



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/organisations/medicines-and-healthcare-products-regulatory-agency/email-signup>

First, we advise on risks with use of nebulisers to deliver nebulised asthma rescue medications for children and adolescents with asthma. Use of nebulised medicines outside of clinical guidance may increase the risk of potentially fatal delays in seeking medical attention if asthma deteriorates. As such, nebulisers should only be used at home for paediatric asthma under specialist clinical management.

On page 5, we summarise recent advice relating to COVID-19 vaccines and medicines published since the July 2022 issue of Drug Safety Update. And on page 7, we include recent letters, recalls, and notifications sent to healthcare professionals about medicines and medical devices.

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

Nebulised asthma rescue therapy in children: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists

Use of a nebuliser purchased independently of medical advice for use in the home to deliver nebulised asthma rescue medications to children can mask a deterioration in the underlying disease and may increase the risk of potentially fatal delays in seeking medical attention if asthma deteriorates. If home use of a nebuliser for the acute treatment of asthma in children under 18 years of age is considered necessary, this should be initiated and managed by an appropriate specialist. This is consistent with current clinical guidance.

Advice for healthcare professionals:

- use of nebuliser devices at home to deliver asthma rescue medication to children and adolescents, without adequate medical supervision, can mask a deterioration in the underlying disease, which could result in delays in seeking medical attention and have fatal or serious consequences
- only specialists in asthma should initiate and clinically manage use of nebulisers and associated nebulised medicines at home for acute treatment of asthma in children and adolescents (see definition of specialists on page 3)
- independent purchase of nebuliser devices outside of medical advice for use at home to deliver rescue therapy for the acute treatment of asthma in children and adolescents is not recommended
- pharmacists are asked to advise people seeking to purchase a nebuliser for this purpose that such home use of nebulisers is not recommended without specialist clinical management
- continue to report suspected adverse reactions to nebulised medications and adverse incidents involving nebulisers on a [Yellow Card](#)

Advice to provide to patients or caregivers:

- seek urgent medical assistance **if worsening asthma symptoms are not relieved by rescue medicines** prescribed by a healthcare professional, even if the child has short-term recovery following use of prescribed nebulised medication
- children under 18 years should only use a nebuliser to take asthma reliever medications under specific instructions of a doctor with expertise in asthma, so that deterioration in asthma control can be detected and treated without delay
- only use a nebuliser device recommended by a doctor and ask for training from your asthma nurse, pharmacist, or other healthcare professional on how it should be used and maintained and when to seek medical advice
- if your child or teenager have been using a nebuliser at home, and have not yet been referred to a specialist in asthma, talk to their GP about referral to a specialist

Concerns over nebulisers in paediatric acute asthma

Nebulised rescue (or reliever) asthma medicines are prescription-only medicines.

[Clinical guidance from NICE](#) recommends use of nebulised rescue medicines only in severe or life-threatening acute exacerbations of paediatric asthma, or, on a regular basis, only in patients with severe asthma when they are unable to use other inhalational devices.

Use of a nebuliser under both of these circumstances should be strictly under medical supervision – see [NICE treatment summary](#).

This advice is specific to use of nebulisers to deliver asthma rescue medication in paediatric asthma.

Healthcare professionals have expressed concern to the MHRA that use of nebuliser devices at home to deliver asthma rescue medication to children and adolescents, without adequate medical supervision, could mask a deterioration in asthma control and result in delays in seeking medical attention. These delays could increase the risk that a deterioration of asthma goes unrecognised, which may be fatal or may have serious consequences for the patient. The MHRA is aware of a number of fatal cases in children in England, which occurred between 2008 and 2022, in which clinically unsupervised use of a nebuliser was a potential contributory factor in the child's death from asthma.

The MHRA reviewed the evidence, taking into account independent advice from paediatricians, respiratory specialists, and medicines and medical devices safety experts.

The product information for nebuliser solutions for asthma therapy has been updated to state that use of nebuliser devices, purchased to deliver rescue treatments for acute asthma in children and adolescents in the home without medical supervision, is not recommended.

It is also recommended that any use of home nebulisers for this purpose should be initiated and clinically managed by a specialist such as a respiratory specialist paediatrician.

Nebulised asthma medications affected by the recommendations

The following products are authorised in the UK for use in asthma with a suitable nebuliser device:

Medicine	Specific brands and product information	Indications from the product information:
Ipratropium	Atrovent UDVs Ipratropium Bromide Nebuliser Solution	When used concomitantly with inhaled β_2 -agonists, for treatment of reversible airways obstruction as in acute and chronic asthma: <ul style="list-style-type: none">• for acute asthma in children younger than 5 years• for acute and chronic asthma in adults and children older than 5 years.
Salbutamol	Ventolin Respirator Solution Salbutamol 2mg/ml Nebuliser Solution Salbutamol 2.5mg/2.5ml Nebuliser Solution	For use in the routine management of chronic bronchospasm unresponsive to conventional therapy, and in the treatment of acute severe asthma in adults, adolescents and children aged 4 years or older
Terbutaline	Bricanyl Respules Terbutaline Nebuliser Solution	For the relief of severe bronchospasm in bronchial asthma in adults and children of all ages.

Call for reporting

Please continue to report suspected adverse reactions to nebulised medications and adverse incidents involving nebulisers on a [Yellow Card](#). Report on our [website](#) or via the Yellow Card App ([Apple App Store](#) or [Google Play Store](#)).

Please use the dedicated [COVID-19 Yellow Card reporting site](#) to report any suspected adverse reactions or medical device incidents associated with COVID-19 treatment.

Medical device incidents should be reported to [Health Facilities Scotland](#) in Scotland and to the [Northern Ireland Adverse Incident centre](#) in Northern Ireland.

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COVID-19 vaccines and medicines: updates for August 2022

Recent information relating to COVID-19 vaccines and medicines that has been published since the July 2022 issue of Drug Safety Update, up to 19 August 2022.

Approval of Spikevax bivalent COVID-19 booster vaccine

We have approved Spikevax bivalent Original/Omicron COVID-19 Vaccine after it was found to meet our standards of safety, quality and effectiveness. The decision to grant approval for this booster vaccine in the UK was endorsed by the government's independent expert scientific advisory body, the [Commission on Human Medicines](#), after carefully reviewing the evidence.

Safety monitoring showed that the side effects observed were the same as those seen for the original Moderna booster dose and were typically mild and self-resolving, and no serious safety concerns were identified.

Please see the [Press Release](#) and the [Decision page](#) for more information about Spikevax bivalent Original/Omicron booster vaccine for COVID-19.

Summaries of Yellow Card reporting – update to publication frequency

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](#).

In line with the wider government's Living with COVID-19 agenda strategy, the frequency of publication of the updated summary has transitioned to once per month from August. Our robust safety monitoring and surveillance will continue in the normal way between publications, and we will continue to communicate promptly on any updated safety information.

We have also recently:

- published the [Public Assessment Report](#) for Valneva COVID-19 vaccine
- extended the shelf life of [Paxlovid](#) from 12 months to 18 months following a review of stability data

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 [May 2022](#), [June 2022](#) and [July 2022](#) issues of Drug Safety Update.

Reporting Yellow Cards

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 via the Yellow Card app.

As these products are under additional monitoring, this includes all suspected adverse reactions associated with these vaccines. This will allow quick identification of new safety information. When reporting please provide as much information as possible, including information about medical history, any concomitant medications, onset, treatment dates, and vaccine 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 adverse events.

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Letters and medicine recalls sent to healthcare professionals in July 2022

National Patient Safety Alert on the recall of 3 batches of mexiletine hydrochloride (50mg, 100mg and 200mg hard capsules)

On 4 August 2022, we issued a National Patient Safety Alert to support the recall of 3 batches of Mexiletine hydrochloride hard capsules by manufacturer Clinigen Healthcare Ltd. This recall is due to a potential risk of underdose or overdose that could have consequences for the safety of patients.

Clinigen Healthcare Limited has confirmed that no alternative batches of Mexiletine hydrochloride 50mg, 100mg or 200mg hard capsules will be available until later in the year. Therefore, the recall of these batches from patients should only be considered where patients have access to appropriate alternative products.

Patients should be advised not to stop any treatments without consulting their relevant healthcare professional. The risks of suddenly stopping medication for ventricular arrhythmias is higher than the potential risk presented by too much or too little of the active ingredient in the capsule.

For more information, please see the [National Patient Safety Alert](#) page.

Letters

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

- [Imvanex \(UK\) and Jynneos \(USA\): differences between live modified vaccines for Vaccinia virus Ankara](#)
- [Ponvory \(ponesimod\) 20 mg film-coated tablets \(maintenance pack\): interim supply of Irish stock to mitigate supply disruption](#)
- [Erelzi ▼ \(etanercept\): temporary supply of Erelzi 25mg pre-filled syringe in foreign packaging](#)

Gina 10 microgram vaginal tablets (estradiol): reclassification to a pharmacy medicine product available without prescription

Gina 10 microgram vaginal tablets (containing estradiol hemihydrate) are used for the treatment for the treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women aged 50 years and above, who have not had a period for at least 1 year.

Following advice from the [Commission on Human Medicines](#) and careful consideration of the [response to consultation](#), the MHRA has approved the pharmacy (P) legal status for Gina 10 microgram vaginal tablets. A [Public Assessment Report](#) has been made available.

For more information, please see the [pharmacy training materials](#) containing a [pharmacy guide](#) and a [checklist](#).

Medicine Recalls and Notifications

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

[Class 4 Medicines Defect Information: Thornton & Ross, Covonia Night Time Formula and Covonia Original Bronchial Balsam, EL\(22\)A/30](#). Issued 14 July 2022. Batches of Covonia Night Time Formula (dextromethorphan hydrobromide, diphenhydramine hydrochloride) and Covonia Original Bronchial Balsam (dextromethorphan hydrobromide, menthol) have been identified omitting the 'P' symbol for pharmacy medicine on the bottle. This packaging error does not affect product quality and affected products have only been distributed to pharmacies. Healthcare professionals are advised to manage the supply of the above batches in line with the legal requirements for Pharmacy medicines.

[Class 2 Medicines Recall: hameln pharma ltd, Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion, EL\(22\)A/31](#). Issued 19 July 2022. A batch of amiodarone hydrochloride 50 mg/ml concentrate for solution for injection/infusion is being recalled due to increased presence of visible crystalline particles within the solution. This recall is a precaution as the potential for amiodarone solutions for injection/infusion to crystallise with associated potential for amiodarone-induced phlebitis is known. Stop supplying the batch immediately, quarantine all remaining stock and return to supplier.

[Class 4 Medicines Defect Information: Omega Pharma Limited, Niquitin 14mg Clear Patch \(14 patches\), EL\(22\)A/32](#). Issued 20 July 2022. Two batches of Niquitin 14mg Clear Patch (nicotine) have been identified with a packaging error. Affected packs incorrectly states the patches contain 21mg of nicotine instead of the correct 14mg. Healthcare professionals and other retailers are advised to note the error relating to the product packaging and refer to the dose on the other areas of the carton or sachet which remains correct.

[Class 4 Medicines Defect Information: Novo Nordisk Limited, NovoRapid FlexTouch 100 units/ml, Saxenda FlexTouch \(liraglutide\) 6mg/ml, EL\(22\)A/33](#). Issued 21 July 2022. A defect has been identified with a small number of products in batches of NovoRapid FlexTouch (insulin aspart) 100 units/ml solution for injection in pre-filled pen and Saxenda FlexTouch (liraglutide) 6mg/ml Solution for injection in pre-filled pen. The affected pre-filled pens have a defective dose selectors, no click sound will be heard, and as the dose cannot be selected the pen will not inject. The average number of affected products is 2 to 3 pens per million. Healthcare professionals are advised to follow the usual safety and complaints process to issue replacement pens, and to advise patients to always carry a spare pen.

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

[Sign-up to receive MHRA alerts about drugs and medical devices and subscribe to Drug Safety Update](#).

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