16 June 2020

Dear Healthcare Professional

Important information: Tramal (tramadol hydrochloride) Data Sheet safety update; Updated Precautions and Contraindications

Seqirus is committed to the safe and effective use of medicines and is writing to communicate recent changes relating to the precautions for use and contraindications in the Tramal Data Sheet.

These safety changes are in agreement with Medsafe and are related to the following opioid analgesics for which Seqirus is the sponsor in New Zealand:

- Tramal® (tramadol hydrochloride) immediate release capsules 50 mg
- Tramal® (tramadol hydrochloride) solution for injection 50 mg/mL, 100 mg/2mL
- Tramal® SR tablets (tramadol hydrochloride) sustained release tablets 50 mg, 100 mg, 150 mg, 200 mg.

Summary of Changes

Dose and method of administration
The dose of tramadol should be titrated to the severity of the pain and the clinical response of the individual patient. Tramadol is approved for use in adults, adolescents, and children **12** years of age and over.

Contraindications

Tramal is contraindicated in:

- all children younger than **12** years of age (previously 2 years of age)
- postoperative management of children younger than 18 years of age following tonsillectomy and/or adenoidectomy (addition of this contraindication)

These changes apply to all formulations of Tramal.

Warnings and Precautions
Additional safety information regarding CYP 2D6 metabolism, opioid dependency, withdrawal and toxicity have also been added to the Data Sheet.

The Consumer Medicines Information (CMI)/patient leaflet for Tramal has also been updated to reflect the changes to the Data Sheet.

The updated Data Sheet and Consumer Medicine Information for Tramal are available at www.medsafe.govt.nz.

Additional Information
These contraindications and precautions are now consistent with the US [1] and Europe[2].

Where medically necessary, access to adequate pain medicines is a key element in the multidisciplinary and multimodal pain management plan of patients around the world. While opioid analgesics can provide benefits for patients in pain, they may also carry a risk of inappropriate use including misuse, abuse and diversion, as well as the risk of addiction (Brennan et al., 2019)[3]. It is essential that physicians should only prescribe opioid analgesics after careful consideration of the benefits and risks of all available treatment options. Patients should be carefully selected and regularly monitored to ensure that opioids are prescribed appropriately.

The information in this letter is consistent with that published in Prescriber Update (June 2020, 41(2): 25–26) and is available here https://www.medsafe.govt.nz/profs/PUArticles/June2020/Spotlight-on-tramadol.html.

Adverse Events
Reporting suspected adverse reactions has an important role in monitoring the benefit/risk balance of medicines. Please report any suspected adverse reactions to https://nzphvc.otago.ac.nz/reporting/. Adverse reactions may also be reported to Seqirus Medical Information on 0800 502 757.

Should you require additional information please contact Seqirus Medical Information on 0800 502 757.

Yours sincerely,

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FOOTNOTES

[1] https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-restricts-use-prescription-codeine-pain-and-cough-medicines-and

[2] https://www.ema.europa.eu/en/documents/psusa/tramadol-cmdh-scientific-conclusions-grounds-variation-amendments-product-information-timetable/00003002/201705_en.pdf

[3] Brennan MJ et al https://doi.org/10.1080/00325481.2019.1677383