



Medicines & Healthcare products
Regulatory Agency

Drug Safety Update

Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

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The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicines and medical devices work and are acceptably safe.

The Commission on Human Medicines gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.



NICE has accredited the process used by the MHRA to produce Drug Safety Update guidance. More information on accreditation can be viewed on the [NICE website](https://www.nice.org.uk/accreditation).

To subscribe to monthly email alerts of Drug Safety Update see: <https://www.gov.uk/government/organizations/medicines-and-healthcare-products-regulatory-agency/email-signup>

This month, we ask healthcare professionals to [take part in our consultation](#). We are gathering feedback with a view to transforming how we engage and work together on our common goal of greater patient safety. See page 9.

On page 2, we describe the risk of ocular adverse reactions in patients prescribed dupilumab. We advise healthcare professionals to be alert to new onset or worsening ocular symptoms, such as dry eye (which can also include paradoxical eye watering), keratitis and ulcerative keratitis, and to ensure they are promptly managed.

Next, on page 10 we summarise recent advice relating to COVID-19 vaccines and medicines published since the October 2022 issue of Drug Safety Update. And on page 12, we include recent letters, recalls, and notifications sent to healthcare professionals about medicines.

If you have been forwarded this issue of Drug Safety Update, subscribe directly via [our website](#).

Dupilumab (Dupixent ▼): risk of ocular adverse reactions and need for prompt management

Healthcare professionals prescribing dupilumab should be alert to the risks of ocular reactions. New onset or worsening ocular symptoms require prompt review. Referral for ophthalmological examination should be made as appropriate.

Advice for healthcare professionals:

- dupilumab is commonly associated with cases of conjunctivitis and allergic conjunctivitis, eye pruritus, blepharitis, and dry eye and with infrequent cases of keratitis and ulcerative keratitis, especially in patients with atopic dermatitis
- be alert to the risks of ocular reactions and promptly review new onset or worsening ocular symptoms, referring patients for ophthalmological examination as appropriate
- sudden changes in vision or significant eye pain that does not settle warrant urgent review
- discuss with patients or caregivers the potential for, and symptoms of, ocular side effects at initiation of dupilumab, including symptoms of conjunctivitis and dry eye (which can also include paradoxical eye watering), keratitis and ulcerative keratitis
- advise patients to promptly report new-onset or worsening eye symptoms to their healthcare professional so that appropriate treatment can be initiated – advise patients not to self-manage ocular symptoms
- ensure that patients who develop conjunctivitis or dry eye that does not resolve following initial treatment, or patients with signs and symptoms suggestive of keratitis (especially eye pain and vision changes), undergo ophthalmological examination, as appropriate
- a UK expert consensus-based guidance on the management of people with dupilumab-related ocular surface disorders is currently being developed by relevant national specialty organisations
- we remind healthcare professionals that tralokinumab (Adtralza ▼), another interleukin-13 inhibitor recently licenced for use in atopic dermatitis, is also associated with common cases of conjunctivitis and allergic conjunctivitis as well as uncommon cases of keratitis, and that patients treated with tralokinumab who develop conjunctivitis that does not resolve following standard treatment should undergo ophthalmological examination
- report any suspected adverse drug reactions associated with dupilumab or tralokinumab on a [Yellow Card](#)

Advice for healthcare professionals to give to patients or parents and caregivers:

- dupilumab has been linked to side effects affecting the eye, especially in patients with atopic eczema (atopic dermatitis)
- most side effects of the eye are mild, but some can become serious if they are not managed properly. Do not attempt to self-manage new or worsening eye problems – seek medical help
- talk to your doctor or another healthcare professional promptly if you have any new or worsening eye problems, such as watering, itching, redness, swelling, eye dryness, a feeling of gritty eyes, or a sensation of a foreign body in the eye
- if you experience significant eye pain that does not settle, or changes in your vision, it is important to speak to your doctor without delay

Review of the risk of ocular reactions

Dupilumab is a monoclonal antibody that inhibits interleukin-4 and interleukin-13 signalling and is used in moderate to severe atopic dermatitis in adults and adolescents 12 years and older.

Dupilumab is also used in children aged 6 years and older with severe atopic dermatitis or severe asthma, and in adults with severe asthma (see background section for detailed indication).

The potential for adverse reactions affecting the eye with dupilumab was established in the initial clinical trials. Further ocular adverse reactions have been identified during post-marketing clinical use. Although most ocular reactions are mild, some can become serious. We have received a small number of Yellow Card reports of ulcerative keratitis with serious corneal damage associated with dupilumab treatment.

We recently reviewed the risk of dry eye and also serious ocular side effects associated with dupilumab. We sought independent advice from the [Gastroenterology, Rheumatology, Immunology and Dermatology Expert Advisory Group](#) to the Commission on Human Medicines, as well as ophthalmology expertise.

The review recommended that updates should be made to the product information for dupilumab to include the adverse drug reaction 'dry eye' and also to emphasise the need for prompt and appropriate management of any potential ocular reactions.

It is not currently possible to predict who may experience the rarer and most serious ocular adverse reactions, such as ulcerative keratitis. It is therefore important, with all ocular reactions, for patients to receive prompt care, with treatment provided as appropriate to prevent or minimise damage to the eye.

We are also alerting healthcare professionals prescribing tralokinumab. Tralokinumab, an antibody that inhibits interleukin-13 signalling, has more recently been licenced in the UK for moderate-to-severe atopic dermatitis in adult patients. To date, there is very limited UK clinical experience with its use. Clinical trial data have indicated that keratitis, conjunctivitis and allergic conjunctivitis are associated with tralokinumab use.

We are advising healthcare professionals prescribing dupilumab and tralokinumab to discuss with patients the potential for side effects affecting the eye and to ensure any reactions are managed promptly, especially in a patient experiencing eye pain or changes to their vision.

Frequency of ocular adverse reactions

Dupilumab was first licensed in the UK in September 2017. In the past year it is estimated that the usage of dupilumab in the UK was approximately 6,940 patient years.¹

Based on combined data from all indications studied in the development of dupilumab, the product information lists conjunctivitis and allergic conjunctivitis with a frequency of common (affecting up to 1 in 10 patients); dry eye, blepharitis, eye pruritus and keratitis as uncommon (affecting up to 1 in 100); and ulcerative keratitis as rare (affecting up to 1 in 1,000). Based on studies of patients with atopic dermatitis, the frequencies listed for eye pruritus, dry eye, and blepharitis in this group are common and uncommon for ulcerative keratitis.

Up to 7 September 2022, the MHRA has received 479 UK reports which included suspected ocular side effects with dupilumab. 111 of these reports were considered serious.² 9 reports of ulcerative keratitis were received, representing 5 cases (for some individual cases, the MHRA received more than one report from different sources). 2 of these cases involved corneal perforation. 18 reports involved children ranging from 6 to 17 years of age.

With regards to the ocular events listed for dupilumab, the table below summarises the number of UK reports received by the MHRA up to 7 September 2022.³

Adverse drug reaction (ADR) term	Number of UK reports received by MHRA
Dry eye	151
Conjunctivitis	114
Eye pruritus	99
Blepharitis	22
Conjunctivitis allergic	9
Ulcerative keratitis	9
Keratitis	2

Tralokinumab was first licenced in the UK in June 2021, with NICE recommendation in August 2022. So far in the UK, it has been used at very low levels. Up to 7 September 2022 the MHRA has received no ocular related reports regarding tralokinumab.³

The product information for tralokinumab lists conjunctivitis and conjunctivitis allergic with a frequency of common (affecting up to 1 in 10 patients) and keratitis with a frequency of uncommon (affecting up to 1 in 100) based on information from clinical trials.

Characteristics of ocular adverse reactions

Patients with atopic dermatitis commonly present with ocular surface diseases such as allergic conjunctivitis, blepharitis, and keratitis, as well as infectious conjunctivitis and keratoconus (changes to the shape of the cornea).

The mechanisms by which dupilumab or tralokinumab increase the occurrence of, or exacerbate, ocular adverse events are not fully understood.

Publications, including individual case reports about patients experiencing suspected ocular side effects with dupilumab, show variability in timing of onset and progression, presentation, and sequelae of ocular adverse reactions.⁴⁻¹⁰ In most reports received by the MHRA where patients have experienced ocular adverse reactions with dupilumab, the reactions have not been considered to be serious by the reporter.² However, the MHRA has received 9 reports of 5 patients who experienced ulcerative keratitis with dupilumab, and, where the information was provided, treatment required corneal gluing or tectonic keratoplasty.³ The details of some of the serious reports, and expert advice, indicate that early review and intervention are beneficial to the patient.

Expert ophthalmology and dermatology advice provided to the MHRA indicated that in the UK clinical experience, most ocular reactions seen with dupilumab are mild and can be managed. However, it is not currently possible to predict who may experience the rarer and most severe ocular adverse reactions, such as ulcerative keratitis.

It is therefore important, with all ocular reactions, for patients to receive prompt care, with treatment provided as appropriate to prevent or minimise damage to the eye. It is important to recognise 'red flags' for urgent ophthalmological consultation, such as eye pain, vision loss, and an increase in ocular pressure.

Treatment pathways and UK Expert Consensus for ocular adverse reactions

UK clinical experience is that dupilumab treatment does not usually need to be discontinued in the event of ocular reactions. It is important for the patient to receive timely advice and intervention with appropriate care and management of ocular reactions, and for patients and healthcare professionals to recognise serious reactions, and when ophthalmological referral is necessary.

Consult local treatment pathways to outline the spectrum of differential diagnoses that should be considered and the monitoring and treatment of patients who experience ocular side effects while treated with dupilumab. A UK expert consensus-based guidance on the management of people with dupilumab-related ocular surface disorders is currently being developed by relevant national specialty organisations.

Refer to these guidelines and local treatment pathways to guide management of dupilumab or tralokinumab associated adverse ocular reactions. Prompt referral for ophthalmological examination should be made where appropriate.

Background

Dupilumab

Dupilumab, tradename Dupixent, is a recombinant human IgG4 monoclonal antibody that inhibits interleukin-4 and interleukin-13 signalling. It was first licenced in the UK in September 2017.

For adults and adolescents older than 12 years, it is licensed for use in moderate to severe atopic dermatitis and as add-on maintenance treatment for severe asthma. For adults, it is also licensed as an add-on therapy with intranasal corticosteroids for severe chronic rhinosinusitis with nasal polyposis (see full indication details in the [Summary of Product Characteristics](#)).

For children aged 6 years to 11 years, dupilumab is licensed for severe atopic dermatitis and as add-on maintenance treatment for severe asthma.

UK Technology Appraisal Guidance recommendations on dupilumab for treating moderate to severe atopic dermatitis were published in August – September 2018 (for example, see NICE guidance). Usage of dupilumab in the UK up to 2022 has predominantly been for patients with atopic dermatitis.

UK Technology Appraisal Guidance recommendations on dupilumab for treating severe asthma with type 2 inflammation that is inadequately controlled in people 12 years and over were published in 2021.

Tralokinumab

Tralokinumab, tradename Adtralza, is a fully human IgG4 monoclonal antibody that inhibits interleukin-13 signalling.

Tralokinumab was first licenced in the UK in June 2021 for use in adults with moderate to severe atopic dermatitis (see full indication details in [Summary of Product Characteristics](#)). On 3 August 2022, NICE published recommendations on tralokinumab for treating moderate to severe atopic dermatitis.

Report any suspected reactions on a Yellow Card

Dupilumab and tralokinumab are black triangle medicines and all suspected adverse drug reactions should be reported to the [Yellow Card scheme](#).

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the [Yellow Card website](#)
- the Yellow Card app; download from the [Apple App Store](#) or [Google Play Store](#)
- some clinical IT systems for healthcare professionals (EMIS, SystemOne, Vision, MiDatabank, and Ulysses)

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates. When reporting for a biological medicine or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch number.

Report suspected side effects to medicines, vaccines, medical device and test kit incidents used in coronavirus (COVID-19) testing and treatment using the [dedicated Coronavirus Yellow Card reporting site](#) or the Yellow Card app. See the MHRA website for the [latest information on medicines and vaccines for COVID-19](#).

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References

1. Based on internal analysis by MHRA from the following source: IQVIA MIDAS® Quarterly Sales Audit from Q3 2017 to Q2 2022 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved. The patient years estimate is based on the WHO Defined Daily Dose of 21.4mg
2. Under the CIOMS / ICH E2D case level definition of serious (results in death; is life-threatening; requires inpatient hospitalisation or results in prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; is a medically important event or reaction)
3. In interpreting these data, caution should be exercised as the data may not be complete, and many factors can influence the reporting rates and the information provided within the reports. Reporters are asked to submit a Yellow Card report even if they only have a suspicion that the medicine may have caused the adverse drug reaction
4. Popiela MZ and others. '[Dupilumab-associated ocular surface disease: presentation, management and long-term sequelae](#)', Eye, 2021, published online 28 January 2021.
5. Felfeli T and others. '[Prevalence and Characteristics of Dupilumab-Induced Ocular Surface Disease in Adults With Atopic Dermatitis](#)'. Cornea, 2022, volume 41, pages 1242 to 1247.

6. Faiz S and others. '[Effectiveness and safety of dupilumab for the treatment of atopic dermatitis in a real-life French multicenter adult cohort](#)'. Journal of the American Academy of Dermatology, 2019, volume 81, pages 143 to 151.
7. Phylactou M and others. '[Corneal Perforation in Patients Under Treatment With Dupilumab for Atopic Dermatitis](#)'. Cornea, 2022, volume 41, pages 981 to 985.
8. Woolf RT and others. '[Real-world effectiveness and tolerability of dupilumab in adult atopic dermatitis: a single centre, prospective 1-year observational cohort study of the first 100 patients treated](#)'. British Journal of Dermatology 2021 volume 184, pages 742 to 774.
9. Akinlade B and others. '[Conjunctivitis in dupilumab clinical trials](#)'. British Journal of Dermatology 2019, volume 181, pages 459 to 473.
10. Ivert LU and others. '[Eye Complications During Dupilumab Treatment for Severe Atopic Dermatitis](#)'. Acta Dermato-Venereologica, 2019, volume 99, pages 375 to 378

Consultation with healthcare professionals: please complete our consultation to help influence how we communicate with you

The MHRA is reviewing its approach to engaging with healthcare professionals on the safety of medicines and medical devices. Through our consultation, you can provide your views and help inform our new approach.

What healthcare professionals can do to get involved and influence how the MHRA engages with them

- we are consulting a wide range of healthcare professionals with a view to transforming how we engage and work together on our common goal of greater patient safety – [access the consultation here](#)
- we want to ensure that healthcare professionals are receiving actionable information and guidance on safe use of medicines and medical devices that they can take into their working practice, providing timely advice to patients
- tell us how we can improve our engagement – your feedback will help us to develop a new approach, improving how safety information and reporting systems are communicated and used and maximising our impact on patient safety
- views shared during the consultation will support healthcare professionals to deliver the best care to patients
- we encourage you to take part and talk to your colleagues about supporting this important consultation

About the consultation

Healthcare professionals and their professional bodies have a unique opportunity to share their views and influence the MHRA's safety communications and safety reporting systems – [access the consultation here](#).

The consultation is enabling healthcare professionals across the UK to have their say on how they wish to receive vital safety information, how they'd like to be engaged, and to feedback on the Yellow Card safety reporting system.

General practitioners, nurses, pharmacists, dentists, midwives, specialty care doctors, technicians and other registered medical professionals, including professional bodies and Royal Colleges, are asked to provide views on four key areas. These are: safety reporting systems; MHRA advice and regulatory decisions; awareness and understanding of the MHRA's safety role; and how easy it is for healthcare professionals to share their views and expertise with the Agency. Read more in our [press release](#).

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COVID-19 vaccines and medicines: updates for November 2022

Summaries of Yellow Card reporting

We continue to publish the summaries of the [Yellow Card reporting for the COVID-19 vaccines](#) being used in the UK. The report summarises information received via the Yellow Card scheme and includes other data such as usage of COVID-19 vaccines and relevant epidemiological data. The report is updated regularly to include other safety investigations carried out by the MHRA under the [COVID-19 Vaccine Surveillance Strategy](#).

Other recent MHRA updates on Coronavirus vaccines and medicines

We have also recently:

- issued updated information to reflect the fact that the [shelf life of Paxlovid has been extended from 18 to 24 months](#) from initial manufacture
- granted [approval for a second updated Pfizer/BioNTech 'bivalent' booster vaccine](#) after it was found to meet acceptable standards of safety, quality and effectiveness
- [granted approval](#) for Comirnaty 10 micrograms concentrate for dispersion for injection (one of the licensed Comirnaty vaccines produced by Pfizer/BioNTech) for use as a booster for 5- to 11-year-olds
- updated the [product information for the Comirnaty vaccines](#) on myocarditis and pericarditis after a third dose and in the age group 5-11 years to reflect the most up-to-date information about these known side effects
- granted [approval for Nuvaxovid to be used as an adult booster](#) for those aged 18 and above. The product information has also been updated to add information on additional side effects
- updated the Summary of Product Characteristics (SmPC) and Patient Information Leaflet to reflect the [approval of Evusheld for the treatment of COVID-19 in adults who are at risk of progressing to severe disease](#)

See [guidance on COVID-19 for all our latest information](#), including after publication of this article. We previously included summaries of latest COVID-19 information, including in the [July 2022](#), [August 2022](#), [September 2022](#) and [October 2022](#) issues of Drug Safety Update.

Reporting Yellow Cards

Report suspected side effects to medicines, vaccines and medical device and test kit incidents used in coronavirus (COVID-19) testing and treatment using:

- the dedicated [Coronavirus Yellow Card reporting site](#)
- the Yellow Card app (download from the [Apple App store](#) or [Google Play store](#))

For products under additional monitoring (▼) such as the COVID-19 vaccines, you should report all suspected adverse side effects. This will allow the MHRA to identify new safety information for these products.

When reporting please provide as much information as possible, including information about medical history, any concomitant medications, onset timing, and treatment dates, and for vaccines, the product brand name and batch number.

You may be contacted following submission of a Yellow Card report so that we can gather additional relevant information for the assessment of the report. These contributions form an important part of our understanding of suspected side effects.

If you have been forwarded this article, subscribe directly to Drug Safety Update via our [website](#).

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Letters and medicine recalls sent to healthcare professionals in October 2022

National Patient Safety Alert and Class 4 Medicines Defect Information notice: Prenoxad 1mg/ml Solution for Injection

On 10 November 2022, we issued a [National Patient Safety Alert](#) and a [Class 4 Medicines Defect Information](#) notice highlighting action needed after being notified of a limited number of Prenoxad packs in a batch marketed in France with missing needles. Naloxone is a drug that reverses the effects of an opioid overdose.

Prenoxad kits are packed with two (2) Terumo 23 gauge 1¼ inch needles, along with the pre-filled syringe containing the active ingredient (naloxone hydrochloride), and a Patient Information Leaflet. If no needles are present in the kit, there is a risk that patients, members of the public and/or healthcare professionals may not be able to administer life-saving doses of naloxone from these kits in an emergency. This may impede the treatment for a patient with an opioid overdose, which may result in delay to intervention and possible death.

Healthcare professionals and service providers should check all Prenoxad kits against the batches specified in this alert. If they have any of the batches listed, they should carry out the actions set out in the alert before supplying any of the Prenoxad kits. There are no concerns about the medicine in these kits – the actions will establish the presence or absence of needles in the packs.

We ask providers to contact individuals supplied with Prenoxad kits, where possible, and support checks to ensure kits contain two (2) needles in each kit. Support should be provided to individuals with kits who are unsure how to check their kits. We have provided a [patient letter](#).

Follow the advice in the [National Patient Safety Alert](#) and [Class 4 Medicines Defect Information notice](#).

Letters

In October 2022, the following letters were sent or provided to relevant healthcare professionals:

- [Prednisolone 20 mg/dose Rectal Foam: Supply of packs imported from Ireland](#)
- [Nulojix – risk of medication errors due to change in maintenance dose from 5 mg/kg to 6 mg/kg](#)
- [Natpar \(parathyroid hormone \(rDNA\)\) 100/75/50/25 micrograms/dose powder and solvent for solution for injection: Discontinuation of manufacturing at the end of 2024 and update on 100mcg shortage](#)

- [Supply disruption with Zonegran 25mg/50mg/100mg in the UK \(NI\)](#)
- [Metalyse \(tenecteplase\): 10,000 units \(50 mg\) powder and solvent for solution for injection – temporary supply shortage](#)
- [Ozempic Solution for injection in pre-filled pen \(Semaglutide\): supply shortage in the UK](#)
- [Sialanar 320 mcg/ml oral solution \(Glycopyrronium\): Interim Supply of Ireland / Germany/ Austria Labelled Stock to Mitigate Supply Disruption](#)

Medicine Recalls and Notifications

In October 2022, recalls and notifications for medicines were issued on:

[Class 2 Medicines Recall: Aventis Pharma Limited \(t/a Sanofi\), Stemetil 5mg/5ml Syrup, EL\(22\)A/41](#). Issued on 6 October 2022. Sanofi is recalling all batches of this product as a precautionary measure due to the identification of N-nitrosomethylphenylamine (NMPA) above the acceptable limit. Healthcare professionals should stop supplying the batches immediately, quarantine all remaining stock and return to supplier. However, patients undergoing treatment should be advised not to discontinue Stemetil Syrup without consulting their prescriber. See [letter for healthcare professionals issued 10 November 2022](#).

[Class 2 Medicines Recall: hameln pharma ltd, Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion, EL \(22\)A/42](#). Issued on 11 October 2022. A recall of batch 210505 of Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion has been initiated as a precautionary measure. This is due to an increased presence of visible crystalline particles within the solution, identified during ongoing re-inspection of retained samples. Healthcare professionals should stop supplying the batch immediately, quarantine all remaining stock and return to supplier.

[Class 4 Medicines Defect Information: Flamingo Pharma UK Ltd, Ibuprofen 400mg Tablets, Paracetamol 500mg Tablets \(Caplets\), EL \(22\)A/43](#). Issued on 12 October 2022. An error has been identified relating to the ink printing of the batch number and expiry date on the carton for three batches of Ibuprofen 400mg Tablets. The impacted products are within specification and there is no issue with product quality. Therefore, the affected batches are not being recalled. Healthcare professionals should check the outer carton before dispensing the affected products to ensure the batch number and expiry is present and can be read.

[Class 2 Medicines Recall: hameln pharma ltd, Ephedrine Hydrochloride 30 mg/ml Solution for Injection, EL\(22\)A/44](#). Issued on 20 October 2022. A recall of affected batches of Ephedrine Hydrochloride 30 mg/ml Solution for Injection has been initiated as a precautionary measure. This is due to out of specification results observed at higher storage temperatures during routine ongoing stability studies for related substances. The results mean the affected batches may no longer be in line with the licensed product specification. Healthcare professionals should stop supplying the batch immediately, quarantine all remaining stock and return to supplier.

[Class 4 Medicines Defect Information: Recordati Rare Diseases, Pedeia 5 mg/ml solution for injection, EL\(22\)A/45](#). Issued on 25 October 2022. Certain batches of Pedeia 5 mg/ml solution for injection have been packaged with the incorrect Product Information Leaflet (PIL). The incorrect PIL does not contain important safety information relating to severe skin reactions. In addition, the current Summary of Product Characteristics does not include the relevant safety information. There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. The missing information is included in the alert (link provided above).

[Class 3 Medicines Recall: Medreich PLC, Mebeverine hydrochloride 135mg Film-coated tablets, EL \(22\)A/46](#). Issued on 27 October 2022. A batch of Mebeverine hydrochloride 135mg film-coated tablets has been recalled as a precautionary measure due to out of specification results for tablet dissolution during routine product release testing. Healthcare professionals should stop supplying the above batch immediately, quarantine all remaining stock and return to supplier.

For all of the latest safety notices from the MHRA on drugs and medical devices, see [Alerts and recalls for drugs and medical devices](#).

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