Please note that the information in this Safety log is correct at the time of publication. Clinicians should always refer to the most up to date information.

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# **Medicines Safety Assurance Tool**

**April 2020** 

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



### **Ibuprofen And Coronavirus (Covid-19)**

14 April 2020

The Commission on Human Medicines Expert Working Group on coronavirus (COVID-19) has concluded that there is currently insufficient evidence to establish a link between use of ibuprofen, or other non-steroidal anti-inflammatory drugs (NSAIDs), and contracting or worsening of COVID-19.

Proposed action			
☑ Newsletter	☐ Optimise Rx/ScriptSwit	ch	
☐ Practice audit/search	☐ Other (please specify)		
Action taken			
Status	Action due date	Date completed	
Unassigned ▼			

# **Summary of Product Characteristics updates**

#### Atrolak (quetiapine fumarate) XL prolonged-release tablets - all strengths

SPC updated with warnings of increased risk of self-harm & suicide in patients 25- 64 yrs and increased risk of death in patients >65 years with Parkinson's disease/parkinsonism. Stroke added as an adverse effect of treatment (of unknown frequency).

### Avamys (fluticasone furoate) 27.5 micrograms/spray nasal spray

Section 4.8 now includes bronchospasm and dyspnoea as adverse effects.

Proposed action		
☑ Newsletter	☐ Optimise Rx/ScriptSwitch	h
☐ Practice audit/search	☐ Other (please specify)	
Action taken		
Status	Action due date	Date completed
Unassigned ▼		

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#### Butec (buprenorphine) transdermal patch – all strengths

Section 4.4 now warns of drug dependence, tolerance and potential for abuse, drug withdrawal syndrome, and hyperalgesia. Section 4.6 warns of neonatal withdrawal syndrome and respiratory depression. Section 4.9 recommends carers/relatives should be informed of signs of overdose.

#### Cipralex (escitalopram) oral drops solution, 20mg/mL

Section 4.4 has been updated to note that this medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

#### Colecalciferol 3000IU/ml Oral Solution (Thame laboratories)

SPC now states that the product contains almond oil (10%) and is therefore not suitable for someone with nut allergy.

#### DHC Continus (dihydrocodeine tartrate) prolonged release tablets – all strengths

SPC updated to include additional warnings of drug dependence, tolerance, potential for abuse, drug withdrawal syndrome, hyperalgesia, neonatal withdrawal syndrome & respiratory depression in newborns. Statement regarding requirement for strategy for treatment cessation added.

### Epanutin (phenytoin) 30mg/5ml oral suspension

SPC now highlights that sodium benzoate and sodium are excipients.

### Feldene (piroxicam) - all products

SPC updated to include the warning that alcohol use is a risk factor for gastrointestinal complications in users of non-steroid anti-inflammatory drugs. Section 4.4 now advises this product contains propylene glycol and may cause skin irritation. It should not be used on open wounds or large areas of broken or damaged skin (such as burns). This product also contains benzyl alcohol which may cause allergic reactions.

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#### Fragmin (dalteparin) solution for injection – all strengths

Section 4.8 now states long term treatment with heparin has been associated with a risk of osteoporosis. Although this has not been observed with dalteparin, the risk of osteoporosis cannot be excluded.

#### Madopar (levodopa/benserazide) 200mg/50mg Hard Capsules

SPC notes capsules should be taken 30 min before or one hour after meals (previously stated with, or immediately after, meals). New information added to the 'Warnings related to interactions' section includes advice on use with antipsychotics, sympathomimetics, and others.

#### MST Continus (morphine sulfate) tablets – all strengths

Section 4.4 now warns of drug dependence, tolerance and potential for abuse, drug withdrawal syndrome, and hyperalgesia. Section 4.6 warns of neonatal withdrawal syndrome and respiratory depression. Section 4.9 recommends carers/relatives should be informed of signs of overdose.