

PACKAGE LEAFLET: Information for the patient

MELIODINE

Ovules – 200 mg

(Povidone iodinated)

Read this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet:

1. What Meliodine ovules are and what they are used for
2. What you should know before you use Meliodine ovules
3. How to use Meliodine ovules
4. Possible side effects
5. How to store Meliodine ovules
6. Other information

1. WHAT MELIODINE OVULES ARE AND WHAT THEY ARE USED FOR

The ovules Meliodine contain the active substance povidone iodinated. Povidone iodinated is a complex of iodine with povidone (polyvinylpirrolidone), whereas povidone is a hydrophil synthetic polymer which acts like a iodine carrier.

This polymer alone does not have antibacterial effect, but has greater affinity for cell membrane, whereas in the form of complex with iodine (povidone iodinated), it releases free iodine directly in the bacterial cell membrane. The release of iodine from the povidone iodinated complex in the bacterial cell membrane is very important for the action of iodine. In the presence of free iodine, sulfhydryl groups, peptides, proteins, hormones, enzymes, lipids and cytosine become iodinated

or halogenated and oxidised, which leads to inactivation of important molecules for the regeneration of the organism. Povidone iodinated present in ovules 200 mg acts also in the presence of organic matter, blood, pus, serum and lipids.

Melioidine is indicated for:

- the treatment of vaginitis caused by Trichomonas vaginalis and Monilia albicans;
- the treatment of mixed vaginitis.

2. WHAT YOU SHOULD KNOW BEFORE YOU USE MELIODINE OVULES

Do not use Melioidine ovules if you have:

- known hypersensitivity to iodine, although sensitive persons do not normally react to povidone iodinated, or to any of the excipients of Melioidine ovules;
- disease of thyroid gland.
- dermatitis herpetiformis of Duhring.

Avoid regular or prolonged use of Melioidine if you are taking lithium therapy.

Do not use preparations containing iodine and povidone iodinated before and after radiotherapy (until the end of treatment).

Take special care with Melioidine if you:

- have disorders of the thyroid function;
- have renal;
- desire the conception of a baby because povidone iodinated is spermicidal.

Avoid regular or prolonged use, because it can lead to excessive absorption of iodine, so a considerable amount of serum iodine and also plasmatic protein bound iodine can be found.

If ovules cause irritation, edema, or any other kind of reaction, please stop the treatment.

Melioidine ovules are for vaginal use only and **should not be ingested**.

Other medicines and Meliodine

Concomitant treatment with other drugs can affect or be affected by Meliodine ovules.

Please, tell your doctor or pharmacist if you are taking / using, have recently taken / used other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about the treatment with Meliodine if you are given another drug during treatment.

It is particularly important to inform your doctor that you are taking other drugs.

- Concomitant use of povidone iodinated with silver sulfadiazine or chlorhexidine may cause inactivation.
- The absorbed iodine through damaged or undamaged skin and mucosa may interfere with thyroid function tests.
- It is not recommended to use povidone iodinated and other disinfectant solutions containing mercury salts, benzoin compounds, octenidine-containing antiseptics or other kinds of disinfectants and detergents at the same time.

Pregnancy and breastfeeding

Consult with your doctor or pharmacist before using this drug during pregnancy or breastfeeding. Meliodine ovules should be avoided during pregnancy and breastfeeding.

In cases when it is absolutely necessary, it should be used carefully only under the prescription and the control of the doctor.

3. HOW TO USE MELIODINE OVULES

The ovules are for vaginal use only.

1 ovule per day (usually in the evening, before sleeping). It is advisable to insert deeply the vaginal ovule and remain in a supine position for a few minutes.

If you use more Meliodine

If you use more Meliodine than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

Hyperthyroidism or hypothyroidism may occur if the recommended dose is exceeded.

Ovules should not be ingested. Ingestion of some disinfectants can have serious, sometimes fatal

consequences.

If you forget to use Meliodine

If you forget to use one dose (or more than one dose), use the next dose at its usual time.

Do not use a double dose (or more) to make up a forgotten dose (doses).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Meliodine ovules can cause side effects, although not everybody gets them.

Sometimes they may be serious, sometimes not. Do not worry about this list of possible side effects. None of them may appear to you.

The most common side effects are:

- hypersensitivity reactions which appear with irritation of the skin and mucous membranes, redness and itching in the application area;
- anaphylaxis after vaginal application of the povidone iodinated solution.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MELIODINE OVULES

Keep out of the reach and sight of children!

Do not use Meliodine ovules after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package to protect it from light.

6. OTHER INFORMATION

What Meliodine ovules contain

The active substance is povidone iodinated.

1 vaginal ovule contains 200 mg povidone iodinated.

The excipients are macrogol 400 and macrogol 1500.

Content of the pack

Carton box with 14 ovules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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