Cevidra®

EMERGENCY TREATMENT OF EXTERNAL RADIONUCLIDES CONTAMINATIONS

with americium, antimony, cesium, cobalt, manganese, plutonium, silver, strontium, thorium, uranium, zirconium

TECHNICAL BROCHURE

IRSN * INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE

*The IRSN is the French Institute for Radiation Protection and Nuclear Safety. All tests of efficiency have been performed by IRSN and the results have been published in peer-review journals (references included in the brochure).

DGA **

**GENERAL DIRECTORATE FOR ARMAMENT

Commercial name and presentation

Cevidra® decontaminating cream in 30 or 50 mL tube.
The product is available individually or in boxes of 10 tubes.

Composition

Carboxylic calixarene (0,75 % w/w), paraffin oil, purified water, decyl glucoside, sodium laureth sulfate, sodium cocoyl glycinate, polysorbate 80, laureth-4, citric acid, methyl parahydroxybenzoate and propyl parahydroxybenzoate.

Indications

Cevidra® is a **medical device for first line treatment of external contamination from the following radionuclides:**

- Actinides (uranium, plutonium, americium and thorium)
- Antimony
- Cesium
- Cobalt
- Manganese
- Silver
- Strontium
- Zirconium

For external use on healthy skin

Instructions for use

One tube of Cevidra® is made only for a single decontamination procedure and can be used to decontaminate either the entirety or part of the body and/or hair, during an emergency on-site decontamination procedure.
For effective decontamination, carry out the following operations on the area(s) to be decontaminated:

1. Wet or dampen the skin (optional step): this operation facilitates contact between the Cevidra® cream and the body area to be decontaminated. It proves useful for spreading the cream onto less accessible areas like the hair, the beard, or across large skin areas.

2. Apply the cream and wash thoroughly: areas to be decontaminated are thoroughly washed by gently rubbing Cevidra® cream for optimal contact between the cream and the contaminant. The cream acts immediately. Leaving the product on the contaminated area following application will not improve the results of the decontamination.

3. Remove the cream by rinsing with water or wiping with a wet woven compress. Wet compresses are recommended only for use on the skin. Removing the cream is necessary to complete the decontamination. The rinsing procedure must avoid the eyes area.

In the case decontamination is not total following initial treatment: you can repeat the operation several times on the same area. If one tube is not sufficient to treat the whole of the target area, several tubes may be used.

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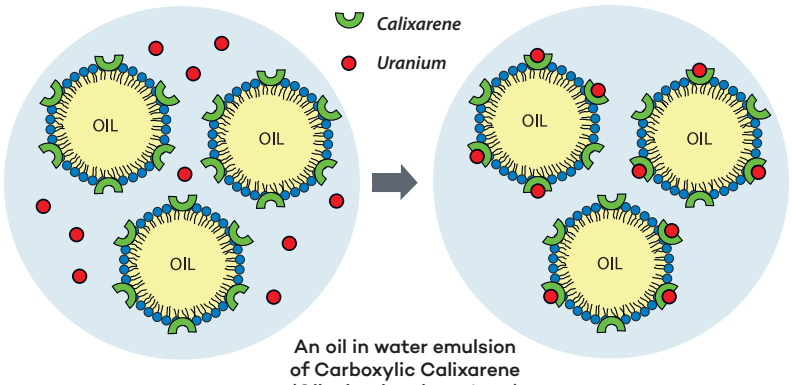
In the case of delayed application of the product relative to time of contamination: The quantity of radionuclides that penetrates the skin depends on the initial quantity of contaminants, their chemical form, and skin condition. Though it is not possible to determine the remaining quantity of contaminants on the skin in cases of delayed application, the risk/benefit analysis remains favourable to use, as Cevidra® cream acts on the unabsorbed portion of radionuclides.

When there is no or no immediate access to a water point.
In the case of contamination it is recommended to apply Cevidra® cream to the contaminated area as quickly as possible. In the absence of water, the product's consistency allows for contact of the active ingredient with the skin and contaminant. This application being more difficult on the hair and beard, decontamination should be followed and completed by removing the cream applied. This removal can be performed by rinsing with water or removing the cream with wet woven compresses from all body areas having made contact with the product. It is recommended to perform this decontamination step in an area designed for this purpose in order to recover and isolate any contaminated effluents and consumable products (compresses, gloves, masks). This step must be taken as soon as possible following application of the product. The biocompatibility studies conducted on Cevidra® cream show that the product does not cause skin irritation after 4 hours of contact on the skin.

In the case a contaminated effluent comes into contact with a non-contaminated area of the body:
The product should be removed from the contaminated area without overflowing on non-contaminated areas. However, this is not always possible. Studies show that, once chelated with the calixarene in the product, the radionuclide remains fixed in the cream. The transfer of contamination from cream containing chelated radionuclides onto intact non-contaminated skin is unlikely.

Mode of action

The composition of Cevidra® cream gives it the potential for multiple interactions: specific by virtue of the carboxylic calixarene and non-specific by virtue of its other ingredients. The carboxylic calixarene is a specific chelating agent that captures actinides (uranium, plutonium, americium, thorium), antimony, cesium, cobalt, manganese, silver, strontium and/or zirconium present on skin or hair/beard. Through its cleansing action, Cevidra® also eliminates from the skin other more or less soluble forms of radionuclides. Cevidra® prevents these radionuclides from penetrating the organism with scientifically proven efficacy. The fineness of Cevidra® cream (average diameter of the oily particles of under one micrometre) allows access to anfractuosities and interstices of the skin and hair/beard.

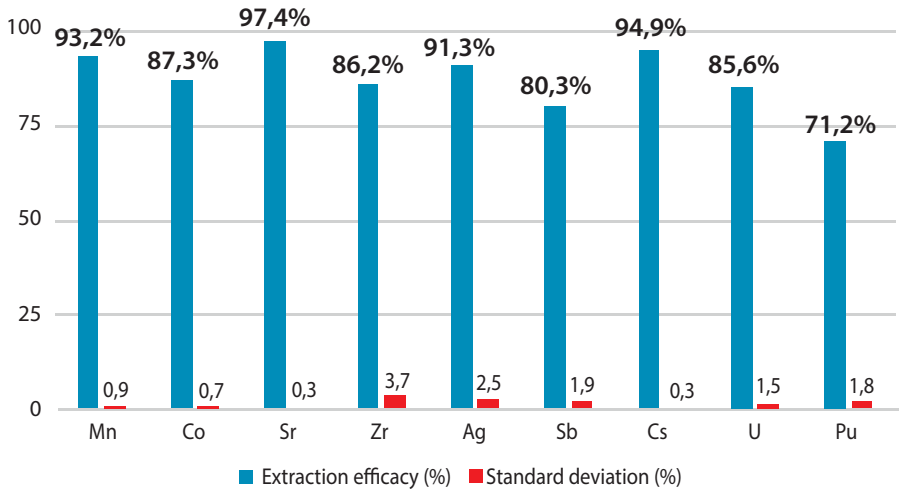


An oil in water emulsion
of Carboxylic Calixarene
(Oily droplet size < 1 µm)

The Cevidra® cream is an oil in water emulsion composed of : carboxylic calixarene (active substance), paraffin oil, water, surfactants and preservatives.

Efficacy

The Cevidra® cream has a proven efficacy in laboratory (IRSN studies)



In-vitro study: average chelation efficacy of Cevidra® on mixed solutions of radionuclides

Expected clinical benefits

The rapid elimination of radionuclides deposited on the skin or hair/beard prevents them from passing into the body, and thus from fixing onto target organs where they are toxic in the short, medium and long terms.

Contraindication

Do not swallow. Avoid direct contact with eyes.

Precautions for use

The product must be used under the supervision of a radio-decontamination qualified person.
There is no data available on the performance of Cevidra® in case of skin lesions.
The characteristics of the lesion (length and depth) having potential influence on the diffusion of calixarene. It is recommended to avoid use on damaged skin.

For external use on healthy skin.

To be used with caution on persons with known allergies to one of the components.

This medical device has not been studied on children or women who are pregnant or breast-feeding. As a precautionary measure, it is recommended to avoid its use in these populations. However, for these populations, a risk/benefit analysis should be carried out on a case-by-case basis by a healthcare professional, and the decision as to its use made taking into account safety and efficacy considerations.

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Shelf life of the product

Expiry date is indicated on each tube next to the following symbol: 

After the expiry, the quality of the cream may be deteriorated and consequently it may affect its levels of safety and effectiveness.

Shelf life after opening 

The presence of this logo on the tube indicates a single-use product.
There is no study analyzing the preservation of the product after opening the tube.

Storage conditions 

The presence of this logo on the product packaging indicates the appropriate storage conditions.
The product must be stored between 15 °C and 25 °C.

Waste management

Used Cevidra® and waste water from the decontamination process must be treated in accordance with the current procedures for the management of contaminated waste.

Contaminant residues may have been left on the tube during use. To avoid later handling of a possibly contaminated product, the opened tube must be disposed of with the other contaminated products.

Expected undesirable effects

The biocompatibility studies conducted on Cevidra® cream and the use of the product in humans, have not identified to date specific adverse events.

It is nevertheless important to monitor the possible occurrence of skin rashes and/or a local allergic reaction related to the use of the product.

Regulatory status of the product

Cevidra® is a class I medical device, pursuant to this regulation, this healthcare product carries CE marking in the form of the logo: CE

Management of serious incidents, undesirable effects and quality problems

Any anomaly noted before, during or after the use of Cevidra® must be notified to the manufacturer of the medical device. CEVIDRA will investigate this anomaly as part of its materiovigilance procedure.

Any serious incident linked to the use of the medical device must be notified to the manufacturer or to the competent authority in the country where the incident occured.

Manufacturer

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The manufacturer is responsible for the compliance of the product with the regulatory requirements that apply to the marketing of a medical device.

IRSN

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Patent FR0858703

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INNOVATIVE
the only decontaminating treatment specifically developed for external contamination

QUICK + EASY + CONVENIENT

ADAPTED TO SEVERAL FIELDS

AVOID/REDUCE THE EFFLUENT

MINIMIZE THE CROSS CONTAMINATION
for the victims and the decontamination team

DELAYED RINSE POSSIBLE

Doc Tech Cevidra Eng – Janvier 2020

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