20 December 2022

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Important information for healthcare professionals
In the case of medical termination of intrauterine pregnancy, a dose adjustment to a higher dose (600 mg) is advised where the patient is being treated concomitantly with CYP3A4 inducers.

Mifepristone
Mifegyne 200mg tablets
PA22946/001/001

Dear Healthcare Professional,

Nordic Pharma would like to inform you of the following:

In a recent clinical drug-drug interaction study, the effect of CYP3A4 inducer rifampicin on the pharmacokinetics of mifepristone was investigated. Concomitant administration of mifepristone with CYP3A4 inducer rifampicin was shown to decrease mifepristone Area Under the Curve (AUC) by 6.3-fold and its metabolites 22-hydroxy mifepristone and N-demethyl mifepristone by 20-fold and 5.9-fold, respectively. Based on this finding, two sections of the Mifegyne® SmPC have been updated:

4.2 Posology and Method of Administration

Posology

1- Medical termination of developing intra-uterine pregnancy

Dose adjustment to a higher dose (600 mg) is needed with concomitant treatment with CYP3A4 inducers (see section 4.5 Interaction with other medicinal products and other forms of interactions).

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant administration of mifepristone with CYP3A4 inducer rifampicin was shown to decrease mifepristone AUC by 6.3-fold and its metabolites 22-hydroxy mifepristone and N-demethyl mifepristone by 20-fold and 5.9-fold, respectively. Therefore, reduced efficacy can be expected when mifepristone is given concomitantly with a CYP3A4 inducer (e.g. rifampicin, dexamethasone, St. John's Wort and certain anticonvulsants as phenytoin, phenobarbital, carbamazepine).

Therefore, in case a medical termination of developing intra-uterine pregnancy is to be done for a patient treated with strong or moderate CYP3A4 inducer, it is advised to administer a single oral dose of 600 mg (i.e. 3 tablets of 200 mg each), followed 36 to 48 hours later by the administration of the prostaglandin analogue (misoprostol 400 µg orally, or gemeprost 1 mg per vaginam).

Please ensure that all relevant staff are made aware of the content of this letter and that the information is communicated to healthcare professionals (HCPs).

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance using the report form on the HPRA website, www.hpra.ie.

Adverse events should also be reported to Nordic Pharma by telephone: 01 468 8998 or email Info@nordicpharma.ie

If you have any questions, please contact Nordic Pharma, 4045 Kingswood Road, CityWest Business Park, Co. Dublin. Telephone: 01 468 8998 or email Info@nordicpharma.ie

Yours faithfully,

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Guen Flanagan
General Manager
Ireland