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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND
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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

20 Apr 2022

Dear Healthcare Professionals,

Pregabalin: Findings of safety study on risks during pregnancy

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that a new study has suggested pregabalin may slightly increase the risk of major congenital malformations if used in pregnancy. Patients should continue to use effective contraception during treatment and avoid use in pregnancy unless clearly necessary.

According to MHRA, fuller data is now available from a Nordic observational study of more than 2,700 pregnancies exposed to pregabalin in the first trimester.

The MHRA has carefully reviewed the results of the study alongside a recent European review of the same findings. The review concluded that pregabalin use during the first trimester of pregnancy may cause a slightly increased risk of major congenital malformations in the unborn child.

The MHRA has considered the recommendations of the European review, together with the other limited safety data available regarding pregabalin safety in pregnancy, and agreed that the product information should be updated to include information from this study. The Summary of Product Characteristics and Patient Information Leaflet have now been updated.

The product information continues to advise that effective contraception should be used during treatment and that use in pregnancy avoided unless clearly necessary. Healthcare professionals are advised to consider our guidance on contraceptive methods, and take into account the patient's personal circumstances when advising on contraception.

Advice for healthcare professionals:

- an observational study of more than 2,700 pregnancies exposed to pregabalin has shown use in the first trimester to be associated with a slightly increased risk of major congenital malformations compared with exposure to no antiepileptic drugs or to lamotrigine or to duloxetine

- continue to provide counselling to patients using pregabalin on:
    - the potential risks to an unborn baby
    - the need to use effective contraception during treatment
- continue to avoid use of pregabalin during pregnancy unless clearly necessary and only if the benefit to the patient clearly outweighs the potential risk to the fetus – ensure the patient has a full understanding of the benefits, risks, and alternatives, and is part of the decision-making process
- advise patients planning a pregnancy or who become pregnant during treatment to make an appointment to discuss their health condition and any medicines they are taking
- in cases where the benefit outweighs the risk, and it is clearly necessary that pregabalin should be used during pregnancy, it is recommended to:
    - use the lowest effective dose
    - report any suspected adverse drug reactions, including for the baby

Please refer to the following website in MHRA for details:
https://www.gov.uk/drug-safety-update/pregabalin-lyrica-findings-of-safety-study-on-risks-during-pregnancy

In Hong Kong, there are 52 registered pharmaceutical products containing pregabalin. All products are prescription-only medicines. So far, the Department of Health (DH) has received 16 cases of adverse drug reaction related to pregabalin, but these cases are not related to congenital malformations. In light of the above MHRA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

PP (Terence MAN)
for Assistant Director (Drug)