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## Medicines Safety Assurance Tool September 2018

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)



Midlands and Lancashire  
Commissioning Support Unit

### Can small volume intramuscular injections be given to patients taking oral anticoagulants?

Specialist Pharmacy Service | 18 September 2018

This Q&A discussing potential risks linked to administration of small volume IM injections to patients on oral anticoagulants, has been partially updated to include latest advice from Public Health England's "green book" on administration of influenza vaccine to this group.

<https://www.sps.nhs.uk/articles/can-small-volume-intramuscular-injections-be-given-to-patients-taking-oral-anticoagulants-2/>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

Status

Unassigned ▼

Action due date

Date completed

### Valproate Pregnancy Prevention Programme: actions required now from GPs, specialists, and dispensers

Medicines and Health Products Regulatory | 25 September 2018

Valproate medicines must not be used in women of childbearing potential unless the Pregnancy Prevention Programme is in place.

<https://www.gov.uk/drug-safety-update/valproate-pregnancy-prevention-programme-actions-required-now-from-gps-specialists-and-dispensers>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

Status

Unassigned ▼

Action due date

Date completed

## EpiPen And EpiPen Junior - Supply Disruption

Central Alerting System | 28 September 2018

EpiPen and EpiPen Junior will be subject to limited availability for the remainder of 2018. Mylan are now out of stock of EpiPen Junior and interruptions in the supply are anticipated to continue for the coming months. This alert provides details of actions to take around the prescribing, dispensing and administration of adrenaline auto-injectors. Whilst the deadline for completing the actions is the end of this year, it is expected for organisations to begin following the actions immediately upon receipt of this alert.

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=102799>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

Action taken

Status

Unassigned ▼

Action due date

Date completed

## Summary of Product Characteristics Update

Electronic Medicines Compendium | September 2018

### Arthrotec (diclofenac/ misoprostol) 50 Tablets

The SPC has been updated with revised warnings related to teratogenicity with misoprostol use and possible risks with exposure to diclofenac/non-steroidal anti-inflammatory drugs during pregnancy.

<https://www.medicines.org.uk/emc/product/6678/smpc>

### Aprovel (irbesartan) 75mg film-coated tablets

The SPC has been updated to state that based on its pharmacodynamic properties, irbesartan is unlikely to affect the ability to drive and use machines, however, when driving vehicles or operating machines, it should be taken into account that dizziness or weariness may occur during treatment.

<https://www.medicines.org.uk/emc/product/3049/smpc>

### Inegy (ezetimibe and simvastatin) tablets

The SPC has been updated with Post-marketing reports of dyspnoea; interstitial lung disease, hypersensitivity, and anaphylaxis have been reported.

<https://www.medicines.org.uk/emc/product/3872/smpc>

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

Action taken

Status

Unassigned ▼

Action due date

Date completed

**Librium capsules 5mg (chlordiazepoxide)**

The SPC now includes a warning for its concomitant use with opioids, which may result in sedation, respiratory depression, coma and death. Concomitant prescribing of such sedative medicines should be reserved for patients for whom alternative treatment options are not possible.

<https://www.medicines.org.uk/emc/product/2045/smpc>

**Neurontin (gabapentin) products**

The SPC now states that gabapentin crosses the human placenta. Teratogenesis data in section 5.3 have been updated.

<https://www.medicines.org.uk/emc/product/158/smpc>

**Relvar Ellipta (fluticasone furoate/ vilanterol) inhalation powder, pre-dispensed**

Hyperglycaemia has been added to SPC as an uncommon adverse effect.

<https://www.medicines.org.uk/emc/product/5226/smpc>

**Travatan (travaprost) eye drops**

The SPC notes that travoprost is a persistent, bioaccumulative and toxic (PBT) substance. Despite very small amounts in eye drops, a risk to the environment cannot be excluded. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

<https://www.medicines.org.uk/emc/product/1556/smpc>

**Zineryt (erythromycin-zinc complex)**

The SPC has been updated and now warns generalised exanthematous pustulosis has been reported. If an allergic reaction occurs, drug should be discontinued, and appropriate therapy instituted. Physicians should be aware reappearance of allergic symptoms may occur when symptomatic therapy is discontinued.

<https://www.medicines.org.uk/emc/product/5488/smpc>