



## Detailed Drug Analysis Print interpretation guide

### Essential information about Drug Analysis Prints

The information in Drug Analysis Prints (including vaccines) can be very useful in helping to identify possible medicine safety issues. However, Drug Analysis Prints do not present a complete overview of the risks associated with specific medicines. Conclusions on the safety and risks of medicines cannot be made on the information in Drug Analysis Prints alone.

For more comprehensive information about the risks of particular medicines, you should refer to the patient information leaflet for the medicine, or ask your doctor, nurse or pharmacist.

When using a Drug Analysis Print, you should remember that:

- The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the information in Drug Analysis Prints. This is because we have limited information about how many people have taken the medicine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the adverse drug reaction. The existence of an adverse drug reaction report on a Drug Analysis Print does not necessarily mean that the medicine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse drug reaction. Sometimes reactions can be part of the condition being treated rather than being caused by a medicine.
- Many factors have to be considered when assessing whether a medicine has caused a reported adverse drug reaction. When monitoring the safety of medicines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the risks of different medicines by comparing the numbers presented in Drug Analysis Prints.

**If you are concerned about the medicine you are taking, you should contact your GP, the health professional who prescribed the medicine, your pharmacist or NHS 111 Service by dialing '111' (textphone 18001 111) in England and Scotland, or from 0845 46 47 (textphone 0845 606 4647) in Wales. You should not stop taking any prescribed medicine without first talking to your health professional.**

### What is a Drug Analysis Print?

The Drug Analysis Prints provided on this website give a complete listing of all UK spontaneous suspected adverse drug reactions (ADRs) reported through the Yellow Card Scheme to the MHRA and the Government's independent scientific committee on medicines safety, the Commission on Human Medicines (CHM).

Since January 2005, patients have been able to submit adverse drug reaction reports through the Yellow Card Scheme, and these are also included in Drug Analysis Prints.

Each Drug Analysis Print lists the suspected reactions reported for a particular medicine. Medicines are listed by the name of the active ingredient, and not by the brand name. The name of the active substances in your medicines can be found on the medicine pack or in the patient information leaflet accompanying your medicine.

**It is important to note that healthcare professionals are asked to report even if they only have a suspicion that the medicine may have caused the adverse drug reaction. The fact that a report has been submitted does not necessarily mean that the medicine has been proven to cause a reaction.**

### Risks and benefits of medicines

For a medicine to be considered safe, the expected benefits of the medicine will be greater than the risk of suffering harmful reactions. It is important to note that most people take medicines without suffering any serious side effects.

All medicines can cause reactions. The patient information leaflet accompanying the medicine, or available from your pharmacist, lists the known side effects associated with the medicine. Healthcare professionals such as doctors and pharmacists can also provide this information.



## Monitoring the safety of medicines

Information collected through the Yellow Card Scheme is an important tool in helping the MHRA and CHM monitor the safety of medicines. Yellow Card reports of suspected adverse drug reactions are evaluated, together with additional sources of evidence such as worldwide literature, in order to identify previously unidentified hazards or side effects.

If a new side effect is identified, information is carefully considered in context of the overall side effect profile for the medicine, and how it compares with other medicines used to treat the same condition.

The MHRA will take action, if necessary, to ensure that the medicine is used in a way that minimises risk, while maximising patient benefit. Such changes may include, for example, restricting the indication, or special warnings and precautions. Rarely, a drug may need to be withdrawn from the market if the risk of side effects is considered to outweigh the benefits of treatment.

## Layout of Drug Analysis Prints

The Drug Analysis Print lists all suspected reactions reported to have occurred in association with the use of a particular medicine through the Yellow Card Scheme.

### The Drug Analysis Print:

- lists all individual suspected adverse drug reactions reported on Yellow Cards by active substance;
- lists medicines by active ingredient - the brand names (Products) included are shown at the beginning of the print when a Yellow Card report has specifically stated the brand name;
- includes data for reports where the drug was given as a single active ingredient (a single-constituent drug) and where the drug was given in a product containing several other active ingredients (a multi-constituent drug);
- lists the total number of reactions and reports on the first page of the print (each report relates to a single patient and may contain multiple reactions); on the last page of the print these are broken down into single constituent drugs, multi constituent drugs and totals;
- groups together suspected adverse drug reactions by medical terms, broken down by more specific conditions; there is a high level grouping by System Organ Class (SOC) (the highest level in MedDRA (**M**edical **D**ictionary for **R**egulatory **A**ctivities)) which groups together reactions that affect similar systems/organs in the body) on page 2 of the print, followed by a more detailed breakdown on the following pages
- to the right of each reaction, lists the total number of reports received for a particular reaction, and the number of reports where there was a fatal outcome by both single constituent and multi-constituent formulations. Totals of the data is displayed in the 'Total unique reports' columns.

**Please note that many Yellow Card reports contain more than one suspected reaction and the total number of suspected reactions listed on the Drug Analysis Print may be higher than the number of reports received for the drug.**

## Use of Yellow Card Data for publication

**If you wish to copy or circulate either the Drug Analysis Print or the information contained within it to anyone else, please ensure that a copy of these guidelines is also provided.**

The MHRA and CHM encourage the use of data from the Yellow Card Scheme in research and for publication, but wish to ensure that the limitations of interpretation of the data are made clear.

If you propose to publish information based on Yellow Card data or Drug Analysis Prints, the MHRA is most willing to provide advice on how the Yellow Card information might be best used and presented. The MHRA is also willing to provide feedback on manuscripts prior to publication. Please write to the Director, Vigilance and Risk Management of Medicines Division at the address below.

### Further information:

If you require further information, please contact the MHRA:

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