

What to include in your Yellow Card of an adverse drug reaction

You should include four critical pieces of information in your Yellow Card report.

Suspect drug(s)

If known, it is helpful to include:

- route of administration
- daily dose, dose frequency and schedule
- dates of administration
- if it is a vaccine, please quote brand and batch number

Suspect reaction(s)

If known, it is helpful to include:

- when the reaction occurred
- seriousness of the reaction
- any treatment given
- outcome of reaction

If the reaction has already been reported (e.g. by another healthcare professional or the patient) but you have additional information to report, please submit a Yellow Card as we can detect duplicate reports and link the information.

Patient details

Please provide at least one of the following:

- patient sex
- patient age at the time of the reaction
- if known, please provide the patient's weight
- patient initials and a local identification number (hospital or practice reference number) to help you identify the patient in any future correspondence

Providing this information does not breach confidentiality agreements between you and your patient.

For the identification number, you can use any number or code that will identify the patient to you, but not to MHRA. For instance, you could use the patient's local practice or hospital number or you may want to set up a file specifically for Yellow Cards.

We recommend that a copy of the Yellow Card report is included on the patient's notes for future reference.

Reporter details

Please include your name and full address so that MHRA can acknowledge receipt of the report and follow up for further information if necessary.

Additional information

If possible please provide the following additional information:

- other drugs taken in the last 3 months prior to the reaction, including over-the-counter (OTC) and herbal medicines
- any information on re-challenge with the suspect drug(s)
- relevant medical history, including allergies
- relevant test results
- for congenital abnormalities, please state all other drugs taken during the pregnancy and the date of the last menstrual period
- attach additional pages (including print-outs of test results) if necessary

Please indicate if the patient was not taking any other drugs, or if no other information is available.

All the information that you provide helps MHRA to interpret the case and evaluate safety issues. Please provide as much relevant information as is readily available to reduce the need for follow-up. However, do not delay reporting just because some details are not known. MHRA will contact you additional information is required.

See [Assessing causality of adverse drug reactions](#) (PDF, 104KB, 2 pages)

You should anonymise any documents that contain personal identifiers.

Once your report has been submitted, you will receive a Yellow Card registration number either by email or by post which you should quote when sending follow-up information to enable us to link the additional information with the initial report.

Serious reactions

Serious reactions include those that:

- are fatal
- are life-threatening
- are disabling or incapacitating
- are congenital abnormalities
- involve or prolong hospitalisation
- are medically significant

A severe reaction might not be life-threatening or disabling but can seriously affect an individual patient. For example, headaches are not normally considered serious in nature, but may be very severe. In such instances please report.

In addition to identifying previously unrecognised side effects, MHRA also investigates well-known side effects in detail. This means we can give safer advice on risk factors for patients such as age or concurrent disease and how medicines can be used more safely. Rare or delayed effects, may still be identified when a medicine has been available for many years. For example, Reye's syndrome was associated with aspirin eight decades after it was first marketed.

MHRA also monitors the frequency of adverse drug reactions associated with medicines which may warrant further investigation and action, for example batch complications.

If enough information about recognised reactions is collected, MHRA may be able to compare medicines in the same therapeutic class to investigate their relative safety.

For instance, data from the Yellow Card Scheme contributed to the evidence that among non-steroidal anti-inflammatory drugs, ibuprofen is associated with the lowest risk of gastrointestinal reactions.

The table below shows examples of adverse reactions that should be reported.

System area	Reaction examples
Blood	bone marrow dyscrasias, coagulopathies, haemolytic anaemias
Cardiovascular	arrhythmias, cardiac arrest, cardiac failure, cardiomyopathy, circulatory failure, hypertension, hypotension, myocardial, ischaemia/infarction, sudden death
Central nervous system	anorexia nervosa, catatonia, cerebrovascular accident, coma, confusional state, dependence, depression, epilepsy (including exacerbations), extrapyramidal reactions, hallucinations, hyperpyrexia, intracranial pressure, myasthenia, neuroleptic malignant
Gastrointestinal	colitis, haemorrhage, hepatic cirrhosis, hepatic dysfunction, hepatic fibrosis, ileus, pancreatitis, perforation, peritonitis (including fibrosing), pseudo-obstruction
Immunological	anaphylaxis, arteritis, drug fever, graft rejection, lupus syndrome, polyarteritis nodosa, vasculitis
Malignancy	any
Metabolic	acidosis, adrenal dysfunction, diabetes, hypercalcaemia, hyperkalaemia, hypokalaemia, hyponatraemia
Musculoskeletal	arthropathy, aseptic bone necrosis, osteomalacia, pathological fracture
Renal	renal dysfunction, urinary retention
Reproduction	spontaneous abortion, antepartum haemorrhage, congenital abnormalities, eclampsia, pre-eclampsia, infertility, uterine haemorrhage / perforation
Respiratory	alveolitis (allergic, fibrosing), bronchospasm (including exacerbation), pneumonitis, respiratory failure, thromboembolism
Skin	angioedema, bullous eruptions, epidermal necrolysis, exfoliation (generalised)
Special senses	cataract