactation or for the relief of symptoms of post-partum pain and engorgement which can be adequately treated with non-pharmacological intervention (such as firm breast support, ice application) and/or simple analgesics.

[...]

[B. For product of higher strengths (5 mg and 10 mg) the indication related to inhibition of lactation in post-partum, including the examples of mastitis and painful breast engorgement, should be removed and the complete SmPC should be revised to remove wording related to the deleted indication]

4.3 Contraindications

[This section should be amended as appropriate to reflect the wording below for all products referred in Annex I]

[...]

Bromocriptine is contraindicated in patients with uncontrolled hypertension, hypertensive disorders of pregnancy (including eclampsia, pre-eclampsia or pregnancy-induced hypertension), hypertension post-partum and in the puerperium.

Bromocriptine is contraindicated for use in the suppression of lactation or other non-life threatening indications in patients with a history of coronary artery disease or other severe cardiovascular conditions, or symptoms/history of severe psychiatric disorders.

[...]

4.4 Special warnings and precautions for use

[For products of 1 mg and 2.5 mg strengths only, this section should be amended as appropriate to reflect the wording below]

[...]

In rare cases serious adverse events, including hypertension, myocardial infarction, seizures, stroke, or psychiatric disorders have been reported in post-partum women treated with bromocriptine for the inhibition of lactation. In some patients the development of seizures or stroke was preceded by severe headache and/or transient visual disturbances. Blood pressure should be carefully monitored, especially during the first days of therapy. If hypertension, suggestive chest pain, severe, progressive,

or unremitting headache (with or without visual disturbances), or evidence of central nervous system toxicity develop, the administration of bromocriptine should be discontinued and the patient should be evaluated promptly.

[...]

B. Package Leaflet

1. What bromocriptine is and what it is used for:

[...]

Bromocriptine may be used for:

[...]

[A. For products of 1 mg and 2.5 mg strengths, the current indication related to lactation inhibition in post-partum, including the examples of mastitis and painful breast engorgement, should be deleted and the below wording should be included in its place]

- Stopping breast milk production for medical reasons only, and when you and your doctor have decided that it is necessary.

Bromocriptine should not routinely be used to stop breast milk production. It should also not be used to relieve symptoms of painful breast engorgement after giving birth if these can be adequately treated with non-medical means (such as firm breast support, ice application...) and/ or a painkiller.

[B. For product of higher strengths (5 mg and 10 mg) the indication related to inhibition of lactation in post-partum, including the examples of mastitis and painful breast engorgement, should be removed and the complete PL should be revised to remove wording related to the deleted indication]

[...]

2. What you need to know before you take bromocriptine

[The wording below should be inserted in this section under the following headings for all products referred to in Annex I]

Do not take bromocriptine if:

[...]

- You have high blood pressure,
- You have ever had blood pressure problems during pregnancy or after giving birth, such as eclampsia, pre-eclampsia, pregnancy-induced high blood pressure, high blood pressure after giving birth.
- You have, or have ever had, heart disease, or other severe blood vessel disease
- You have, or have ever had, serious mental health problems

[...]

Warnings and precautions

[...]

[For products of 1 mg and 2.5 mg strengths only, this section should be amended as appropriate to reflect the wording below]

If you have just given birth you may be more at risk of certain conditions. These are very rare, but may include high blood pressure, heart attack, convulsion, stroke or mental problems. Therefore, your doctor will need to check your blood pressure regularly during the first days of treatment. Speak

immediately to your doctor if you experience high blood pressure, chest pain or unusually severe or persistent headache (with or without vision problems).

[...]