

Amendments to relevant sections of the Product Information as approved by the PRAC and CMDh, pending endorsement by the European Commission

Annex III

Amendments to relevant sections of the Product Information

Note:

These amendments to the relevant sections of the Summary of Product Characteristics, labelling and package leaflet are 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.

Amendments to the relevant sections of the Product Information

[For all products in Annex I, the existing product information shall be amended to reflect the agreed wording as provided below]

A. Medicinal products containing finasteride 1 mg, for oral use

SUMMARY OF PRODUCT CHARACTERISTICS

4.4 Special warnings and precautions for use

Mood alterations and depression

[A warning should be added after the existing warning on mood alterations as follows]

Sexual dysfunction that may contribute to mood alterations, including suicidal ideation, has been reported in some patients. Patients should be informed to seek medical advice in case they experience sexual dysfunction. Treatment discontinuation should be considered (see section 4.8).

A patient card reminding of the above is provided with the package of {Invented name}.

4.8 Undesirable effects

[The following adverse reaction(s) should be added under the System Organ Class (SOC) Psychiatric disorders with a frequency not known]

Not known: Suicidal ideation

LABELLING: PATIENT CARD

[The patient card should be placed inside the outer packaging with the following text]

{Invented name} can cause adverse reactions including depressed mood, depression or suicidal thoughts. If you experience any mood alterations, stop taking finasteride and contact your doctor for further medical advice as soon as possible.

In some patients, impaired sexual function may contribute to mood alterations, including suicidal thoughts. If you experience symptoms of impaired sexual function, contact your doctor for further medical advice.

PACKAGE LEAFLET

2. What you need to know before you take {Invented name}

Mood alterations and depression

[The following text should be inserted after the existing one on mood alterations as follows]

Impaired sexual function that may contribute to mood alterations, including suicidal thoughts, has been reported in some patients. If you experience symptoms of impaired sexual function, contact your doctor for further medical advice. Your doctor may consider stopping the treatment (see section 4 below for more information about these side effects).

A patient card reminding of the above is provided with the package of {Invented name}.

4. Possible side effects

[The following adverse reaction(s) should be added under the following instruction as well as under the frequency mentioned below]

Stop taking {Invented name} and talk to your doctor if you experience:

- Suicidal thoughts

Frequency not known:

Suicidal thoughts

B. Medicinal products containing finasteride 5 mg, for oral use

SUMMARY OF PRODUCT CHARACTERISTICS

4.8 Undesirable effects

[The following adverse reaction(s) should be added under the SOC Psychiatric disorders with a frequency not known]

SOC Psychiatric disorders

Not known: Suicidal ideation

PACKAGE LEAFLET

4. Possible side effects

[The following adverse reaction(s) should be added under the frequency mentioned below]

Frequency not known:

Suicidal thoughts

C. Medicinal products containing dutasteride, for oral use

SUMMARY OF PRODUCT CHARACTERISTICS

4.4 Special warnings and precautions for use

[The following warning should be added as follows]

Mood alterations and depression

Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with another oral 5-alpha reductase inhibitor. Patients should be advised to seek medical advice if any of these symptoms occur.

PACKAGE LEAFLET

2. What you need to know before you take {Invented name}

[The following warning should be added as follows]

Mood changes and depression

Depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients taking another medicine from the same therapeutic class (5-alpha reductase inhibitor) by mouth. If any of these symptoms occur, contact your doctor for further medical advice as soon as possible.