Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

AMIDAFLUID 1 mg/ml, eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains 1 mg propamidine isetionate. Each drop contains approximatively 0.004 mg of Propamidine Isetionate.
Excipient(s) with known effect:
Each ml of solution contains 0.05 mg benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.
A clear, colourless, aqueous solution.
pH: 5.0-7.0
Osmolality: 280-320 mOsm/kg

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

AMIDAFLUID 1 mg/ml is indicated for the topical treatment of milder bacterial external ocular infections in adults such as
• milder forms of bacterial conjunctivitis caused by susceptible microorganisms (see section 4.4 and 5.1).
• milder forms of infectious blepharitis caused by susceptible microorganisms (see section 4.4 and 5.1).

4.2 Posology and method of administration

Posology

For ocular use.
The usual dosage is 1-2 drops into the affected eye up to three to four times daily depending on severity. The duration is 7 days with a maximum of 10 days of treatment.

Paediatric population

The safety and efficacy of AMIDAFLUID 1mg/ml, eye drops, solution in children have not yet been established.

Method of administration

For ocular use.
If more than one topical ophthalmic medicine is being used, the medicinal products should be administered at least 15 minutes apart.
To prevent contaminating the dropper tip and solution, the dropper tip should not come into contact with the eyelids or surrounding areas.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
The wearing of contact lenses is contraindicated with this medicine.

4.4 Special warnings and precautions for use

There is always the possibility, although rare, of a sensitisation reaction resulting from the use of AMIDAFLUID 1 mg/ml, eye drops, solution. In such an event treatment should be discontinue immediately. Should erythema or other evidence of increased inflammation occur application should cease immediately and medical opinion should be sought.

If problems of visual acuity occur or its symptoms are detected, the doctor should be consulted immediately.

Avoid prolonged or frequently repeated treatments due to the risk of emergence of resistant strains.
The total length of treatment against bacterial infection should not exceed 10 days.
Propamidine is not indicated in cases of suspected bacterial conjunctivitis caused by Pseudomonas spp. or Escherichia coli.

Excipients

This medicinal product contains 0,05 mg benzalkonium chloride in each ml of solution which is equivalent to 0.05 mg/ml.
Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. AMIDAFLUID 1 mg/ml, eye drops, solution should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

If Propamidine isetionate 1 mg/ml, eye drops solution is used with other eye medications, an interval of at least 15 minutes must be observed between the administration of the two medications.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to Propamidine isetionate is negligible. Propamidine isetionate can be used during pregnancy.

Lactation
No effects on the breastfed newborn/infant are anticipated, since the systemic exposure of the breast-feeding woman to Propamidine isetionate is negligible.
Propamidine isetionate can be used during breast-feeding.

Fertility
There are no data on potential effects of Propamidine isetionate on male and female fertility. However, no effects on fertility are anticipated, since systemic exposure to Propamidine isetionate is negligible.

4.7 Effects on ability to drive and use machines

AMIDAFLUID 1 mg/ml, eye drops, solution may cause transient blurring of vision on instillation. Patients should be warned not to drive or operate machinery unless vision is clear.

4.8 Undesirable effects

Adverse events are categorized by frequency as follows: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (frequency cannot be estimated from available data).

Immune system disorder
Not known: Hypersensitivity may occur, in which case treatment should be discontinued immediately.

Eye disorders
Not known: Eye pain or irritation, usually in the form of a stinging or burning sensation, may also occur.

In such cases, use should be discontinued immediately and a physician should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance www.hpra.ie.

4.9 Overdose

No information is available on overdose in humans; overdose is unlikely to occur after ocular administration. If overdose occurs, treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other anti-infectives ATC code: S01AX15
Propamidine is a member of the aromatic diamidine group of compounds which possess bacteriostatic properties against a wide range of organisms. These diamidines exert antibacterial action against pyrogenic cocci, antibiotic resistant staphylococci and some gram-negative bacilli. The activity of the diamidines is retained in the presence of organic matter such as tissue fluids, pus, and semen.

Mechanism of action
The exact mechanism of action of diamidines remains partially unknown, but some effects were described such as inhibition of oxygen uptake and catabolic (oxidative) metabolism of bacteria, and induction of leakage of amino acids by effects on cell membrane. Such effects are actually consistent with their structure of cationic surface-active agents. Damage to the cell surface of some Gram-negative bacteria such as P. aeruginosa and Enterobacter cloacae has been also described.
Propamidine isetionate is effective in both Gram-positive and Gram-negative bacteria.

5.2 Pharmacokinetic properties

Pharmacokinetics were not studied. AMIDAFLUID 1 mg/ml is intended for topical ophthalmic application and systemic absorption of propamidine is expected to be negligible after topical administration to the eye.

5.3 Preclinical safety data

There is no other information available which could be of relevance to the prescriber in recognising the safety profile of AMIDAFLUID 1 mg/ml, eye drops, solution and which is not included in the relevant sections of this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonium chloride
Sodium chloride
Benzalkonium chloride
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
Opened bottle: 28 days after first opening the bottle.
Do not store above 25°C.

6.4 Special precautions for storage

Do not store above 25°C.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

The container is a low density polyethylene bottle with a dropper of high density polyethylene and tamperproof cap.
One bottle contains 10 ml of solution.

Carton containing 1 bottle.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Horus Pharma
Inedi 5
22 Allee Camille Muffat
Nice
06200
France

8 MARKETING AUTHORISATION NUMBER

PA23520/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 13th June 2025

10 DATE OF REVISION OF THE TEXT