

Medicines Safety Assurance Tool
April 2017



Valproate and developmental disorders: new alert asking for patient review and further consideration of risk minimisation measures

Medicines and Healthcare products Regulatory Agency

Patient Safety Alerts have now been issued asking all organisations to undertake systematic identification of women and girls taking valproate. Babies born to mothers who take valproate medicines (Epilim ▼, Depakote ▼) during pregnancy have a 30–40% risk of developmental disability and a 10% risk of birth defects.

Advice for healthcare professionals

- Do not prescribe valproate medicines for epilepsy or bipolar disorder in women and girls unless other treatments are ineffective or not tolerated; migraine is not a licensed indication.
- Ensure women and girls taking valproate medicines understand the 30–40% risk of neurodevelopmental disorders and 10% risk of birth defects and are using effective contraception.
- Valproate use in women and girls of childbearing potential must be initiated and supervised by specialists in the treatment of epilepsy or bipolar disorder.

<https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102582>

<https://www.gov.uk/drug-safety-update/valproate-and-developmental-disorders-new-alert-asking-for-patient-review-and-further-consideration-of-risk-minimisation-measures>

Date of alert	Status	Date completed
24-Apr-2017		
Proposed action		
<input checked="" type="checkbox"/> Newsletter	<input checked="" type="checkbox"/> Prescribing decision support	<input checked="" type="checkbox"/> Search/audit
Action taken		

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Mucodyne® Paediatric Syrup 250 mg/5 mL (carbocisteine oral liquid): new double-strength presentation - check dose volume to ensure appropriate dose is given

Medicines and Healthcare products Regulatory Agency

Summary

Mucodyne Paediatric Syrup has been re-launched and has **double the concentration of the active ingredient** carbocisteine per millilitre compared with the previous formulation.

To reduce the risk of accidental overdose, dose volumes must be checked to ensure the appropriate dose is administered, especially if they have used Mucodyne Syrup in the past.

https://assets.publishing.service.gov.uk/media/58fa19a7ed915d06b00001a2/MucodynePaediatricReformulation_October_2016.pdf

Date of alert	Status	Date completed
24-Apr-2017		

Proposed action

Newsletter Prescribing decision support Search/audit

Action taken

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Evidence of harm from fentanyl-contaminated heroin

Central Alerting System: CMO Messaging

This alert advises of the availability of, and harms from, heroin that has been mixed with fentanyl or carfentanyl, both unusually potent synthetic opioids.

There is significant evidence from a small number of post-mortem results of recent drug user deaths and from police seizures that some heroin may contain fentanyl or carfentanyl added by dealers. These are highly potent synthetic opioids and very small amounts can cause severe or even fatal toxicity.

Those of you in contact with heroin users should be alert to the increased possibility of overdose arising from heroin cut with these synthetic opioids, be able to recognise possible symptoms of overdose and respond appropriately.

<https://www.cas.dh.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102588>

Date of alert
27-Apr-2017

Status

Date completed

Proposed action

Newsletter Prescribing decision support Search/audit

Action taken