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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards



14 January 2015

Dear Healthcare Professional,

DRUG ALERT CLASS 2 no 1 2015 – Action within 48 hours

Please see the attached drug alert for onward transmission as below.
Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

Please could Medical Directors forward this alert to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Healthcare Quality and Strategy Directorate

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level Recall

Date: 14 January 2015

EL (15)A/01

Our Ref: MDR 03-01/15

Dear Healthcare Professional,

Recall of all oral diclofenac presentations with legal status 'P'

Novartis Consumer Health UK Limited

Voltarol Pain-eze tablets

PL 00030/0073

Voltarol Pain-eze Extra Strength 25mg tablets

PL 00030/0054

Voltarol Joint Pain 12.5mg tablets

PL 00030/0073

(Diclofenac Potassium)

Product Name	Pharmaceutical Form	Pack Size	Legal Status
Voltarol Pain-eze Tablets	12.5mg tablets	18	P
Voltarol Pain-eze Extra Strength 25mg Tablets	25mg tablets	9	P
Votarol Joint Pain 12.5mg Tablets	12.5mg tablets	18	P

Contact details Novartis products: All enquiries to Novartis Consumer Health Call Centre on 0800 307 7621

Actavis Group PTC EHF

First Resort Double Action Pain Relief 12.5mg tablets

PL 30306/0243

Boots Joint Pain Relief 12.5mg tablets

PL 30306/0243

(Diclofenac Potassium)

Product Name	Pharmaceutical Form	Pack Size	Legal Status
First Resort Double Action Pain Relief 12.5mg Tablets	12.5mg tablets	18	P
Boots Joint Pain Relief 12.5mg tablets	12.5mg tablets	18	P

Contact details First Resort and Boots products: Stock control enquiries, Actavis Customer Services team 0800 373573; medical information enquiries, Actavis Medical Information Department, 01271 385257

All unexpired stock of the above products marketed by Novartis Consumer Health UK and Actavis Group PTC EHF is being recalled and should immediately be quarantined. This follows a review of the safety of oral diclofenac products which has resulted in the conclusion by the UK Commission on Human Medicines (CHM) that oral products containing diclofenac no longer meet the requirements for

Date: 14 January 2015

EL (15)A/01

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supply with legal status 'P' (i.e. available in a pharmacy without prescription but under the supervision of a pharmacist.)

For Novartis products:

Quarantined stock should be returned to the original supplier for credit.

For any enquiries regarding this recall, please contact Novartis Consumer Health Call Centre on 0800 307 7621

For First Resort and Boots products:

Quarantined stock should be returned to the original supplier for credit.

For stock control enquiries please contact Actavis Customer Services Team, 0800 373573

For medical information enquiries, please contact Actavis Medical Information department on 01271 385 257

Please note, topical gels containing diclofenac are not included in the scope of this review and so are not being recalled.

Advice to Pharmacists

Oral diclofenac containing products must not be sold to anyone without a prescription from 15th January 2015. This medicine is associated with a small increased risk of serious cardiac effects hence patients need to have a medical assessment before taking diclofenac to determine whether it is suitable for them (please see further details in the appendix).

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to community pharmacists.

Yours faithfully

Alison Bunce

**Pharmaceutical Assessor
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14 January 2015

Dear Healthcare Professional

Oral Diclofenac: available only as a prescription medicine from 15th January 2015

Summary

Tablets containing diclofenac will be available only as a Prescription Only Medicine (POM) from 15th January 2015. Topical formulations containing diclofenac will continue to be available without a prescription.

Diclofenac is associated with a small increased risk of serious cardiac side effects in some patients, particularly if used at high doses and for long-term treatment.

The UK Commission on Human Medicines (CHM) has therefore concluded that patients need to have a medical assessment before taking oral diclofenac to determine if it is suitable for them.

Background

In 2013, a Europe-wide review concluded that systemic diclofenac is associated with a small increased risk of arterial thromboembolic events, similar to that of COX-2 inhibitors. The European review recommended that the precautions to minimise the risks of arterial thromboembolic events with selective COX-2 inhibitors should be applied to systemic diclofenac. Product information for all systemic formulations of diclofenac was amended, adding a new cardiovascular contraindication and strengthening the warnings and precautions section.

The MHRA communicated the new recommendations to healthcare professionals on 28th June 2013.

Taking into account the new recommendations and the contraindications and warnings now in place to minimise the small risk of serious cardiovascular effects, and following a public consultation, the CHM concluded that diclofenac is no longer suitable for supply without prescription in the UK.

Advice for healthcare professionals

- Diclofenac tablets must not be sold without prescription from 15th January 2015.
- The sale of non-prescription oral diclofenac products must cease from 15th January 2015. Remaining stock labelled for non-prescription use will be recalled from pharmacy.
- The updated prescription advice should be taken into consideration before prescribing diclofenac (see MHRA Drug Safety Update article from June 2013 <http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON286975>)

There is no requirement for patients to return these products if already purchased. However, pharmacists are no longer permitted to supply non-prescription, oral diclofenac, and are advised to consider other treatment options for the management of pain in the non-prescription setting. Other oral non-steroidal anti-inflammatory drugs and topical diclofenac containing products (gels) remain available without prescription, the latter due to their low systemic absorption.

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Advice to give to patients

- There is no requirement to return oral diclofenac products which were available without a prescription if already purchased
- Your doctor or pharmacist can advise on suitable alternatives for pain relief which are available without prescription.
- This recall applies only to non-prescription diclofenac products – products applied to the skin (gels) are not included.
- If you have been prescribed diclofenac, there is no need to stop taking it. Speak to your doctor or pharmacist at your next routine visit if you have any heart problems or other concerns about the treatment.

Reporting side effects

Please report any suspected side effects to any medicine or vaccine to the Yellow Card Scheme via the website (www.mhra.gov.uk/yellowcard) or by calling the free phone line (0800 731 6789). By reporting side effects you can help provide more information on the safety of medicines.

Yours sincerely,

Dr Sarah Branch

Vigilance and Risk Management of Medicines Division
MHRA
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