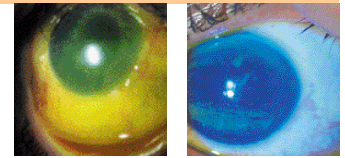


# DIPHOTERINE® IN USE

## I NATURE AND PROPERTIES

> **Diphoterine®** is a washing solution designed for ocular and cutaneous chemical splashes. Set up at the work station and used as first-aid, it allows the minimisation or avoidance of the development of chemical burns, stopping both the effect and the penetration of the irritant and/or corrosive by way of its amphoteric, chelating and hypertonic properties. Diphoterine®, dispensed in specially designed containers, permits and facilitates effective decontamination, reduces pain, the need for secondary care, sequelae and lost work time.



A clinical study carried out in a hospital setting has shown the advantages of even delayed washing with Diphoterine® for the management of ocular chemical burns, combined with a therapeutic protocol aimed at reducing inflammation and at preventing infection while encouraging healing. A published grade IV case likewise developed progressive reepithelialization in less than 21 days and complete and stable healing without surgery after 180 days ■

## 2 HOW SHOULD THIS DEVICE BE USED?

### > In the workplace

- Washing within the first minute and as the primary action with the entire Diphoterine® container.

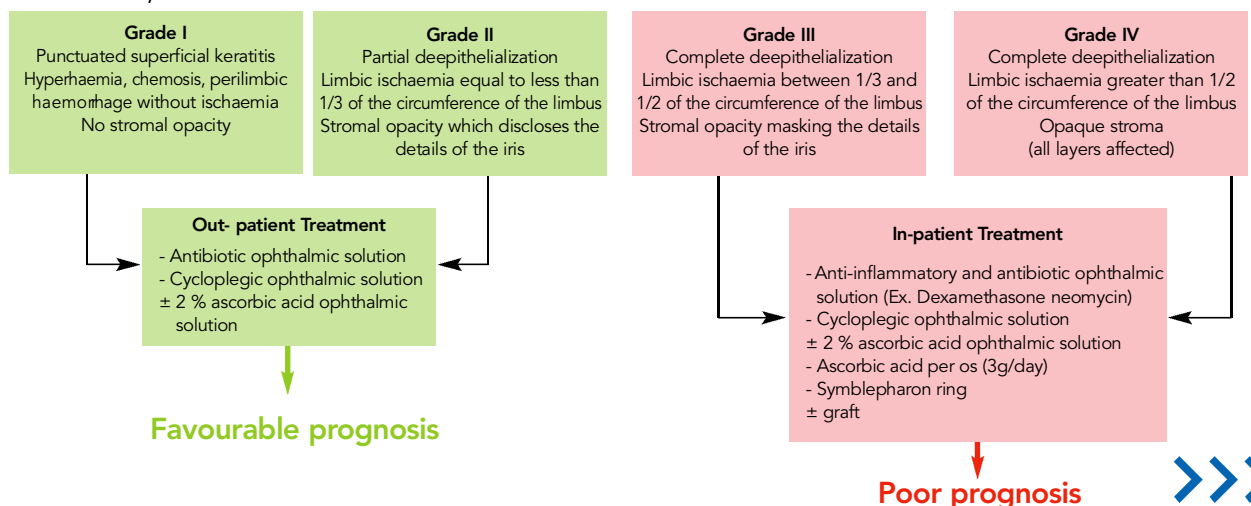
SIEW	Portable eyewash	Mural eyewash	Micro DAP	Mini DAP	DAP
					
50 ml within the first 10 seconds	500 ml within the first minute	500 ml within the first minute	100 ml within the first minute to wash one hand	200 ml within the first minute to wash one arm	5 Litres within the first minute to wash a body

### > At the accident and emergency department

#### • For an ocular splash

- Wash again with 500ml of Diphoterine® followed by a secondary therapeutic protocol.

Based on Roper-Hall classification of ocular chemical burns: prognostic and therapeutic protocol from "Ophtalmologie en urgence" [Emergency Ophthalmology] by Dr Tuil, De Nicola, Mann, Miléa and Barale; Elsevier-Masson Editions 2007.



• **For a cutaneous splash**

- Wash with a quantity of Diphoterine® in proportion to the surface area exposed.
- In the case of delayed use, washing with Diphoterine® should be continued 3 to 5 times the contact time if necessary or by spraying in a constant stream to keep the area moist and to reduce pain.

## 3 INNOCUOUSNESS

Test	Results	References
In vitro evaluation of the <b>ocular irritating potential</b> of a medical device (10 min or 24 hours)	Non-cytotoxic or irritating	Test n°REL/032/05/IRRO/ELB, Integra Laboratory test, Italy, 2005
<b>Cutaneous irritation</b>	Non-irritating	Test n°2005-024, <i>in vitro</i> , Dermal Irritation® test method, Integra Laboratory, Italy, 2005
<b>Local cutaneous tolerance</b> (occlusive test - 48 h on healthy volunteers)	Non-irritating	Test n°1.01-48h, in humans, IDEA, France, 2007
<b>Sensitization</b>	Non-allergenic	Test n°20030418ST, CERB, in the guinea pig, OECD 406, France, 2003
<b>Toxicity by oral route</b>	Non-toxic ; oral DL <sub>50</sub> > 2000 mg/kg	Test n°6564 TAR, in the rat, CIT Laboratory, France, 1990

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

> **Therapeutic indications:**

Washing of ocular and cutaneous chemical splashes (or oral mucous membranes, followed by spitting out).

> **Manufacture's name and address**



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## 4 CONTRAINDICATIONS

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

Do not use in cases of splashes due to white phosphorous. In these cases please use an emergency treatment specifically designed for thermal burns (such as a hydrogel).

Diphoterine® is currently being tested for the treatment of chemical digestive burns but has not yet been validated. However, it has already been tested and classed as non-toxic if swallowed.

Diphoterine® has a limited effect on hydrofluoric acid splashes due to the double corrosive and toxic mechanism of this acid. Washing with Hexafluorine® is better adapted to these two requirements.

> **Side effects**

**No side effects have been reported by our vigilance system.**

Washing with Diphoterine® may cause temporary 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 container.

Products for single use only.



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