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Update: Gabapentin – hältige Arzneispezialitäten – Änderungen der Fach- und Gebrauchsinformationen aufgrund des HBD – PSUR Worksharing Projektes

Sehr geehrte Damen und Herren,

basierend auf der Evaluierung des PSURs im EU-HBD-worksharing Projekt (Verfahrensnummer: DE/H/PSUR/0035/002) kommt es zu der Empfehlung, folgende Ergänzungen in die **Fach- und Gebrauchsinformation** aller Gabapentin– hältigen Arzneispezialitäten aufzunehmen.

RECOMMENDED CHANGES TO THE PRODUCT INFORMATION

The following changes to the product information of medicinal products containing the active substance gabapentin are recommended:

SmPC section 4.4:

Dizziness, somnolence, loss of consciousness, confusion, and mental impairment

Gabapentin treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in the elderly population. There have also been post-marketing reports of loss of consciousness, confusion and mental impairment. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicinal product.

SmPC section 4.8:

General disorders and administration site conditions:

Uncommon: fall

Nervous system disorders:

Uncommon: mental impairment

Rare: Loss of consciousness



Metabolism and nutrition disorder:

Uncommon: hyperglycaemia (most often observed in patients with diabetes)

Rare: hypoglycaemia (most often observed in patients with diabetes)

Not known: hyponatraemia

PIL section 3:

If you or someone else accidentally takes too many capsules, or if you think a child has swallowed any, contact your doctor or go to your nearest hospital casualty department immediately. As Gabapentin capsules may make you drowsy, it is recommended that you ask someone else to drive you to the doctor or hospital, or that you call an ambulance. Symptoms of an overdose are dizziness, double vision, slurred speech, **loss of consciousness**, drowsiness and mild diarrhoea.

PIL section 4:

Uncommon side-effects which may affect more than 1 person in 1000 are listed below:

- Fall
- difficulty with thinking
- High blood sugar (most often observed in patients with diabetes)

Rare side-effects which may affect less than 1 person in 1000 are listed below:

- Low blood sugar (most often observed in patients with diabetes)
- Loss of consciousness

Side-effects for which the frequency cannot be estimated based on the available data are listed below:

- Low blood sodium level