Agence nationale de sécurité du médicament et des produits de santé

Clarification on the conservation of drugs in the event of heat wave

Before any marketing authorization (MA), all drugs are subject to stability tests under standardized and internationally recognized conditions. The duration and the conditions of conservation of drugs are fixed according to the results of these stability tests.

The particular conditions of conservation are mentioned on the packaging of drugs:drugs to be kept between +2 and +8 C,

- drugs to be kept at a temperature lower than 25 or 30 C,drugs with no particular conservation information: conservation at ambient temperature prevails (by ambient temperature a continental climate is to be understood).

In the event of exposure to heat, either during a heat wave, or during transport under conditions where the temperature is not controlled, the following recommendations can be made:

Drugs to be kept between +2 and +8 C

The conservation of these drugs is generally carried out in refrigerators or cold rooms. The heat wave will thus be without consequence on their stability if the conditions of conservation are strictly respected and that the drug is removed from the refrigerator a few minutes before its use.

In the event of raised outside temperature, it is recommended to use them quickly after removal from the refrigerator.

These conservation conditions impose an upper limit of temperatures to which drugs can be exposed.However, temporarily going beyond these temperatures (a few days to a few weeks) does not have any impact on the stability or the quality of the drugs.Indeed, to be able to profit from these conservation conditions, it has been shown that after several weeks exposure to a controlled constant temperature of 40°C, drugs are not deteriorated. Thus, a few days of exposure of a drug to temperatures higher than 30°C will be without effect on its quality. Indeed, during a heat wave, the ambient temperatures are not constantly at 40°C, and in addition the temperature reached in the core of the drug remains lower in the majority of cases than the ambient temperature thanks to the limitation of heat exchange provided by the packaging and storage places of which are generally closed.Thus, drugs stored under normal conditions in the residence of patients or in pharmacies are exposed, during a heat wave, to conditions of thermal stress lower than the temperatures of the stability tests.

Drugs preserved at ambient temperature (with no conservation notice)

In usual conditions of drug conservation (medicine chest, normally ventilated warehouse), these drugs do not suffer from exposure to the kind of high temperatures observed in periods of heat wav. Indeed, for these drugs, it has been shown in stability tests that they do not deteriorate when they are exposed to temperatures of 40 C for 6 months.

Particular cases

Particular dosage forms

Certain dosage forms (suppositories, ovules, creams etc.) are sensitive to rises in temperature. In this case, it is not the active ingredient which is sensitive to heat, but the dosage form. It is then relatively easy to evaluate the conservation of the quality of these drugs after exposure to heat since it is the aspect of the product after opening (normal and regular aspect , non-molten suppository and so on) which will indicate the stability of these drugs. Any product whose external appearance has obviously been modified should not be used, insofar as this deterioration of the appearance could be an indicator of a modification of the properties of the dosage form.

Drugs used under particular conditions

- ***Transport by private individuals***

  When private individuals transport their drugs, the same precautions of conservation should apply. Thus,

  - drugs to be preserved between +2 and +8°C must be transported under conditions which respect the cold chain (cooled isothermal packing), but without causing freezing of the product.
  - drugs to be preserved at a temperature lower than 25 or 30°C, just like drugs to be preserved at ambient temperature, should not be exposed for too long to high temperatures such as those frequently found in the trunk or the passenger compartments of cars exposed to full sun.It is advised, as a safety measure, to transport them in non-cooled isothermal packing.

- ***Use in emergency medical vehicles***

  At the time of storage, conservation and transport and use in medical vehicles **the temperature can exceed 40°C**. This excess in temperature is particularly risky for drugs in solution (heat exchange with ambient air and rise in temperature is much faster for a solution than for a solid form) and drugs for which the conditions of conservation impose a temperature not exceeding 25°C. Taking into account the relative fragility of these products, exposure to high temperatures for more or less variable periods, could lead to potential degradation leading to a probable loss of activity of the product, and even the formation of breakdown products which could potentially be toxic.Thus, by way of precaution, it is recommended, in periods of strong heat:

  - to adopt optimized conditions of conservation for these products (for example to have isothermal packing which reduces heat exchange),
  - and/or, when it is not possible to guarantee their conservation under optimal conditions, to perform regular replacement of the products thus exposed.