

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

Patient Information Leaflet

SCHEDULING STATUS:

S2

Zidoval Douche vaginal solution

Benzydamine hydrochloride

Contains bezalkonium chloride (preservative)

Read all of this leaflet carefully because it contains important information for you

Zidoval Douche is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use Zidoval Douche carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Zidoval Douche with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What Zidoval Douche is and what it is used for
2. What you need to know before you take Zidoval Douche
3. How to take Zidoval Douche
4. Possible side effects
5. How to store Zidoval Douche
6. Contents of the pack and other information

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

1. What Zidoval Douche is and what it is used for

Zidoval Douche contains the active substance benzydamine hydrochloride and is used in patients 18 years of age and older.

Zidoval Douche is used as an antiseptic, anti-inflammatory and pain reliever for vulvovaginitis featuring vaginal discharges, itching, irritation, burning and vulvar pain. If symptoms do not resolve within 7 days, consult your doctor.

Zidoval Douche is used for personal hygiene after giving birth.

2. What you need to know before you use Zidoval Douche

Do not use Zidoval Douche if:

- you are hypersensitive to benzydamine hydrochloride or to any of the other ingredients of Zidoval Douche (listed in section 6).

Warnings and precautions

Take special care with Zidoval Douche:

- Repeated use can give rise to sensitisation phenomena (allergic reactions).
In this case, stop the treatment and consult your doctor to start a suitable therapy. See section 4 "Possible side effects".
- Tell you doctor before you use Zidoval Douche if you have a whitish or yellowish discharge of mucus or bleeding from the vagina.

Other medicines and Zidoval Douche

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

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

Pregnancy, breastfeeding and fertility

Safety in pregnancy has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before using Zidoval Douche.

Driving and using machines

It is not always possible to predict to what extent Zidoval Douche may interfere with the daily activities of a patient. Patients should ensure that they do not engage in driving a vehicle or use machines until they are aware of the measure to which Zidoval Douche affects them.

Zidoval Douche contains benzalkonium chloride

Benzalkonium chloride may cause local irritation.

3. How to use Zidoval Douche

Do not share medicines prescribed for you with any other person.

Always use Zidoval Douche exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Zidoval Douche is inserted into the vagina undiluted with the applicator (applied intravaginally).

Use 1-2 irrigations per day for seven days consecutively.

Zidoval Douche can be used at room temperature. If necessary, it can be tempered by immersing the sealed bottle in warm water. Do not overheat the douche.

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

For optimal treatment success, use Zidoval Douche as follows:

1. If possible, the vagina should be rinsed while lying down, either in a bathtub or over a wash bowl. However, it can also be used while sitting on the toilet or on the bidet.
2. Take the bottle in one hand and hold the edge of the bottle underneath the protective cap between your thumb and forefinger (no screw cap).
3. Now break off the protective cap with your other hand by moving it sideways and remove it.
4. Pull out the white applicator until it clicks into place. In order for the applicator to click into place, a certain resistance must be overcome, which is noticeable by a cracking noise.
5. Now insert the applicator into the vagina and push the bottle out until it is empty.
6. Then pull the applicator out of the vagina while it is compressed.

In order for the effect of Zidoval Douche to take full effect, the liquid should remain in the vagina for a few minutes.

If you use more Zidoval Douche than you should

If you accidentally swallow some medicine, contact immediately your doctor or pharmacist for advice. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Zidoval Douche

Do not use a double dose to make up for forgotten individual doses.

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

4. Possible side effects

Zidoval Douche can have side effects.

Not all side effects reported for Zidoval Douche are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Zidoval Douche, please consult your healthcare provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Local irritation in the form of burning and itching.

These are all serious side effects. You may need urgent medical attention.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Zidoval Douche.

5. How to store Zidoval Douche

Store all medicine out of reach of children.

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.

Do not use the vaginal solution after the expiry date shown on the container.

Return the expired medicine to your pharmacist for safe disposal.

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

6. Contents of the pack and other information

What Zidoval Douche contains

The active ingredient is benzydamine hydrochloride.

The other ingredients are benzalkonium chloride, disodium edetate, ethanol

96 %, polysorbate 20, purified water and rose oil.

What Zidoval Douche looks like and contents of the pack

Zidoval Douche is a colourless, clear solution with rose fragrance.

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.

Holder of Certificate of Registration

iNOVA Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

SOUTH AFRICA

Tel: +27 11 087 0000

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

This leaflet was last revised in

13 September 2022

Registration number

55/18.6/0243