Pharmaceutical Blister:

First Choice for Child Resistant

As primary packaging for tablets and pills, blisters have several advantages compared to alternatives such as bottles or cans.

Assuming the use of the correct materials (films) and a faultless manufacturing process, with an appropriate design, blister packaging has the ability to provide a high level of protection against negative external influences such as light, dirt or moisture. Pharmaceutical blisters have additional features: when properly designed, they protect young children from the dangers of the products contained inside and fulfil the requirements of EN 14375. This is a particular challenge for the packaging development perspective. On the one hand, the packaging has to fit the drug inside it in its pharmaceutical form, and on the other, the access by young children has to be made difficult or impossible.

Pharmaceutical blisters are not child resistant by nature, just because they feature a perforation or a particular foil, for example. What is required is a combination of appropriate measures taking into consideration certain factors; only if these requirements are met a packaging can justifiably be referred to as child-resistant. A review of the safety functions is necessary before the packaging is released to the market. Experience shows that small children often manage to open non-certified packaging, although it takes a while to access the individually packaged units.

PROTECTING INFANTS

Children are curious and experience their surroundings with all their senses. Coloured pills or tablets are easily confused with candy or sweets and this is one reason that especially younger children under the age of four are most commonly affected by domestic poisonings. Blisters that have design and material barriers to complicate or prevent the extraction of the packaged product by small children are crucial step to protect children from poisoning. While child resistant packaging doesn't relieve parents and caregivers from their supervisory obligations, they can constitute a final hurdle and effective help to reduce the number of poisoning incidents involving small children.

To achieve this goal, pharmaceutical blister have to comply with the standard EN 14375 for non-reclosable packaging of pharmaceutical products. The necessary test report and certificate is issued by an accredited institute based on an appropriate test method with a certification (see www.ivm-childsafe.de / kindergesicherte-verpackungen / zertifizierung.

LEGAL FRAMEWORK

In order to protect young children from accidental misuse or poisoning, medication must be marketed in a child-resistant method. Internationally, regulations have been adopted which differ in some details, but place similar demands on the packaging. In Europe, pharmaceutical blisters are considered safe for children, if they meet the requirements of EN 14375. Worth mentioning also is regulation U.S. 16 CFR § 1700.20 in the United States which places different requirements for drug packaging testing and certification, if the products are to be marketed in the United States.

The EN standard describes the test methods for the examination and evaluation of the proper functioning of pharmaceutical blisters, but also assessment of the packaging regarding its suitability for senior citizens. Importantly the test procedures described are designed to show compliance with the requirements of a complete package. However, they are not suitable to assess individual components, such as a type of foil alone.

THE TEST PROCEDURE

To test child resistance, up to 200 infants aged 42 between 51 months will be asked twice for a period of five minutes to open a package filled with placebos. Prior to the second five-minute test period there is a single demonstration by an adult of the opening process with no further explanation. The certification requirements are fulfilled if, within the first five minutes, no more than 15 percent during the whole ten minutes and no more than 20 percent of children can be found in the package contents.

The prescribed age of the children to be used in the testing process are slightly above the highest risk group for accidents, poisoning, namely, children up to the age of 36 months, thus providing great difficulty for children in the high risk range of 36 months to gain access to the blister content.

To ensure access for seniors despite the hurdles for small children and to ensure that there are no restrictions in administering the drug, use of the package is tested with individuals between 50 - 70 years of age. After five minute preparation time, at least 90 percent of the test subjects need to be able to remove a unit within a minute. Continued

Pharmaceutical Blister: Continued

Only packages where both tests result comply with the requirements of EN 14375 are in accordance with the standard. Certification is carried out by an independent institution, accredited in accordance with EN 45011 (www.ivm-childsafe.com).

BACKGROUND AND DESIGN OF THE BLISTER

Whether a package meets the requirements of EN 14375, is influenced by a number of factors, some of which are interdependent. These include for example:

Blister cavities and packaged content: In many cases, size and shape of the tablets, pills and capsules, in conjunction with the cavities, have a significant impact on child-resistance according to the standard. In principle, infants experience more difficulty in removing small and flat units from the blister than larger ones. This only holds true under the condition that the cavities are optimally adjusted to the size and shape of the packaged unit. A comparatively large air pouch inside the units enable the infants to peel, pierce or scratch it open, despite the reinforced foil.

The opening principle: The best-known principle is the push blister, where specially reinforced foil can pose an additional hurdle before the units can be extracted. Blisters with tear notch (so-called tear-blister) can almost never be pushed through. With these, first the cavity needs to be separated along the perforation, and then opened at the tear notch within the blister. Tear-blister requires perforation and a type of foil that cannot be pushed through all the way.

Another alternative is the so-called peel blister. Again, the units need to be separated. Each cavity has a part of the lidding foil where there the formable is not sealed. This allows tearing off the lidding foil from the formable foil. If another step is needed, in which the tablet then needs to be pushed through an additional layer of foil, it is the so called a peel-push blister.

Shape and size of the blister, perforation: The basic principle is that in many cases a larger blister gives the child increased leverage when force is applied and it is therefore easier to open. A perforation which permits easy separation is more difficult to open for children. However, what needs to be ensured that the individual cavities are not damaged, since this can facilitate removal of the tablets. What needs to be taken into consideration is that toddlers apply uncontrolled force to get to the content; accordingly the cavities need to be sufficiently "tear-resistant."

Foil: Single layer aluminium foil usually does not meet child-resistance standards. Types of foil in use are usually made from multilayer combinations for example, polyester, paper, aluminium, and the requisite additional composite coatings.

Conclusion

Child-resistant pharmaceutical blisters are gaining importance. As a consequence, the demand for suitable, high-quality packaging solutions is increasing, since those solutions guarantee individual safety functions for certain products. Developing appropriate solutions at a reasonable expense of time and money should happen in collaboration between the partners involved. This requires early communication between pharmaceutical companies, producers of packaging materials, and the accrediting institution. In this way it is possible to guarantee the necessary exchange of information as a basis for a successful packaging development. The certification according to EN 14375 is part of this process and serves as evidence of the quality and functioning of the safety function towards market players and society at large.

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