PACKAGE LEAFLET: INFORMATION FOR THE USER

Novgos 3.6mg Implant

Goserelin

Read all of 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, please ask your doctor.
- This medicine has been prescribed for you. You should 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 get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Novgos is and what it is used for
2. Before you use Novgos
3. How to use Novgos
4. Possible side-effects
5. How to store Novgos
6. Further information

1 WHAT NOVGOS IS AND WHAT IT IS USED FOR

Novgos is a medicine that acts like a hormone. It belongs to a group of medicines called LHRH agonists. It reduces the production of the male sexual hormone (testosterone) or the female sexual hormone (oestrogen) in the body.

Novgos is used in men to treat prostate cancer.

2 BEFORE YOU USE NOVGOS

Do not use Novgos:

- if you are allergic to goserelin or any of the other ingredients of Novgos
- in children.

Take special care with Novgos:

- if you have or have had problems passing urine or if you have or have had problems with your back. Please, tell your doctor if so.

Previous treatment

- if you had a previous treatment with another medicine in this group because they can cause a small loss of calcium from the bones (thinning of bones). Some recovery of this loss can occur when treatment is stopped. If you are suffering from any disease which affects the strength of your bones please make sure that your doctor is aware of this.

Children

Novgos must not be used in children.

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Driving and using machines:

We do not know whether Novgos could affect your ability to drive a car or operate machines.

3 HOW TO USE NOVGOS

The implant is given as an injection under the skin on your stomach by your doctor.
Novgos should be given every month (four weeks). Always remind your doctor or nurse to set up an appointment for your next injection.

This dosage is the same for patients with impaired kidney or liver function and for elderly patients.

If you think that the symptoms have changed or worsened, please ask your doctor. He will be able to decide if any changes are needed to your treatment.

If you use more Novgos than you should

If you receive an injection too early (less than four weeks after the previous injection) please inform your doctor.

If you forget to use Novgos

Please talk to your doctor if you think the 4-weekly use of Novgos has been forgotten.

If you stop using Novgos

Generally the treatment with Novgos is a long-term treatment.

It is important that you keep on receiving your treatment, even if you are feeling well, unless your doctor decides that it is time to stop the treatment.

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

4 POSSIBLE SIDE-EFFECTS

Like all medicines, Novgos can cause side-effects, although not everybody gets them.

Frequencies of side-effects are defined as:

Very common:	more than 1 in 10 treated patients
Common:	more than 1 in 100 treated patients, less than 1 in 10 treated patients
Uncommon:	more than 1 in 1,000 treated patients, less than 1 in 100 treated patients
Rare:	more than 1 in 10,000 treated patients, less than 1 in 1,000 treated patients
Very rare:	1 or less in 10,000 treated patients including isolated reports

General

Cardiac disorders:

Uncommon: too low or too high blood pressure.

Nervous system disorders:
Very common: tingling in fingers or toes.
Very rare: severe headaches, sickness, loss of eyesight or unconsciousness caused if there is a tumour in the pituitary gland that bleeds or collapses.

Skin and subcutaneous tissue disorders:
Common: mild skin rash.

Musculoskeletal and connective tissue disorders:
Very rare: pain in the joints.

General disorders and administration site conditions:
Rare: local reactions at the injection site.

Immune system disorders:
Rare: allergic reactions, including the symptoms of an immediate allergy.

At the beginning of the treatment certain symptoms may occur:

Nervous system disorders:
Very rare: lower back pain.

Renal and urinary disorders:
Very rare: problems with passing urine.

Musculoskeletal and connective tissue disorders:
Common: bone pain.

During treatment the following symptoms may occur:

Nervous system disorders:
Very rare: benign tumours of the pituitary gland.

Endocrine disorders:
Very common: hot flushes and sweating.

Reproductive system and breast disorders:
Very common: reduced sex drive, reduction in the size of the testicles.
Common: breast swelling.
Very rare: breast tenderness.

Treatment with Novgos may affect the strength of your bones. Therefore you may have a higher risk of suffering from bone fractures than usual.

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

5 HOW TO STORE NOVGOS

Keep out of reach and sight of children.

Novgos should not be used after EXP which is stated on the pouches and the carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not use the implant or applicator if you notice that the packaging is damaged.

After opening the pouch the product should be used immediately.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Novgos contains

The active substance is goserelin.
1 implant contains 3.6mg goserelin (as goserelin acetate).
The other ingredient is poly (D,L-lactide-co-glycolide).

What Novgos looks like and contents of the pack

Novgos is a sterile, cylindrical, white to cream coloured implant placed in a sterile injection needle.

The package contains:

One pouch including one sterile injection needle and a desiccant.
One pouch including one sterile applicator.
Novgos is available in packs of 1, 3 and 6 implants.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Genus Pharmaceuticals
Park View House, 65 London Road, Newbury
Berkshire RG14 1JN, UK

Manufacturers:

Acino AG
Carl-Feichtner-Ring 1, 83714 Miesbach, Germany

Cellpharm GmbH
Feodor-Lynen-Str. 35, 30625 Hannover, Germany

POM

PL 06831/0233 Novgos 3.6mg Implant

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: Novgos 3.6mg Implant
Austria: Novgos 3.6mg Implant
Italy: Novgos 3.6mg Implant
Spain: Novgos 3.6mg Implant
United Kingdom: Novgos 3.6mg Implant

This leaflet was last approved in: March 2009.

Notes for the doctor:

1. Novgos consists of two pouches, the sterile injection needle and the sterile applicator. Note that the implant is visibly fixed in the injection needle. Open both pouches and connect the injection needle to the applicator via the Luer lock. Make sure that the connection is tight and that the plunger remains unchanged in its position.
2. Check that the implant is visible in the control window in the needle.
3. Remove the locking device from the plunger. Insert the cannula into the anterior abdominal wall and insert the implant by depressing the plunger completely.

In addition please pay attention to the detailed application advice on the outer pack.

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