Excipients explained

Introduction

Excipients are inactive ingredients which are added during the manufacturing process of pharmaceutical products, such as oral and injectable preparations, topical products, eye, ear and nasal formulations, and suppositories. Their purpose is to aid the manufacturing process.

Although excipients are regarded as inactive, they can cause allergic reactions or adverse effects, such as hyperactivity, bronchoconstriction, itching and rashes on the skin, and gastrointestinal symptoms. The excipients contained in a medication do not always appear on the package insert.

Excipients include diluents, also known as bulking agents, such as lactose and sucrose, which are used in the manufacture of tablets. Lactose is also used widely in infant formula.

Colouring agents serve to improve the acceptability of a product to a patient. However, some colourants, for example, tartrazine, can cause skin rashes and asthma, and have been associated with hyperactive behaviour in children.

Flavouring aims to increase patient compliance. Sweeteners, such as sucrose, are often used to flavour oral medication for both adults and children.

Preservatives prevent the increased risk of contamination to pharmaceutical products, and some have been associated with serious side-effects:

- Benzalkonium chloride: Benzalkonium chloride is used in eye and nasal preparations, has been associated with toxicity of the eyes and bronchoconstriction when contained in nebulising solutions
- Sodium benzoate: Sodium benzoate is widely used as a preservative in oral and injectable pharmaceutical drugs. It should be used with extreme caution in newborn infants
- Benzyl alcohol: Benzyl alcohol is frequently used as a preservative in a variety of preparations, both injectable and oral. It has been associated with serious side-effects in neonates, and is used with great caution in this setting.

Alcohol, also known as ethanol or ethyl alcohol, is present in a variety of medications where it is used as a solvent to help dissolve the ingredients in a formulation, and as a preservative. It is used in over-the-counter oral formulations according to the prescribed maximum percentages per age group in some countries. Alcohol is also used as a topical disinfectant.

Do:

- Enquire if the patient has any known allergies when advising on over-the-counter preparations
- Check the package insert for excipients
- Inform the client or caregiver which excipients are contained in a product
- Familiarise yourself as far as possible with the excipients in products
- Inform parents when considering tartrazine-containing products for children
- Be mindful that benzalkonium chloride is present in many over-the-counter eye preparations, and has been associated with side-effects involving the eyes, as well as bronchoconstriction if contained in nebulising solutions
- Remember that sucrose-containing syrups can cause tooth decay if used in the long term
- Be on the alert if alcohol-containing medications are requested frequently by a client, and inform the pharmacist
- Remember that overdosing with alcohol-containing products can result in acute toxicity, while chronic toxicity can be caused by the long-term use of these products
- Remember that the side-effects of excipients can be serious, particularly in children
- Consider alternative preparations, such as those which are colour and preservative free, should the need arise

Don’t:

- Assume that an adverse reaction has been caused by the active ingredient in a product
- Recommend eye preparations containing benzalkonium chloride to a client without alerting him or her to this
- Recommend tartrazine-containing products for a child with a history of hyperactivity, unless you have discussed this with the caregiver

Refer to the doctor if:

- Any adverse drug reaction occurs after a pharmaceutical preparation has been used
- Any medication which has been prescribed has caused an adverse reaction in the past, so that an alternative prescription can be obtained

A final word on excipients:

- Excipients are considered to be inert, but this is not necessarily the case
- An adverse reaction might have been caused by the active ingredient in a medication, but the possibility that the adverse reaction might have been caused by an excipient should also be taken into consideration
- Excipients are not necessarily detailed on the package insert
- Adverse reactions from excipients can be serious
- Alternative preparations should be considered in the event of an adverse reaction

Bibliography