

Applicant: iNOVA Pharmaceuticals (Pty) Ltd
Product Name Zidoval Douche, vaginal solution
(Dosage form): One bottle of 140 ml contains 140 mg of benzydamine hydrochloride (0,1 % w/v)

Professional Information

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SCHEDULING STATUS

S2

1 NAME OF THE MEDICINE

Zidoval Douche (vaginal solution)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One bottle of 140 ml contains 140 mg of benzydamine hydrochloride (0,1 % w/v).

Excipients with known effect: Benzalkonium chloride 0,02 % v/v.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Vaginal solution.

Colourless, clear solution with rose fragrance.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Zidoval Douche is indicated for the treatment of mild to moderate non-specific vulvovaginitis featuring small vaginal discharges, itching, irritation, burning and vulvar pain or can be used for personal hygiene after giving birth.

Zidoval Douche is for use in patients 18 years of age and older.

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4.2 Posology and method of administration

Posology

1-2 vaginal irrigations per day for seven days consecutively. If not resolved within 7 days, further investigation is necessary.

The solution can be used at room temperature. If you wish to warm it a little, place the closed bottle under hot running water.

Method of administration

For vaginal use only.

4.3 Contraindications

Hypersensitivity to benzydamine, or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Use of topical products, especially if prolonged, can give rise to sensitisation phenomena, in which case the treatment must be suspended and suitable therapeutic measures must be adopted.

The patient should contact her doctor before use in the case of vaginal bleeding and/or leucorrhoea.

Zidoval Douche contains benzalkonium chloride which may cause local irritation.

4.5 Interaction with other medicines and other forms of interaction

No negative interactions with other pharmaceutical products commonly used for the conditions in question have been observed.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy has not been proven.

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4.7 Effects on ability to drive and use machines

Zidoval Douche has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Skin irritation has been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions

Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Intoxication is only expected in the event of accidental oral ingestion of large amounts of benzidamine (> 300 mg).

Symptoms associated with overdose of ingested benzydamine are mainly gastrointestinal symptoms and symptoms of the central nervous system. Most frequent gastrointestinal symptoms are nausea, vomiting, abdominal pain and oesophageal irritation. Symptoms of the central nervous system include dizziness, hallucinations, agitation, anxiety and irritability.

In acute overdose only symptomatic treatment is possible. Patients should be kept under close observation and supportive treatment should be given. Adequate hydration must be maintained.

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5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: anti-inflammatory products for vaginal administration, ATC code: G02CC03.

Benzydamine is a non-steroidal anti-inflammatory that has analgesic and anti-exudative properties. Applied locally, it also has a disinfecting and surface anaesthetising effect.

5.2 Pharmacokinetic properties

Absorption

The gradual absorption through the mucus produces very low haematic levels that are insufficient for systemic pharmacological effects.

Distribution

Spectrofluorimetric investigations have shown that the benzydamine contained in the vaginal solution fixes to the vaginal epithelium and concentrates there at $9,7 \pm 6,24 \mu\text{g/g}$ of fresh tissue.

Elimination

It is prevalently excreted with the urine and mainly in the form of inactive metabolites or conjugation products.

5.3 Preclinical safety data

Benzydamine has very low toxicity, linked more to disturbances of a pharmacodynamic nature rather than anatomical-pathological alterations. The margin between LD50 and the single therapeutic dose by oral administration is 1000:1. Benzydamine does not have harmful gastrointestinal effects; it does not have teratogenic effects and does not interfere with normal embryonic development.

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6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride, solution

Disodium Edetate

Ethanol (96 per cent)

Polysorbate 20

Purified Water

Rose Oil

6.2 Incompatibilities

Not applicable

6.3 Shelf life

4 years

6.4 Special precautions for storage

Store at or below 25 °C in a dry place.

Store in the original package in order to protect the medicine from light and moisture.

6.5 Nature and contents of container

Zidoval Douche is packaged in a single-dose, pear-shaped, 140 ml LDPE bottle equipped with a white cannula including a return valve and a guide-plug and protected with a suitable cap.

The bottles are packaged into lithographed cardboard boxes, together with the instructions leaflet.

Pack size: 1 or 5 bottles.

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6.6 Special precautions for disposal and other handling

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

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNOVA Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

SOUTH AFRICA

8 REGISTRATION NUMBER

55/18.6/0243

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13 September 2022

10 DATE OF REVISION OF THE TEXT

13 September 2022