

PART III: CONSUMER INFORMATION

Prevegyne® Vaginal vitamin C tablets

This leaflet is part III of a three-part "Product Monograph" published when Prevegyne® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Prevegyne®. Contact your doctor, pharmacist or healthcare professional if you have any questions about this natural health product.

ABOUT THIS MEDICATION

What the medication is used for:

Prevegyne® helps to reduce/relieve symptoms of non-specific vaginitis/bacterial vaginosis.

What it does:

Prevegyne® is characterised by a special formulation that releases the vitamin over hours to allow an efficient action and at the same time to reduce the risk of an irritation of the vaginal epithelium by high ascorbic acid concentrations. It represents a modern approach for the decrease of the intravaginal pH value and for the consequent inhibition of all bacteria that cannot grow in a pH ≤ 4 environment. Therefore, bacteria like lactobacilli (major constituents of the normal vaginal flora), capable of reproduction even at pH values below 4, are favoured.

When it should not be used:

You should not use Prevegyne® if:

- you are hypersensitive to ascorbic acid or to any ingredient in the formulation
- you are pregnant or breastfeeding

What the medicinal ingredient is:

The medicinal ingredient of Prevegyne® is vitamin C (ascorbic acid) 250 mg.

What the important nonmedicinal ingredients are:

Nonmedicinal ingredients are as follows: polydimethylsiloxane-methyltrisiloxane-copolymer, lactose monohydrate, hydroxypropylmethylcellulose, magnesium stearate and acetone.

What dosage forms it comes in:

Prevegyne® is supplied in the form of a controlled-release vaginal tablet. Each tablet contains 250 mg of ascorbic acid.

A box contains six (6) tablets.

WARNINGS AND PRECAUTIONS

If you have never been diagnosed with a bacterial vaginosis, it is recommended to consult your doctor, pharmacist or healthcare professional.

Vaginal use only. Do not swallow.

BEFORE you use Prevegyne® talk to your doctor, pharmacist or healthcare professional if you are:

- suffering from a vaginal infection due to Candida
- taking anticoagulants (blood thinners)
- suffering from hemolytic anemia (premature destruction of red blood cells)

Do not use if you are pregnant or breastfeeding.

INTERACTIONS WITH THIS MEDICATION

No interaction has been established with the intravaginal use of Prevegyne®.

PROPER USE OF THIS MEDICATION

Usual dose:

Wash your hands thoroughly before and after inserting Prevegyne® vaginal tablets. Insert one (1) Prevegyne® tablet deeply into your vagina using your index and/or middle finger. To ease insertion it is recommended to insert the tablet in a lying position, preferably at bedtime. In order to decrease the risk of tablet breaking, a localized pressure should be applied at the edge of the blister (direct pressure in the center of the tablet should be avoided). The tip of a spoon or a fingernail may be used to gently break the foil underneath the blister.

The recommended dosage to help reduce/relieve symptoms of bacterial vaginosis is one (1) Prevegyne® vaginal tablet a day. A treatment of six (6) days is recommended to restore the physiological pH and the normal vaginal flora. If after six (6) days, you are still experiencing symptoms or if your symptoms increase while using Prevegyne®, please consult your doctor or healthcare professional.

Prevegyne® tablets are a special vaginal formulation capable of slowly releasing moderate amounts of ascorbic acid over hours. Prevegyne® tablets should not be crushed or intentionally split.

In the event the tablet is accidentally split, both halves of the tablet should be used at once. For your comfort, insert both halves by their rounded parts.

Overdose:

Vitamin C inserted in the vagina is not absorbed in significant amounts. Only one (1) tablet should be inserted vaginally per day.

Missed Dose:

When a tablet has been missed, it should be inserted as soon as possible.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common adverse reactions associated with Prevegyn[®] are vaginal itching and burning. Other adverse reactions associated with Prevegyn[®] may include leucorrhoea (vaginal discharge), pain or insomnia.

This is not a complete list of side effects.

For any unexpected side effects while taking Prevegyn[®] contact your doctor, pharmacist or healthcare professional.

HOW TO STORE IT

Store at room temperature.

Store in a dry place.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or
- Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Duchesnay Inc., at:

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