APSM

Association of Pharmaceutical Specials Manufacturers

Medicines Manipulation – Crushing, Opening or Splitting Tablets

A guide for prescribers

Crushing, opening or splitting tablets or capsules can provide a solution for non-compliance in patients with dysphagia. However, in some cases the pharmacological nature of the drug is altered with potentially wide-ranging implications. This requires the prescribing physician to have a detailed knowledge of the pharmaceutical properties of any new formulation created as a result of manipulation.

Altering the dosage form of a licensed medicine in this way, also renders it unlicensed, in which case the manufacturer no longer has liability or responsibility for safety and efficacy, and the prescribing physician assumes this responsibility.

In many cases, a liquid special manufactured to a specific instruction by a licensed Specials manufacturer provides a lower risk alternative (see Royal Pharmaceutical Society Guidance below).

Regulatory and market

- Healthcare professionals or carers could be exposed to health risks through powder aerosolisation
- Irritation if the drug was inhaled or came into contact with eyes, skin or other mucous membranes and, in some cases, causing skin toxicity
- Negative impact on the stability of the drug substance
- Less drug available to produce the desired clinical effect (eg through powder loss or uneven split)
- Loss of protection of the drug from the effects of light
- Changes in the drug pharmacokinetics and bioavailability resulting in under dosing or adverse effects
- May cause oesophageal or stomach irritation or ulceration if tablets are crushed or capsules opened
- Refusal of taking the medication due to unpleasant taste

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- Possible anaesthetic effect on the tongue, particularly if sertraline is given in a powdered form
- Potential of an unintended large bolus dose being delivered rather than controlled release over the intended timescale, resulting in a potentially toxic dose with an increased risk of adverse effects
- Crushing enteric coated tablets may result in the drug being released too early, destroyed by stomach acid, or irritating the stomach lining.

Responsibility of Prescribers

GMC guidelines on prescribing unlicensed medicines require that doctors:

Be satisfied that an alternative, licensed medicine would not meet the patient's needs

Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy

Take responsibility for prescribing the unlicensed medicine and for overseeing the patient's care, including monitoring and any follow up treatment

Record the medicine prescribed and, where you are not following common practice, the reasons for choosing this medicine in the patient's notes.

On the basis that manipulation of a medicine renders it as an unlicensed medicine, the APSM would also recommend:

To make sure there is no licensed alternative in dispersible or oral liquid form

To check that by changing the form of the medicine, the action is not altered, this includes reactions with foods, etc

To consider options for prescribing an oral liquid form as an unlicensed Special.

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Legal Aspects of Medicines Manipulation

Medicines Act 1968

The 1968 Medicines Act regulates the licensing, supply and administration of medicines. Prescription only medicines can only be given in accordance with the directions of an appropriate practitioner. Unless instructed, there is no scope to alter the dose or change the form of a prescription only medicine, for example, by crushing or opening a capsule. To do so would be a breach of the 1968 Act.

Consumer Protection Act 1987

The crushing of a tablet before administration in most cases renders its use unlicensed. Consequently the manufacturer will not be liable for any ensuing harm that may come to the patient or the person administering it under the Consumer Protection Act 1987. Where harm is caused as a result of the tablet being altered by crushing, it will not be the producer who is liable but the person who crushed or advised the crushing of the tablet.

Disability Discrimination Act 1995

The 1995 Disability Discrimination Act means that it is unlawful to discriminate against a person because of their disability. This includes the right of access to and benefit from medicinal products.

Providing disabled patients with the support to manage and take a medicine safely is an essential duty under the Act. If a person, due to their disability, had difficulty taking medicines, the doctor, practice nurse and pharmacist would have a duty to ameliorate that impairment. A person with swallowing difficulties may require their medication in a suitable format like a liquid rather than a tablet or capsule.

The Human Rights Act 1998

In October 2000, The Human Rights Act came into effect in the UK meaning that people in the UK can take cases about their human rights into a UK court. The “right to life” is fundamental and now enshrined in UK law. The Act states that: “Care must be given with respect and be proportionate to the needs of the person.” Therefore, medication should be given in its safest form to protect patients from any adverse clinical outcome.

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Royal Pharmaceutical Society of Great Britain (RPSGB), 2005

The RPSGB states that 'If a formulation is tampered with then the product will be unlicensed. Pharmacists must consider and advise on the potential for distortion of bioavailability profile of the medicine.' Pharmacists 'must also consider whether alternative licensed products are available, such as the same drug with a different formulation or a different drug for the same indication.'

The Nursing & Midwifery Council (2007 and 2008)

The NMC has issued advice for registered nurses and standards for medicines management on the issue of tablet crushing. It advises nurses not to crush any medication or open capsules that are not specifically designed for that purpose, as by doing so the chemical properties of the medication could be altered.

The NMC states that "The mechanics of crushing medicines may alter their therapeutic properties rendering them ineffective and are not covered by their product licence. Medicinal products should not routinely be crushed unless a pharmacist advises that the medication is not compromised by crushing, and crushing has been determined to be within the patient's best interest."

Nurses are reminded by the NMC that under the Medicines Act 1968, only medical practitioners can authorise the administration of unlicensed medicines to humans. It is therefore unlawful to crush a tablet before administration without the authorisation of the independent prescriber (Nursing & Midwifery Council 2007b).

A nurse who advises that a tablet is crushed or a capsule opened to assist with swallowing difficulties must proceed with caution. Even when an independent prescriber authorises a medicine to be administered by crushing a tablet a percentage of liability for any harm that is caused will still lie with the administering nurse. The balance of this liability would be assessed in court.

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