Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/42

Caution In Use

Issued 26 August 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Ipca Laboratories UK Limited

MEDICINE DETAILS

Allopurinol 100 mg tablets

PL: 28278/0035

Active Ingredient: allopurinol

SNOMED code: 40127111000001108

GTIN:18901079119732, 05060777420482

MEDICINE DETAILS

Allopurinol 300 mg tablets

PL: 28278/0036

Active Ingredient: allopurinol

SNOMED code: 40127311000001105

GTIN:18901079119749, 05060777420499

MEDICINE DETAILS

Amlodipine 5 mg Tablets

PL: 28278/0012

Active Ingredient: amlodipine besilate

SNOMED code: 41103211000001109

GTIN:05060777420024

MEDICINE DETAILS

Amlodipine 10mg Tablets
PL: 28278/0013
Active Ingredient: amlodipine besilate
SNOMED code: 41103411000001108
GTIN:05060777420031

MEDICINE DETAILS

Hydroxychloroquine sulfate 200 mg film-coated tablets
PL: 28278/0023
Active Ingredient: hydroxychloroquine sulfate
SNOMED code: 38375911000001109
GTIN:18901079116236, 05060777420543

MEDICINE DETAILS

Levofloxacin 250mg Film Coated Tablets
PL: 28278/0001
Active Ingredient: levofloxacin Hemihydrate
SNOMED code: 39891911000001101
GTIN:05060777420413

MEDICINE DETAILS

Levofloxacin 500mg Film Coated Tablets
PL: 28278/0002
Active Ingredient: levofloxacin Hemihydrate
SNOMED code: 39892211000001103
GTIN:05060777420437

MEDICINE DETAILS

Gabapentin Ipca 100 mg Hard Capsules
PL: 28278/0098
Active Ingredient: gabapentin
SNOMED code: Not Available
GTIN:05060777420666

MEDICINE DETAILS

Gabapentin Ipca 300 mg Hard Capsules

PL: 28278/0099

Active Ingredient: gabapentin

SNOMED code: Not Available

GTIN:05060777420673

MEDICINE DETAILS

Gabapentin Ipca 400 mg Hard Capsules

PL: 28278/0100

Active Ingredient: gabapentin

SNOMED code: Not Available

GTIN:05060777420680

Background

Ipca Laboratories UK Ltd has informed the MHRA that the Patient Information Leaflet (PIL) in the products listed in this notification do not contain all the required safety information. The errors were identified following a MHRA Good Pharmacovigilance Practice (GPvP) inspection and further investigation by the Marketing Authorisation Holder, Ipca Laboratories UK Ltd.

This issue impacts all current batches of the impacted products. Please see the Appendices for detailed information regarding the missing information in each PIL and the table below for information on where to find the up-to-date PIL.

- Appendix 1 - Allopurinol 100 mg tablets & Allopurinol 300 mg tablets
- Appendix 2 - Amlodipine 5 mg Tablets & Amlodipine 10 mg Tablets
- Appendix 3- Hydroxychloroquine sulfate 200 mg film-coated tablets
- Appendix 4- Levofloxacin 250mg Film Coated Tablets & Levofloxacin 500mg Film Coated Tablets
- Appendix 5 - Gabapentin 100mg capsules, Gabapentin 300mg capsules and Gabapentin 400mg capsules

Advice for Healthcare Professionals:

Healthcare professionals are advised to review the content of this notification, as it provides information that is missing from the current PIL. Whilst this information may already be known, this notification provides a reminder of the safety information, which should be considered when prescribing and dispensing these products.

Healthcare professionals involved in dispensing of these products should, where possible, signpost new patients on these medicines to the missing safety information in the PIL. Upon request, Ipca Laboratories UK Ltd will provide hard copies of the updated PIL to pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information. To request hard copies of the PIL, please contact quality@ipcauk.com with your details, i.e. address, product with batch details, required number of leaflets.

The product quality is not impacted. Due to the requirement for these products to support the UK market, the MHRA in discussion with the Department of Health and Social Care (DHSC) consider that batches which are currently packed and available for distribution, will continue to be distributed. Details of the specific batches can be obtained by contacting quality@ipcauk.com directly.

Ipca Laboratories UK Ltd have confirmed that all new batches produced by the manufacturing site, will be packed with the corrected PILs only and these batches will be available for distribution to UK market from November 2025 onwards.

Advice for Patients:

Patients should continue to take medicines as prescribed by your healthcare professional. The product quality of the impacted batches is not affected, however there is some missing safety information in the Patient Information Leaflet (PIL) that patients should be aware of. Details of the missing safety information can be found in the Appendices related to each individual product.

Appendix 1 - Allopurinol 100 mg tablets & Allopurinol 300 mg tablets

Appendix 2 - Amlodipine 5 mg Tablets & Amlodipine 10 mg Tablets

Appendix 3- Hydroxychloroquine sulfate 200 mg film-coated tablets

Appendix 4- Levofloxacin 250mg Film Coated Tablets & Levofloxacin 500mg Film Coated Tablets

Appendix 5 - Gabapentin 100mg capsules, Gabapentin 300mg capsules and Gabapentin 400mg capsules

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Additional information:

For all medical information enquiries and information on this product, please contact via email address:pharmacovigilance@ipcauk.com or via telephone: 08003685328

For stock control enquiries please contact via telephone: +44 (0)7446 189 936.

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU

Telephone +44 (0)20 3080 6574

DMRC@mhra.gov.uk

APPENDIX 1 Allopurinol 100 mg tablets & Allopurinol 300 mg tablets

Updated PIL	QR Code
Allopurinol 100 mg tablets	
Allopurinol 300 mg tablets	

Missing information from the PIL:

Section 4 Possible side effects	Not known (cannot be estimated from available data): • Aseptic meningitis (inflammation of the membranes that surround the brain and spinal cord): symptoms include neck stiffness, headache, nausea, fever or consciousness clouding. Seek medical attention immediately if these occur.

APPENDIX 2 Amlodipine 5 mg Tablets & Amlodipine 10 mg Tablets

Updated PIL	QR Code
Amlodipine 5 mg Tablets	
Amlodipine 10 mg Tablets	

Missing information from the PIL:

Section 3. If you take more Amlodipine than you should	Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.
Section 4 Possible side effects	toxic epidermal necrolysis Not known: frequency cannot be estimated from the available data • Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk

APPENDIX 3 Hydroxychloroquine sulfate 200 mg film-coated tablets

Updated PIL	QR Code
Hydroxychloroquine sulfate 200 mg film-coated tablets	

Missing information from the PIL:

Section 2 What you need to know before you take Hydroxychloroquine sulfate	Warnings and Precautions Talk to your doctor or pharmacist before taking Hydroxychloroquine sulfate if: • have a genetic condition known as 'glucose-6-dehydrogenase deficiency'. • have a rare illness called 'porphyria' which affects your metabolism • have an inactive chronic infection with hepatitis B virus. • are taking any medicines known to cause any damage to the eyes (such as tamoxifen) • were born with or have family history of prolonged QT interval or have acquired QT prolongation (seen on ECG, electrical recording of the heart) • have heart disorders or have a history of heart attack (myocardial infarction)as hydroxychloroquine may cause heart rhythm disorders in some patients • experience palpitations or irregular heartbeat, you should inform your doctor immediately. The risk of heart problems may increase with increase of the dose. Therefore, the recommended dosage should be followed. • Serious skin rashes have been reported with the use of hydroxychloroquine (see section 4 possible side effects). Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by flu-like symptoms such as fever, headache and body ache. The rash may progress to widespread blistering and peeling of the skin. If you develop these skin symptoms, stop taking hydroxychloroquine and contact your doctor immediately.

	Before treatment with Hydroxychloroquine sulfate: • Some people being treated with hydroxychloroquine sulfate can experiencemental health problems such as irrational thoughts, anxiety, hallucinations, feelingconfused or feeling depressed, including thoughts of self-harm or suicide, even those who have never had similar problems before. If you or others around you notice any of these side effects (see section 4) seek medical advice straight away. **Other medicines and Hydroxychloroquine sulfate** • Medicines that affect the eyes (suchas tamoxifen) • Medicines used for psychiatric disorders (such as amisulpride, quetiapine, risperidone). **Pregnancy and breast-feeding** Hydroxychloroquine sulfate may be associated with a small increased risk of major malformations and should not be used during pregnancy unless your doctor considers the benefits outweigh the risks. If you discover that you are pregnant or are planning to have a baby, consult your doctor right away to re-assess the need for treatment. Hydroxychloroquine should not be used during breast-feeding unless your doctor considers the benefits outweigh the risks. This is because small amounts may pass into mother's milk. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding. Your doctor will discuss with you whether Hydroxychloroquine sulfate is suitable for you.
Section 4 Possible side effects	Not known (frequency cannot be estimated from available data): Severe skin reactions (see section 2 Warnings and precautions) such as: • Rash with a fever and flu-like symptoms and enlarged lymph nodes. This could be a condition called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). • Blistering, widespread scaly skin, pus-filled spots together with fever. This could be a condition

	calledAcute Generalized Exanthematous Pustulosis (AGEP). • Multiple skin lesions, itching of the skin, joint aches, fever and a general ill feeling. This could be a condition called Toxic Epidermal Necrolysis (TEN) • Skin reaction including plum-coloured, raised, painful sores, particularly on your arms, hands, fingers, face and neck, which may also be accompanied by fever. This could be a condition called Sweet syndrome Liver problems: Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes), dark urine, nausea, vomiting and/or abdominal pain. Rare cases of liver failure (including fatal cases) have been observed. **Common** (may affect less than 1 in 10 people) You have any eye problems. This includes problems with your eyesight such as blurring sensitivity to light or the way you see colour. **Uncommon** (may affect less than 1 in 100 people) • You have any muscle weakness, cramps, stiffness or spasms or changes in sensation such as tingling which can lead to difficult in moving. If you take this medicine for a long time, your doctor will occasionally check your muscles and tendons to make sure they are working properly. **Not known (frequency cannot be estimated from available data)** • Chest pain and shortness of breath and irregular heartbeat (these could be signs of a condition called “Torsade de pointes”), or fast heartbeat (tachycardia)” **Tests** **Your doctor may monitor:** • Your muscle function and tendon reflexes The levels of specific cells in your blood using occasional blood tests.

APPENDIX 4 Levofloxacin 250mg Film Coated Tablets & Levofloxacin 50mg Film Coated Tablets

Updated PIL	QR Code
Levofloxacin 250mg Film Coated Tablets	
Levofloxacin 500mg Film Coated Tablets	

Missing information from the PIL:

Section 2 What do you need to know before you take Levofloxacin Film-coated tablets	Warnings and Precautions • You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking levofloxacin. • Serious skin reactions Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of levofloxacin. • Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN)can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal. • DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

	If you develop a serious rash or another of these skin symptoms, stop taking levofloxacin and contact your doctor or seek medical attention immediately.
Section 4 Possible side effects	Rare (may affect up to 1 in 1,000 people) • Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). • Syndrome associated with impaired water excretion and low levels of sodium (SIADH) Not known (frequency cannot be estimated from the available data) Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms.

APPENDIX 5 Gabapentin 100mg capsules, Gabapentin 300mg capsules and Gabapentin 400mg capsules

Updated PIL	QR Code
Gabapentin 100mg capsules	
Gabapentin 300mg capsules	
Gabapentin 400mg capsules	

Missing information from the PIL:

Section 2 Warnings and Precautions	**Important information about potentially serious reactions** Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with gabapentin. Stop using gabapentin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4. **Pregnancy, breast-feeding and fertility** - If you are pregnant or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the medicine you are taking might pose to your unborn baby. - You should not stop your treatment without discussing this with your doctor. - If you are planning to become pregnant you should discuss your treatment with your doctor or pharmacist as early as possible before you become pregnant.

	If you are breast - feeding or planning to breastfeed, ask your doctor or pharmacist for advice before taking this medicine. **Pregnancy** Gabapentin capsules can be used during the first trimester of pregnancy if needed. In a study reviewing data from women in Nordic countries who took gabapentin in the first 3 months of pregnancy, there was no increased risk of birth defects or problems with the development of brain function (neurodevelopment disorders). However, babies of women who took gabapentin during pregnancy had an increased risk of low birth weight and preterm birth. If used during pregnancy, gabapentin may lead to withdrawal symptoms in newborn infants. This risk might be increased when gabapentin is taken together with opioid analgesics (drugs for treatment of severe pain).
Section 3 How to take Gabapentin capsules	Do not take more medicine than prescribed. **If you stop taking Gabapentin capsules** After stopping a short or long-term treatment with Gabapentin capsules, you need to know that you may experience certain side effects, so-called withdrawal effects. These effects can include seizures, anxiety, difficulty sleeping, feeling sick (nausea), pain, sweating, shaking, headache, depression, feeling abnormal, dizziness, and feeling generally unwell. These effects usually occur within 48 hours after stopping Gabapentin capsules. If you experience withdrawal effects, you should contact your doctor.
Section 4 Possible side effects	Stop using Gabapentin capsules and seek medical attention immediately if you notice any of the following symptoms: • reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like

	symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis). • Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). **After marketing Gabapentin capsules the following side effects have been reported:** **Not known: frequency cannot be estimated from the available data** • Becoming dependent on Gabapentin capsules('drug dependence') After stopping a short or long-term treatment with Gabapentin capsules, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking Gabapentin capsules").