

Controlled Drug changes to the legal classification of Tramadol

Tramadol will become a Schedule 3 controlled drug (CD) from Tuesday 10 June 2014.

Why?

The Advisory Council of the Misuse of Drugs (ACMD) has a duty to keep drug misuse in the UK under review and to advise the government on measures for preventing misuse and social problems arising from it. From a review of tramadol the ACMD recommended the legislative changes following an increasing number of reports within the NHS involving tramadol and the significant harm when misused including death. The legislative changes are considered to provide the correct controls to prevent the diversion and misuse of tramadol.

The ACMD also recommended that prescribers and other healthcare professionals who prescribe, or come into contact with people who use tramadol should be given appropriate training and support concerning its misuse and adverse effects, especially with regards to its “dual-action”.

Tramadol's pharmacology, misuse and harms (ref. ACMD letter 13.2.2013)

‘Tramadol is a synthetic analogue of the phenanthrene alkaloid codeine and is an analgesic of significant medical use for treating moderate to severe pain. Tramadol has wide ranging applications, including the treatment of fibromyalgia (chronic widespread pain), cancer pain and moderate to severe musculoskeletal pain. In a similar way to other psychoactive agents of the opioid class, it can be liable to misuse.

Tramadol has a unique dual-action pharmacological profile that increases the risk of adverse effects seen in overdose. Opioids such as tramadol exhibit weak agonist activity at opiate receptors in the brain and may contribute towards euphoria and respiratory depression. In addition, tramadol enhances serotonergic and noradrenergic systems in the brain by inhibiting their reuptake mechanisms.

Prescribing data from the NHS Business Services Authority (NHSBSA) indicate an increase in prescribing, with the number of Daily Defined Doses (England) increasing from approximately 5.9 million in September 2005 to 11.1 million in September 2012. This may be associated with co-proxamol's phased withdrawal from 2005.

Data from the Office of National Statistics (ONS) for 2011 shows 154 deaths where tramadol had been mentioned on the death certificates; in 2009 there were 87 such mentions and in 2008 this figure was 83. The majority of tramadol related deaths are where it has been obtained through non-prescribed means.’

What are the changes?

Tramadol will become a Schedule 3 controlled drug (CD No Register POM) but will be exempt from safe custody regulations. This means that from Tuesday 10 June 2014 tramadol prescriptions will need to comply with Controlled Drug prescription requirements.

Please note if a community pharmacist is presented with a prescription for tramadol that has been written, signed and dated before 10 June 2014, the Royal Pharmaceutical Society has advised the pharmacist either contacts the prescriber for a replacement prescription, or, if there is an immediate need for the medicine and there is likely to be a delay in obtaining a replacement prescription, after exercising professional judgement, the pharmacist may make a supply from the prescription that is currently in their possession.

What are the implications?

The following are the prescription requirements for the Schedule 3 controlled drug:

- Tramadol prescriptions will only be valid for 28 days.
- **Prescriber** – the prescription needs to be signed by the prescriber, with the date it was signed and the address of the prescriber/practice included on the prescription (which must be within the UK).
- **Quantity** - The maximum quantity to be supplied should not exceed 30 days, in line with the Department of Health recommendations for Schedule 2, 3 and 4 controlled drugs. This is not a legal restriction but a prescriber must be able to justify the quantity requested on a clinical basis if more than 30 days' supply is prescribed. When required quantities should also not exceed the month's supply. Please note this may result in additional prescription charges for some patients that they should be made aware of.
The total quantity of medicine to be supplied must be stated in words and figures on the prescription.
- **Dose** – the dose must be clearly defined. For example:
Not legally acceptable: Take as directed; When required; Decrease dose by 50mg every four days.
Legally acceptable: Take One as directed; Take Two every six hours when required.
- The **formulation** and **strength** (as tramadol is available in more than one strength) must also be stated on the prescription.

From 10 June 2014, community pharmacists may contact the Practice for non-urgent replacement prescriptions if they are presented with a tramadol prescription dated before the legislation came into force. The community pharmacist may also contact the Practice if they have a tramadol prescription that is awaiting collection or owing, to ask the prescriber to review the prescription and issue a replacement.

Tramadol can no longer be prescribed as part of the NHS repeat dispensing scheme as Schedule 2 and 3 controlled drugs cannot be prescribed under these arrangements. Community pharmacists have been advised to check all NHS repeat dispensing prescriptions that they hold for tramadol and to contact the Prescriber to request a review of any tramadol prescriptions and if needed, a replacement FP10 prescription.

We advise that all practice staff involved in processing repeat prescriptions are made aware of the restrictions to tramadol and highlight to the prescriber those patients

- **issued tramadol via EPS2 as the patient will need to be contacted and their prescription(s) re-issued**
- **issued tramadol where the supply is greater than one month.**

Because of the number of patients that may be affected, your practice may want to put these measures in place before the legislation comes into force.

EMIS, Vision and SystemOne computer systems are all aware of the legislative changes and are updating their systems to incorporate the proper prescription writing and EPS2 restrictions to be applied for tramadol. **We suggest that on Tuesday 10 June the Practice checks their system by prescribing tramadol for a test patient.** If your system has not yet been updated, in the interim, prescriptions for tramadol will need to be annotated with a hand-written quantity (in words), include a dose and be signed by the prescriber.

For information or any issues regarding the system update, contact your computer system support directly.

Further information

The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) (England, Wales and Scotland) Regulations 2014. Details of the legislation can be found at <http://www.legislation.gov.uk/>

ACMD Advice on Tramadol. Letter 13.2.13

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144116/advice-tramadol.pdf

Medicines Management
27.5.2014