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Ihr Zeichen:

PHV-issue: Methotrexat

Sehr geehrte Damen und Herren,
Aufgrund eines Outcomes of PSUSA follow-up via variation (PSUFU), dessen Ergebnis durch das CMDh bestätigt wurde, kommt es zu der Änderung der Genehmigungen für das Inverkehrbringen der Arzneimittel mit dem Wirkstoff Methotrexat.

(siehe: <http://www.hma.eu/611.html>)

Auszug aus dem Final Lead Member State PSUR Follow-Up assessment report for methotrexate

Recommendations

Based on the review of data submitted, the LMS considers that the product information should be updated as follows:

Of note, the following wording proposal is based on the wording in the SmPC and PL of Jylamvo. MAHs of other products will need to adapt their product information as applicable to ensure that the amended threshold (3 instead of 6 months) is reflected properly.

Update of section 4.6 of the SmPC to amend recommendations for contraception in males. The Package leaflet is updated accordingly.

The following changes to the product information of medicinal products containing the active substance methotrexate are recommended (new text **underlined and in bold**, deleted text ~~strike through~~):

Summary of Product Characteristics

All methotrexate-containing products:

- Section 4.6

The recommendations for contraception in males should be amended as follows:

Contraception in males

[...]

As precautionary measures, sexually active male patients or their female partners are recommended to use reliable contraception during treatment of the male patient and for at least ~~6~~ **3** months after cessation of methotrexate. Men should not donate semen during therapy or for ~~6~~ **3** months following discontinuation of methotrexate.

Package Leaflet

Warnings and precautions

[...]

Methotrexate temporarily affects sperm and egg production. Methotrexate can cause miscarriage and severe birth defects. You ~~and your partner~~ should avoid having a baby if you are being given methotrexate at the time and for at least 6 months after the end of your treatment with methotrexate **if you are a woman. If you are a man you should avoid fathering a child if you are being given methotrexate at the time and for at least 3 months after the end of your treatment.** See also section "Pregnancy, breast-feeding and fertility".

[...]

Male fertility

[...]

You should avoid fathering a child or to donate semen during treatment with methotrexate and for at least ~~6~~ **3** months after the end of treatment. [...]