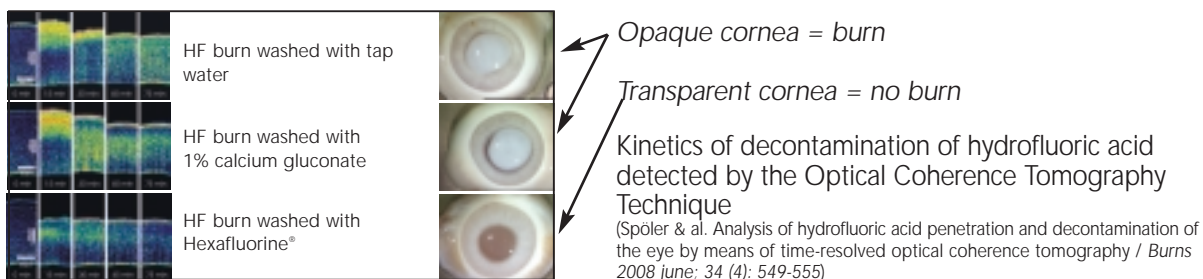


HEXAFLUORINE® IN USE

I NATURE AND PROPERTIES

> Hexafluorine® is a washing solution designed specifically for ocular and cutaneous chemical splashes due to hydrofluoric acid (HF) and due to fluorides in an acid medium. Set up at the workplace and used as first-aid, it allows the minimisation or avoidance of the burn's appearance, stopping the corrosive and toxic effects of solutions containing HF and by avoiding the penetration of the tissues by way of its chelating and hypertonic properties. Hexafluorine®, dispensed in specially designed containers, permits and facilitates effective decontamination, reduces pain, the need for secondary care, sequelae (after-effects) and lost work time ■

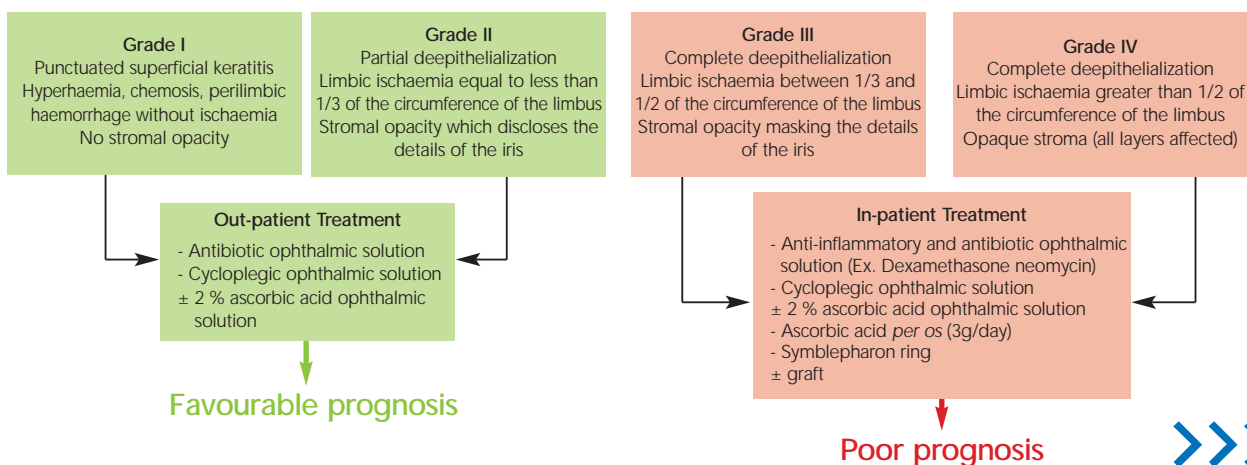


2 HOW SHOULD THIS DEVICE BE USED?

- > **In the workplace**
- Washing in the first minute and as the primary action with the entire container of Hexafluorine®.
 - Specific antidotes, such as calcium gluconate may be used according to the protocol established by the doctor in charge. This is especially important in cases of delayed or insufficient washing, when the burn has already developed.

Portable eyewash	Mural eyewash	DAP
500 ml within the first minute	500 ml within the first minute	5 Litres within the first minute to wash an entire body

- > **At the accident and emergency department**
- **For an ocular splash**, wash with 500 ml of Hexafluorine® followed by a secondary therapeutic protocol. Based on Roper-Hall classification of chemical ocular burns: prognostic and therapeutic protocol from « Ophtalmologie en Urgence [Emergency Ophthalmology] » Dr Tuil, De Nicola, Mann, Miléa et Barale; Elsevier-Masson Editions 2007.



- For a cutaneous splash

The use of specific topical antidotes, such as calcium gluconate or Zephiran® salts, by subcutaneous injections, or intravenous (Beir Block technique), by intra-arterial injections (for fingers or the hand) is recommended in the scientific literature. This may be combined with a symptomatic analgesic treatment. Monitoring of cardiovascular functions may be justified by the systemic diffusion in relation to the cutaneous surface area affected and the concentration.

If the burn surpasses 1% of the surface of the body, complementary analyses should be requested: calcemia, kaliemia, serum magnesemia, phosphatemia.

> **Classification:** medical device, class IIa

> Therapeutic indications

Washing of ocular and cutaneous splashes due to hydrofluoric acid and fluorides in an acidic medium.

> Name and address of the manufacturer:



PREVOR

ANTICIPATE AND SAVE

Toxicology Laboratory & Chemical Risk Management

Moulin de Verville - F95760 Valmondois

Tél : +33130347676

www.prevor.com

3 INNOCUOUSNESS

Test	Results	References
Ocular irritation	Non irritating	Test n°133/8, in the rabbit, Safepharm Laboratories Limited, UK, 1987
Cutaneous irritation	Non irritating	Test n°133/7, in the rabbit, Safepharm Laboratories Limited, UK, 1987
Sensitization	Non allergenic	Test n°20040231STC, Magnusson & Kligman method in the guinea pig, CERB, France, 2004
Toxicity by oral route	Non toxic ; oral LD ₅₀ > 2000 mg/kg	Test n°990533ST, in the rat, CERB, France, 2000

4 CONTRAINDICATIONS

There are no known negative interactions with the different families of medicines or devices and more specifically with ophthalmic solutions used in specific chemical burn protocols.

At this time there is no evaluation program for burns due to swallowing. However, Hexafluorine® has been classified as non-toxic by ingestion.

Hexafluorine® has a reduced effect on alkaline substances. Washing with Diphotérine® is much better adapted in this type of situation.

> Side effects

Our vigilance system has not highlighted any side effects.

Hypertonic ocular washing with Hexafluorine® may leave a temporary sensation of ocular discomfort. The secondary use of the solution Afterwash II®, isotonic with tears, brings about a more rapid return to a physiological state.

> Precautions for use

To avoid any microbial contamination, keep containers closed.

Do not use after the expiry date which appears on the containers.

Products for single use only.



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