bijwerkingen centrumlareb

Acid-Base drops and eye damage

Introduction

There are several brands of acid-base drops on the market. In the Netherlands there are two manufacturers of acid-base drops, namely AlkaVitae producing Alka® drops and Lucovitaal producing ZuurBase In balance® drops. These drops are basic mineral concentrates, packed in a dropper bottle, that claim to neutralize and remove excess acid waste in the body. The recommended use is daily 5 times drinking one glass of water with three drops on an empty stomach [1,2].
Both products are on the market as a food supplement and have not been authorized as a registered drug by the Dutch Medicines evaluation Board (MEB-CBG).
The Netherlands Pharmacovigilance Centre Lareb received in December 2018 a report of serious eye damage due to the accidental use of the Alka® drops in the eye. This report was shared with the Netherlands Food and Consumer Product Safety Authority (NVWA), Inspectorate for Healthcare and Youth (IGJ), the Central Bureau Drugstore Business (CBD) and National Poison and Control Centre (NVIC). A news item about this was also posted on the Lareb website [3]. In September 2019 a new case of serious eye damage in association with Alka® drops was reported to Lareb.

Reports

Lareb received 2 reports concerning patients who experienced serious eye damage after accidentally exchanging Alka® drops with eye drops they were using at the time. Both reports were submitted by their treating physician.

Case A (NL-LRB-00312504)
This serious report, submitted by an ER doctor, concerns a 60-70 years old female with serious eye burns following wrong administration of Alka® drops. The bottle was very similar to the eye drops that she normally used and she mistook the Alka® drops for her eye drops and used them undiluted in the eye. The outcome of the eye damage was at the reporting time still unknown. Since the vision was no longer intact, the prognosis was unclear.

Case B (NL-LRB-00351081)
This serious report from a physician concerns a male aged 60-70 years, with eye damage following accidentally administration of Alka® drops in to eyes. Alka® drops were used as self-medication for fibromyalgia. The bottle was mistaken for the bottle of Eye drops® VSM. This is a product which is used for treatment of the tired, swollen, irritated and dry eyes. The reported eye damage involves chemical injury of the left eye with limbal ischaemia, a complete corneal erosion, major chemosis, hyperaemia and greatly reduced vision. Chemical injury was rated by Roper hall classification and falls into grade 2-3.
The patient rinsed his eye with lukewarm water and in the hospital he was treated by administration of atropine 1% 2dd, PredForte® sc and Terracortril® eye ointment every four hours, sodium-ascorbate 10% and sodium -citrate 10% every hour, doxycycline 100mg two time per day and vitamin C 2000mg once daily. The patient is recovering from eye damage. His vision is still very poor (16%). The healing process is difficult and the progress is weekly followed at the outpatient clinic. According to the ophthalmologist it is still premature to predict the outcome and to judge whether the damage will be permanent.

Cases reported to the National Poison and Control Centre (NVIC)

NVIC provided the following data on their cases to Lareb on 26-09-2019: from 2013 up to and including August 2019 the NVIC has been consulted on a total of 55 exposures to acid-base drops. In 36 cases (64%) the acid-base drops were confused with eye drops. There were 34 reports on Alka® drops (including Lareb report case A), 1 on Lucovitaal ZuurBase in balance® drops and 1 on unknown brand.
Eight reports concern visual impairment from which one report of serious conjunctiva damage and three reports of serious corneal damage. In one case the corneal damage lead to possible permanent visual impairment. All those reports concerned Alka® drops [4,5].

Product information
Acid / base drops contain high concentrations of sodium and potassium hydroxide. The undiluted drops have a pH around 14 and are corrosive [4].

Composition of Alka® drops per 100 ml [1]
Zinc (zinc gluconate) 1.5 mg 15%
Ingredients: water, acidity regulators (potassium hydroxide, sodium hydroxide), mineral

What you need to know before use [1]
Do not drop Alka® Drops undiluted into eyes, mouth or skin. **In case of contact (in particular the eyes), rinse well with water. Any wounds or irritations that have arisen will recover automatically.**

Composition of Lucovitaal ZuurBase In balance® drops [2]
Distilled water, Potassium hydroxide, Sodium hydroxide, Zinc chloride (1.5 mg zinc per daily dose of 15 drops = 15% Recommended Daily Allowance.

Warning [2]
Not to be used by persons using gastric wall protectors. If used in combination with diuretics, consult your doctor first.
Pay attention! Always add the drops to water. Do not use undiluted (never drip directly into the mouth)

Mechanism

Chemical injuries to the eye can produce extensive damage to the ocular surface and anterior segment leading to visual impairment and disfigurement. Alkali burns of the eye are more severe than acid burns. Alkali agents are lipophilic and therefore penetrate tissues more rapidly than acids. They saponify the fatty acids of cell membranes, penetrate the corneal stroma and destroy proteoglycan ground substance and collagen bundles. The damaged tissues then secrete proteolytic enzymes, which lead to further damage [7,8]. The magnitude of damage to these stem cells depends on several factors, including type and pH of the alkali agent and length of ocular exposure [9].
The speed at which initial irrigation of the eye begins, has the greatest influence on the prognosis and outcome of eye burns. Water is commonly recommended as an irrigation fluid [10].

Discussion and conclusion
The two cases reported to Lareb concern acid-base drops from the manufacturer AlkaVitae (Alka® drops) and the reports to NVIC concern beside Alka® drops also drops from the manufacturer Lucovitaal (Lucovitaal ZuurBase In balance® drops) which pose the same potential risk.

Acid-base drops can only be used safely if the instructions for use are followed. It is necessary that the information is provided to the consumer through the label and the information available on the website to ensure that accidents can be avoided. Already in 2018 drugstores issued a warning based on NVIC cases. Druggists were made aware of the importance of giving good sales information [11].
Until now 36 consumers experienced serious eye damage, some of them with permanent vision loss.

Lareb informed the NVWA in January 2019 about a serious eye damage after administration of Alka® drops into the eye. The NVWA took action towards the manufacturer AlkaVitae to ensure that the manufacturer indicates even more clearly how the product should be used. It was urged to include a warning in the package leaflet and website about what a consumer should do if the product accidentally as an eye drop is used [12].
But in practice, the recent report underlines this action is not enough to prevent ocular damage in users. Consumers are still in serious danger despite the custom warning. The recommendation: "*In case of contact (in particular the eyes), rinse well with water. Any wounds or irritations that have arisen will recover automatically* " [1] does not indicate the clinical practice. Because of the pain involved, reflex blepharospasm is likely to occur, which hampers rinsing of the eye. Based on the evidence from

the received reports only rinsing is not sufficient and erosions are not small and do not recover spontaneously.
Besides, it is assumptive that the consumers who accidentally swap Alka® drops with their real eye drops suffer from an eye condition, that may cause them to see poorly, and they might have difficulty reading the warning on the package.

There are different types of products on the market packed in dropper bottles. The risk of this variation in products in dropper bottles is that people are mistaken and misapplied the product [4].
After the request of the NVWA, the packaging of the drops has not changed. The manufacturer AlkaVitae refused to modify the bottle and states that the current bottle meets the safety requirements and user-friendliness [13]. But given the number of reports received, the question arises whether this is the case?

Lareb and NVIC are still receiving reports of (serious) eye damage. The measures mentioned so far prove to be insufficient. Therefore it is necessary to find out which additional options and measures remain to protect consumers against these serious consequences.

References

1. Productinformatie Alka druppels via https://www.alka.nl/Alka-druppels, access date 10-09-2019.
2. Productinformatie Zuur-basische druppels Lucovitaal via https://www.lucovitaal.nl/zuur-base-basische-druppels.html, access date 10-09-2019.
3. Oogschade door Alka druppels via https://www.lareb.nl/nl/news/oogschade-door-alka-druppels/ , access date 10-09-2019.
4. NVIC-Jaaroverzicht 2016 via https://www.umcutrecht.nl/getmedia/7f6543a2-6609-46f2-a043-a554bef36475/NVIC-Jaaroverzicht-2016.pdf.aspx?ext=.pdf access date 10-09-2019.
5. NVIC-Jaaroverzicht 2015 via https://www.umcutrecht.nl/getmedia/25d1c213-78f8-4580-ae66-2728af974adb/NVIC -Jaaroverzicht2015.pdf.aspx?ext=.pdf, access date 10-09-2019.
6. Scientific Opinion on the substantiation of health claims related to zinc etc, EFSA Journal 2009; 7(9):1229. via https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2009.1229, access date 10-09-2019.
7. Chemical (Alkali and Acid) injury of the Conjunctiva and Cornea, American Academy of ophthalmology via https://eyewiki.aao.org/Chemical_(Alkali_and_Acid)_Injury_of_the_Conjunctiva and Cornea, access date 10-09-2019.
8. Chemical burns of the eye with special reference to alkali burns, Rozenbaum D, Baruchin AM, Dafna Z., Burns. 1991Apr;17(2):136-40.
9. Alkali burns to the right eye, Singh A, Cullen CL, Grahn BH., Can Vet J. 2004 Sep;45(9):777-8.
10. Emergency treatment of chemical and thermal eye burns, Kuckelkorn R, Schrage N, Keller G, Redbrake C., Acta Ophthalmol Scand. 2002 Feb;80(1):4-1.
11. Verkeerd gebruik zuur-base druppels kan ernstige gevolgen hebben via http://www.drogistensite.nl/nieuws/detail/verkeerdgebruik-zuur-base-druppels-kan-ernstige-gevolgen-hebben, access date 10-09-2019.
12. Reactie NVWA via https://kassa.bnnvara.nl/data/files/3139645955.pdf, access date 10-09-2019.
13. Reactie AlkaVitae via https://kassa.bnnvara.nl/data/files/3120752800.pdf, access date 10-09-2019.

This signal has been raised on September 30, 2019. It is possible that in the meantime other information became available