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Considerations for prescribing and supply of medicines to patients with an allergy or hypersensitivity to pharmaceutical excipient(s)

Pharmaceutical excipients are constituents of a medicine that are not used for their direct therapeutic action, but to aid the manufacturing process, such as to enhance stability or bioavailability.

Patients may want or need to avoid certain pharmaceutical excipient(s) for a number of reasons. Medicines free from specific pharmaceutical excipient(s) may be requested for particular patient groups (e.g. neonates), patients with an allergy/ hypersensitivity or with particular cultural or religious beliefs. Some excipients are more commonly associated with hypersensitivity reactions than others e.g. preservatives, colourants, lanolin and arachis oil (from peanuts). Several other excipients such as lactose can trigger intolerance.

The Medicines and Healthcare Products Regulatory Agency (MHRA) has recommended that patients known to be allergic to peanuts should not use medicines containing arachis oil (from peanuts). Due to potential cross-sensitivity between allergy to peanut and soya, some manufacturers advise that patients with soya allergy should also avoid their products that contain arachis oil.

All excipients must be declared on the outer packaging or, where there is no outer packaging, on the immediate packaging of the medicinal product and the SmPC (Summary of Product Characteristics) of injectable, topical or eye preparations. Some excipients e.g. arachis oil (from peanuts) require additional warnings when any of the substance is present at all; others only require a warning above a certain threshold. Further information on which excipients must feature in the leaflet packaging of medicinal products and the way in which these excipients must be indicated is available from the European Medicines Agency: https://www.ema.europa.eu/en/annex-european-commission-guideline-excipients-labelling-package-leaflet-medicinal-products-human.

A manufacturer may not guarantee that a medicinal product has not come into contact with a substance during the manufacturing process, even if the product does not actually contain the substance (such as an allergen or latex). Advice may therefore rely on balancing the potential risk to the patient against the benefit or need.

Medicines (including generic medicines) produced from different manufacturers can have different excipients. Sometimes excipients can be batch specific, or a formulation change can change the excipients present.

Examples of some medicines containing some relevant excipients (NOT exhaustive)

Peanut	Soya	Sesame
• Progesterone capsules • Some multivitamin drops (e.g. Abidec® drops) • Arachis oil (e.g. Arachis oil enema) • Zinc and castor oil cream/ointment • Naseptin® cream • Estriol cream • Peppermint oil capsules	• Some desogestrel tablets • Some multivitamins (e.g. Forceval® capsules, Paravit-CF®) • Some colecalciferol and calcium preparations (e.g. Accrete D3® standard tablets, Adcal D3® chewable) • Isotretinoin capsules	• Alfacalcidol capsules • Haloperidol decanoate injection

Extra care should be taken when prescribing, dispensing and/or administering medicines for patients with serious allergies:

- **Refer to the patient's clinical record and ensure the allergy is appropriately documented on GP prescribing systems and dispensing software** so that this information is readily accessible to out of hours clinicians.
- **Check for the presence of excipients in each medicine box/package by checking the Patient Information Leaflet (PIL) that is included in the medicine package**. This is because there can sometimes be a short time lapse between any batch formulation changes and online PIL and SmPC updates. If you do not have the pack leaflet, the online PIL and SmPC (via the electronic Medicines Compendium (eMC)) will list the excipients.

- If checking the online SmPC, always check the excipient list in each of the SmPC individually to confirm that the excipients(s) that are to be avoided are not listed before prescribing or supplying.
- Some SmPCs are not available via the eMC but can be accessed via the MHRA website.
- **Be aware that unlicensed medicines and food supplements may not be manufactured to the same standards as licensed pharmaceuticals and can consequently carry additional risk.**
- **The Tayside Medicines Information Service (Tay.medinfo@nhs.scot) can also provide support with any patient enquiries relating to allergies caused by excipients**.
- The Tayside Area Formulary also has links from each medicine entry included to the eMC (via SPC tab). The text within each medicine formulary entry does not contain information on excipients for reference in prescribing or supplying medicines to patients with allergy or hypersensitivity as it is not possible to ensure that this information will be accurate due to possible formulation changes.
- **If considered vital to avoid all exposure to a given excipient, it is advisable wherever possible, to contact the manufacturer to check the product contents**. If you are unable to contact the manufacturer, a judgement is to be made, based on the available information as to the need for the medicine and the likelihood of, and the risk associated with, the presence of that excipient.
- **Consider the severity of the patient's allergy and only prescribe in exceptional circumstances where benefits outweigh risks AND there is no alternative available.**
- **Educate and empower patients to check whether products contain relevant excipients when purchasing medicines and/or collecting prescriptions.**
- **Check that the patient has at least two in date adrenaline auto-injectors if already routinely prescribed.**

References

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