**UKMI Medicines Compliance Aid Stability Information**

Please note - the information on individual drugs and their stability in medicines compliance aids is being updated in 2019. The references on this document have been updated in anticipation of this.

**The information UKMI provides about the stability of medicines in medicines compliance aids (MCAs) is intended for use by healthcare professionals**

**For any enquiries about this database please email Tiffany Barrett at** **ubh-tr.swmi@nhs.net**

**About UKMI MCA stability information**

**Manufacturers of medicines have robust data on the stability of their products when stored in their original packaging. There is very little reliable data available on the stability of medicines after they are removed from their original packaging and stored under different conditions.**

**What UKMI MCA stability information does** – it makes recommendations on the suitability of solid dose forms for transfer from the manufacturers’ original packaging to multi-compartment compliance aids (MCAs). These recommendations are based on

* physico-chemical stability and characteristics of the medicine and its formulation(s).
* advice, where available, from manufacturers
* data, where available, on storage in MCAs

Most entries are based on a lead brand. Some, but not all, generic products are included. Some medicines are not included in this guide. For example there are very few oral chemotherapy agents included as it is widely accepted that these medicines are unsuitable for use in a MCA. Similarly some dose forms are generally not included for similar reasons e.g. effervescent, dispersible tablets.

The recommendations should be used alongside the guidance from the Royal Pharmaceutical Society guidance *Improving Patient Outcomes: The better use of multi-compartment compliance aids* ([RPS MCA 2013](https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/rps-mca-july-2013.pdf)) which is fully endorsed by the UKMi executive.

**What UKMI MCA stability information does not do** – it does not endorse the routine use of MCAs. For some patients, there may not be an alternative way to achieve safe medicine administration and the use of MCAs is likely to continue. However, in line with RPS guidance ([RPS MCA 2013](https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/rps-mca-july-2013.pdf)), the use of original packs and appropriate pharmaceutical support is the preferred option.

**Your own professional judgement is required - UKMI offers general advice**. We have not attempted to produce advice for the various types of MCA e.g. heat or cold sealed, patient self- filled, pharmacy packed etc. Users should use the recommendations to make a professional, clinical decision about the appropriateness of transferring their patient’s medicines to a specific MCA in the context of other issues such as

* relevant organisational policies and procedures,
* the patient’s characteristics,
* the complexity of the dose regime (e.g. irregular dosing or dose titrations),
* storage and transport considerations,
* measures to mitigate against factors that may affect stability e.g. heat and light.

Decisions to transfer a specific product to a MCA may vary depending on the above factors.

You should read the following sections before using the UKMI MCA stability information in practice

* *Developing a dataset for MCA stability information* – this is a brief explanation of the sources used to compile the stability information for each drug and the process UKMI followed. There are also links to guidance issued by the relevant national professional organisations
* *UKMI MCA stability information descriptors* – this explains the standardised recommendations and risk mitigation suggestions

We advise you have a copy of this document open so that you can refer back to it whilst working with UKMI MCA stability information.

We welcome feedback. All feedback should be emailed to: **SWMI@uhbristol.nhs.uk**

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**Developing a dataset for MCA stability information**

The UKMi recommendations are based on an assessment of information from a number of standard sources by regional Medicines Information Services across the UK. The resources include

* American Society of Health-System Pharmacists. AHFS Drug Information. Accessed online via: [www.medicinescomplete.com](http://www.medicinescomplete.com)
* Sweetman S. Martindale: The Complete Drug Reference. Accessed online via [www.medicinescomplete.com](http://www.medicinescomplete.com)
* Summary of Product Characteristics for [drug & strength & form]. Accessed via: [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)
* Baxter K (BNF Director). British National Formulary. Accessed online via: <https://bnf.nice.org.uk/>
* PSNC Special Container Database. Accessed online via: <http://psnc.org.uk/dispensing-supply/dispensing-a-prescription/special-containers/special-container-database/>
* Pharmaceutical Industry colleagues contacted individually, supported by PIPA (Pharmaceutical Information and Pharmacovigilance Association)
* Historical guidance including
	+ Stability of Drugs in Compliance Aids. Prepared and updated by Medicines Information, Pharmacy Department, Pinderfields General Hospital, Wakefield. January 2006.
	+ Smith J and Church C How stable are medicines moved from original packs into compliance aids? Pharm J 2006; 276: 75-81

Each record is dated. The references used (from the above list) will have been the contemporaneous versions.

In the main, the available data do not allow firm recommendations on the duration that products will maintain their stability in a MCA. Therefore, these time periods should be kept as short as is practically possible unless specific guidance is given.

In addition, for many preparations, medical information departments in the pharmaceutical manufacturers provided helpful comments and information. The guidance also takes account of a number of conventional exclusions e.g. cytotoxics. We also collated data from past enquiries across the UKMi network to gauge consensus where possible.

It must be stressed however that the information and guidance reflects the professional advice of the UKMi service that compiled the entry.

Guidance is offered for specific forms and brands that we have included. In some cases, there are multiple manufacturers of the same medicine e.g. common generic preparations. It has not been possible to include information about every such generic version.

Many manufacturers recommend that their products should only be stored within their original packaging. It is clear that, in many cases, the subsequent repackaging of medicines constitutes a change in the licensed status of the product. This has implications for the patient and professionals making this choice for prescribing, dispensing and administering medicines in this way. The links below are to the relevant national professional advice. Individual organisations and services may also have their own policies and procedures which must also be considered.

*Royal Pharmaceutical Society - Improving patient outcomes through the better use of multi-compartment compliance aids (MCA) (July 2013)*

<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/rps-mca-july-2013.pdf>

*Royal Pharmaceutical Society – section containing RPS Specials guidance documents (members only)*

<https://www.rpharms.com/resources/toolkits/improving-patient-outcomes-through-mca>

*General Medical Council – guidance on prescribing unlicensed medicines (January 2013)*

[*http://www.gmc-uk.org/guidance/ethical\_guidance/prescriptions\_faqs.asp#9*](http://www.gmc-uk.org/guidance/ethical_guidance/prescriptions_faqs.asp#9)

*Nursing and Midwifery Council Standards for Medicines Management (April 2010) [Including minor updates to references and the Code (2015)*

[*http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf*](http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf)

*Note: These standards were withdrawn 28 1 2019. More information can be found* [*here*](https://www.nmc.org.uk/standards/standards-for-post-registration/standards-for-medicines-management/)

*NHS Choices – Why are medicines licensed by the MHRA? (Last reviewed Feb 2019)*

[*http://www.nhs.uk/chq/pages/1004.aspx*](http://www.nhs.uk/chq/pages/1004.aspx)

**UKMI Process for updating – this process is under review and will be finalised in 2019**

**The following process for updating the UKMI MCA stability information will be followed**

* 1. SWMIT will hold a master file of the current live version of the database. In house SOPs will cover its access, storage and management.
	2. SWMIT will hold a separate file to record additions and revisions to the information in the master file.
	3. Individual regional centres will retain responsibility for maintaining the BNF chapters and sections that they contributed originally. The aim should be to revise the whole database every two years unless new information or new products become available before that.
	4. SWMIT will receive feedback from users by email. This feedback will, where useful, be shared with contributing centres.
	5. SWMIT will provide a new master file for publication every three months.

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**UKMI MCA stability information descriptors**

*The recommendation for each preparation is standardised and explained as follows –*

* ***Drug name*** *– this refers to the generic medicinal name of the product*
* ***Brand name and manufacturer*** *– the name(s) of the branded versions of the medicine plus the relevant manufacturer. In addition, where there are a number of generic versions of a drug, one generic manufacturer may have been contacted and data from that manufacturer included. Where no specific manufacturer has been contacted the text will read “generic” for brand name and “non-proprietary” for manufacturer.*
* ***Formulation (strength and form)*** *– for example Tablets f/c 2.5 mg.*
* ***Relevant theoretical considerations*** *– this includes information from the resources used.*
* ***UKMI recommendations*** *– risk is expressed using a standardised red/amber/green system (see key below)*
* ***Date of Record*** *– the date that the record was completed by the contributing UKMi service*

|  |  |
| --- | --- |
| **Green** | **1. Stability data indicates that the drug is suitable for MCAs and there are no theoretical concerns with the product.** |
| **2. No stability data is available, but manufacturer suggests it is suitable for use in CAs.** |
| **Amber** | **1. Stability data is available in an alternative container (not CAs) that may be extrapolated to support storage in CAs.** |
| **2. No stability data is available, the manufacturer does not, or cannot recommend use in CAs but there are no theoretical concerns with the product.** |
| **3. No stability data is available. There are theoretical concerns with use in CAs, which may be mitigated by risk minimisation.** |
| **Red** | **1. Stability data indicates that the drug is not suitable for CAs.** |
| **2. Drug is not suitable for CAs due to theoretical reasons that cannot be mitigated.** |

***Suggested risk minimisation*** *– it is expected that all medicines should be stored within normal temperature ranges (below 25 degrees C, away from direct light and in dry conditions e.g. not stored in bathrooms or kitchens. The database will therefore only comment on temperature, light, moisture and exposure to air where there have been specific references found that highlight an issue. The database risk minimisation statements are therefore to highlight that a product requires additional consideration, over and above normal storage requirements, if being put into a MCA and some MCAs may be less suitable than others.*

* ***Protect from moisture*** *– the product must not be exposed to additional moisture*
* ***Protect from light*** *– the product should be stored in dark conditions for the majority of the time*
* ***Airtight container*** *– the MCA used should be airtight*
* ***Protect from heat*** *– there is a specific issue outside of standard storage conditions that needs to be considered*
* ***Unsuitable –****transfer to a MCA is not recommended*
* ***No special precautions for storage*** *– most manufacturers will state that if kept in the original pack there are no special precautions for storage of a produce. By removing a product from the original pack to put into a MCA, most manufacturers will state that they cannot guarantee stability.*

*The information about MCA stability for each drug describes the risks associated with individual preparations. It does not consider the effect that having multiple medicines in a MCA, for example if one drug may affect the stability of another drug within the MCA e.g the water content of some gelatin capsules may affect the stability of moisture sensitive drugs*

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