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Pregabalin – Important Safety Messages

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Pregabalin is licensed for the treatment of peripheral and central neuropathic pain; adjunctive therapy in adults with partial seizures; the treatment of Generalised Anxiety Disorder in adults.

Risk of severe respiratory depression

Pregabalin has been associated with infrequent reports of severe respiratory depression, including some cases without the presence of concomitant opioid medicines. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment; those using concomitant central nervous system (CNS) depressants; and people older than 65 years might be at higher risk of experiencing these events and adjustments in dose or dosing regimen may be necessary.

Concurrent use with other medicines and alcohol

Care must be taken when prescribing to individuals who are also taking benzodiazepines, opioids, or alcohol, because it can cause depression of the central nervous system, resulting in drowsiness, profound sedation, syncope and potentially fatal respiratory depression.

Potential for abuse

Product information warns about cases of abuse and dependence. People prescribed pregabalin should be carefully evaluated for a history of drug abuse and observed for possible signs of misuse, abuse, or dependence. These include drug-seeking behaviour, dose escalation, and development of tolerance. Illicit drug users may present specifically requesting pregabalin for pain or anxiety, stating they have 'tried' it and it really works!

Commonly reported events observed when pregabalin is taken in high dose (from 800 mg/day) include affective disorder, somnolence, confusional state, depression, agitation, and restlessness. Seizures are also reported.

Withdrawal reactions

These occur in some people after discontinuation of short- or long-term treatment, and include insomnia, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, convulsions, hyperhidrosis and dizziness. They are more common and severe in people who have been abusing pregabalin and taking excessive doses.

Abrupt or Rapid Discontinuation

Following abrupt or rapid discontinuation of pregabalin, reported symptoms include insomnia, nausea, headache, anxiety, hyperhidrosis, and diarrhoea. Pregabalin should be tapered gradually over weeks or months.

It is suggested to reduce by 25-30% every week when pregabalin is used therapeutically. Reduction should not exceed 50-100mg at any step. However, it may be possible to reduce doses in excess of the therapeutic range more quickly initially.

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Advice for prescribers

- Consider whether adjustments in dose or dosing regimen are necessary for patients at higher risk of respiratory depression, this includes people:
    - with compromised respiratory function, respiratory or neurological disease, or renal impairment
    - taking other CNS depressants (including opioid-containing medicines)
    - aged older than 65 years
- Patients need to be given information on the benefits, risks and side effects of pregabalin.
- Patients should be told about the potential for pregabalin to lead to abuse or dependence.
- Prescribers must have a complete list of medications (including any over-the-counter products or illicit drugs) that patients are taking to avoid hazardous drug interactions.
- Any patient features that increase the likelihood of misuse should be discussed with the patient and the rationale for prescribing should be discussed fully and documented.
- Regularly evaluate the risks of continued prescribing and consider the quantity of drugs prescribed and the intervals at which the patient should be reviewed.
- Report suspected adverse drug reactions associated with use of pregabalin on a Yellow Card

Advice for patients and carers:

- Some patients have experienced breathing difficulties when taking pregabalin – certain people may need a lower dose to reduce the risks of these issues
- Contact your doctor if you notice new or increased trouble breathing or you experience shallow breathing after taking pregabalin; a noticeable change in breathing might be associated with sleepiness
- Read the leaflet that comes with your medicine and talk to your doctor or pharmacist if you are worried about the other prescribed medicines you are taking with pregabalin;
- Avoid drinking alcohol during pregabalin treatment

Note that the above concerns also apply to gabapentin, although pregabalin may have a higher abuse potential than gabapentin due to its rapid absorption, faster onset of action and higher potency.