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BY EMAIL

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Dear Colleague

MHRA DRUG SAFETY UPDATE – CODEINE LINCTUS (CODEINE ORAL SOLUTIONS): RECLASSIFICATION TO PRESCRIPTION-ONLY MEDICINE

The Medicines and Healthcare products Regulatory Agency (MHRA) have issued a Drug Safety Update Codeine linctus (codeine oral solutions): reclassification to prescription-only medicine.

The Drug Safety Update contains advice for healthcare professionals on the reclassification of codeine linctus to a prescription-only medicine (POM), following a public consultation.

All market authorisation holders (MAH) are in the process of updating their product licences to reflect the change to POM. Once the licences have been updated the MAHs have committed to implement the changes to their product information within 3 months. The MHRA made a public announcement as soon as possible in the interests of public safety. To avoid any 'stockpiling', **all existing codeine linctus stock should now be treated as POM.**

Advice for healthcare professionals:

- codeine linctus is to be reclassified from a pharmacy-only medicine (P) to a prescription-only medicine (POM) owing to the risk of dependence, addiction, and overdose
- codeine linctus is only authorised for the treatment of dry cough
- codeine linctus is only considered to be effective in the treatment of chronic cough lasting over 8 weeks [footnote 1]
- advise patients that those with a long-term cough should see a healthcare professional, for review of symptoms and may require medical assessments to check for other conditions which may be the cause of the cough
- the MHRA would encourage healthcare professionals to read the Summary of Product Characteristics for special warnings and contraindications for the use of codeine linctus, especially in patients with a history of substance abuse
- record prescription details in the patient's summary care record (or equivalent) and encourage patients to read the Patient Information Leaflet that comes with their medicine
- report suspected adverse drug reactions to codeine linctus to the Yellow Card scheme

1. Morice A and Kardos P. 'Comprehensive evidence based review on European antitussives'. BMJ Open Respiratory Research 2016: volume 3, article e000137.

Advice for healthcare professionals to provide to patients:

- codeine linctus (also known as codeine oral solution) is used in the treatment of dry cough, in adults and children aged 12 to 18 years without breathing difficulties
- codeine is an opioid medicine and is addictive. Codeine linctus will only be available on prescription following assessment with a healthcare professional. This action is being taken to reduce the risk of addiction or overdose
- evidence is limited that codeine linctus is effective in the treatment of short-term cough but may be effective in the treatment of long-term cough (lasting over 8 weeks)
- alternative non-prescription cough medicines are available for short-term cough to sooth an irritated throat, including honey and lemon mixtures and cough suppressants. You can speak to a pharmacist for advice
- if you have a long-term cough, you may be asked to attend further medical assessments to check for other conditions which could be causing the cough. This is to make sure you are on the best treatment
- addiction can happen gradually especially if you have been taking codeine for a long time. If you want to stop taking it and have been taking codeine linctus for a long time, then it is important to reduce the amount you take slowly with the help of your prescriber
- if you feel that you are addicted, speak to your doctor, or if you are concerned for someone who has been using more than the prescribed amount of codeine linctus, you can also access advice and information about support on the Drugs and Alcohol NI website.
- patients are urged not to buy codeine linctus from an unregistered website as it could be dangerous

Background

Codeine linctus (also known as codeine oral solution) is authorised for the treatment of dry coughs in adults and children aged 12 to 18 years without breathing difficulties. Codeine linctus is not authorised for the treatment of pain.

Codeine linctus has been used as a cough medicine for many years, although the evidence for effectiveness in short-term cough is limited.[footnote 1]

Codeine is converted into morphine by the liver enzyme CYP2D6. Some people (known as ultra-rapid metabolisers) convert codeine into morphine faster than others. Evidence indicates that morphine is effective in the treatment of chronic cough.[footnote 2] However, patients with chronic cough may have underlying conditions, and they should undergo medical investigation to establish the best treatment.

As an opioid medicine, codeine linctus is known to be addictive.

Recent review of safety of codeine linctus

Recent safety information has revealed that codeine linctus is being used recreationally for its opioid effects, rather than for its intended use as a cough suppressant. This carries a serious risk of addiction and overdose which can be fatal.

Significant concerns have been raised concerning the use of codeine linctus as an ingredient in the recreational drink known as 'Purple Drank' (alternative names: 'Lean', 'Sizzurp', 'Dirty Sprite'). As codeine linctus is used in varying amounts in this drink, consumers may not be aware of how much they are taking, and this can have serious risks such as loss of consciousness, respiratory suppression and death. Concomitant use with a central nervous system (CNS) depressant, such as alcohol, sedatives or other medicines, will further increase these risks. The MHRA has found evidence of

Purple Drank being popularised through social media targeting young adults and has received an increased number of reports of the sale of codeine linctus through non-regulated and potentially illicit websites. Healthcare professionals have also identified individuals repeatedly requesting codeine linctus who are potentially addicted to it.

In October 2022, the Commission on Human Medicines (CHM) advised that codeine linctus should be made available as a prescription-only medicine (POM). The MHRA undertook a public consultation to obtain views on its reclassification. The consultation ran from 18 July 2023 to 15 August 2023.

1. Morice A and Kardos P. 'Comprehensive evidence based review on European antitussives'. BMJ Open Respiratory Research 2016: volume 3, article e000137.
2. Morice AH and others. 'Opiate therapy in chronic cough'. American Journal of Respiratory and Critical Care Medicine 2007: volume 175, issue 4, pages 312 to 315

Following the results of the public consultation and the further advice of the CHM, codeine linctus will no longer be supplied without a prescription. This is a risk minimisation measure to protect the health of patients in need of treatment, to prevent recreational use and to enable the identification of individuals who may have become unintentionally addicted to codeine.

Patients will still be able to access codeine linctus with a prescription from a qualified healthcare professional. This will ensure that the medicine is used safely and appropriately under medical supervision.

All market authorisation holders (MAH) are in the process of updating their product licences to reflect the change to POM. Once the licences have been updated the MAHs have committed to implement the changes to their product information within 3 months. The MHRA made a public announcement as soon as possible in the interests of public safety. **To avoid any 'stockpiling', all existing codeine linctus stock should now be treated as POM**.

Monitoring of codeine linctus side effects

The MHRA has been monitoring the risk of addiction to codeine for a number of years and regulatory action has been taken to improve product information and labelling. However, codeine linctus usage may result in dependence or addiction and we have seen abuse of this medicine when used in recreational drinks such as Purple Drank. For those who are ultra-rapid metabolisers of codeine, the risk of opioid toxicity is increased.

Opioid toxicity may resemble overdose in presentation with symptoms such as respiratory depression, pinpoint pupils, coma and death.

The consumption of codeine in recreational drinks leads to an increased risk of sedation and may cause the user to lose track of how much they have consumed.

Between January 2017 and May 2022, the UK National Poison Information Service received 19 calls in relation to codeine linctus, including codeine paediatric linctus, 'Purple Drank', 'Lean', 'Sizzurp', 'Dirty Sprite' and pholcodine linctus.

Data from the Office for National Statistics revealed an increase in the annual number of deaths where codeine was involved from 88 deaths in 2011 to 200 deaths in 2021. This does not include deaths where codeine was used in a compound formulation, for example, where codeine has been combined with paracetamol, but may include deaths where patients were obtaining codeine by prescription as well as non-prescription methods. It is not possible to determine how many patients have overdosed or died because of the misuse of codeine linctus itself, as case reports may simply name codeine as the implicated drug and do not specify the brand name or pharmaceutical form.

The MHRA has received 3 case reports describing addiction specifically with codeine linctus. The public have also informed us of several suspected cases of addiction through our consultation. However significant under-reporting of addiction is likely as those using codeine recreationally may be less likely to submit reports.

Report side effects, including dependence

Please continue to report any suspected adverse drug reactions through the Yellow Card scheme. If a patient experiences any side effect related to dependence to a medicine or is recognised by the prescriber to be dependent, the CHM encourages prescribers, patients, or carers to report this to the MHRA through the Yellow Card scheme with the term 'dependence'. Your report will help the MHRA safeguard public health.

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store
- some clinical IT systems for healthcare professionals

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

The MHRA Drug Safety update is available at the following link Codeine linctus (codeine oral solutions): reclassification to prescription-only medicine.

Yours sincerely

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Chief Medical Officer

Professor Cathy Harrison
Chief Pharmaceutical Officer

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