PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

NOVA T 380

Intrauterine device (IUD)

Read all of this leaflet carefully before you start using NOVA T 380.
Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor or your pharmacist.
Nova T 380 has been prescribed for you personally.

1. WHAT NOVA T 380 CONTAINS:

Nova T 380 is a T-shaped intrauterine device that is inserted into the womb as a contraceptive (to prevent pregnancy). The polyethylene body, shaped as a modified T, is impregnated with barium sulphate. The vertical arm of the T-frame is wound with a pure copper wire, resulting in a copper surface area of approximately 380 mm². The wire contains a silver core which has been shown to prevent breaking of the wire. Two removal threads pigmented with iron oxide are tied to the loop at the lower end of the vertical arm.

2. WHAT NOVA T 380 IS USED FOR:

Nova T 380 affects reproduction at an early stage by preventing fertilisation. Nova T 380 affects the movement of the sperm and egg and also inhibits the capacity of sperm to fertilise eggs.
After the removal of Nova T 380 fertility is promptly restored.
The pregnancy rate with Nova T 380 has been 0, 6 per 100 woman-years.

3. BEFORE YOU USE NOVA T 380

Do not use Nova T 380

The device should not be used if you have any of the following conditions:

- known or suspected pregnancy
- current or recurrent pelvic inflammatory disease; lower genital tract infection
- infection of the womb after delivery or after abortion during the past 3 months
- untreated cervicitis
- cancer of the cervix or womb
- untreated cervical dysplasia
- undiagnosed abnormal uterine bleeding
- abnormality of the cervix or womb including fibroids if they distort the uterine cavity
- copper allergy
- Wilson's disease (a disturbance of the body's copper balance)
- disturbances in blood clotting
- conditions associated with increased susceptibility to infections.

Take special care with Nova T 380

Nova T 380 may increase menstrual blood loss and dysmenorrhoea. Nova T 380 may not be the method of first choice for women with excessive menstrual bleeding, anaemia, dysmenorrhoea, or for women receiving anticoagulants. If these conditions develop during use of Nova T 380, removal of the device should be considered.

Nova T 380 may be used with caution in women who have congenital heart disease or valvular heart disease at risk of infective endocarditis. Antibiotic prophylaxis should be administered to these patients when inserting or removing Nova T 380.

Nova T 380 is not the method of first choice for young women who have not given birth. In this group, the pregnancy rates and removal rates for expulsion, bleeding and/or pain, and for infection have been reported higher than in other users.

Pelvic Infection
During insertion, Nova T 380 is protected within the insertion tube in order to reduce the risk of infection. Despite this, there is an increased risk of pelvic infection immediately after the insertion. Pelvic infections in Nova T 380 users are often related to sexually transmitted diseases. The risk of infection is increased if the woman or her partner has multiple sexual partners. Pelvic infections must be treated promptly. Pelvic infection may impair fertility and increase the risk of ectopic pregnancy. Severe infection or sepsis (very severe infection, which may be fatal) can occur shortly after Nova T 380 insertion. Nova T 380 must be removed if there are recurrent pelvic infections or if an acute infection does not respond to treatment within a few days.

Consult a healthcare professional without delay if you have persistent lower abdominal pain, fever, pain in conjunction with sexual intercourse or abnormal bleeding. Severe pain or fever developing shortly after insertion may mean that you have a severe infection which must be treated immediately.

Expulsion
The muscular contractions of the womb during menstruation may sometimes push Nova T 380 out of place or expel it. Possible symptoms are pain and abnormal bleeding. If Nova T 380 is displaced, the effectiveness is reduced.

Perforation
The Nova T 380 IUD may perforate or penetrate the womb or neck of the womb. This usually happens during insertion. Tell your doctor if you feel pain during insertion or afterwards. The risk of perforation by the Nova T 380 IUD is increased in breastfeeding women, and in women who had a delivery up to 36 weeks before insertion, and may be increased in women whose womb is tilted backwards and fixed. In case of perforation or penetration of the womb the Nova T 380 IUD must be removed as soon as possible.

Ectopic pregnancy (pregnancy outside the womb)

Ectopic pregnancies may occur when Nova T 380 IUD is used.

If a woman using Nova T 380 becomes pregnant, she should be examined carefully.
Women with a previous ectopic pregnancy, pelvic surgery or pelvic infection carry a higher risk of ectopic pregnancy. The possibility of an ectopic pregnancy should be considered if the start of your period was delayed, the bleeding is scanty and you have lower abdominal pain.

Lost threads
If the retrieval threads are not visible at the cervix on follow-up examinations, pregnancy must be excluded. The threads may have been drawn up into the uterus or cervical canal and may reappear during the next menstrual period. If pregnancy has been excluded, the threads may usually be located by gently probing with a suitable instrument. If they cannot be found, the possibility of expulsion or perforation should be considered. Ultrasound diagnosis may then be used to determine the position of the IUD. If ultrasound is not available or unsuccessful, X-ray may be used to locate Nova T 380.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby while using Nova T 380, please consult your doctor, pharmacist or other healthcare professional for advice.

Nova T 380 is not to be used if you are pregnant or if you suspect that you may be pregnant. A pregnancy is unlikely while using Nova T 380. However, if you become pregnant with the device in place and wish to continue the pregnancy, removal of the device is recommended.

If it is not removed, there is a risk of miscarriage or premature birth. The pregnancy should be observed carefully. There is no evidence of birth defects in cases when a pregnancy continues to term with the device in place. If the device cannot be gently removed, termination of the pregnancy may be considered. If you wish to continue the pregnancy and the device cannot be withdrawn talk to your doctor who will offer you more information how to proceed. Especially if you experience cramping abdominal pain with fever you need to contact your doctor immediately**.**

Nova T 380 does not interfere with breastfeeding.

Driving and using machinery
There are no known effects on the ability to drive or use machines.

Using other medicines with Nova T 380.
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Nova T with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Limited available experience with Nova T 380 indicates that it is unlikely for other medicine's effects to interfere with Nova T 380's contraceptive efficacy.

4. HOW TO USE NOVA T 380

Do not share medicines prescribed for you with others.
Nova T 380 is supplied sterile. It is sterilised by irradiation. It is for single use only. It must not be re-sterilised. Do not use it if the pouch is damaged or open. The device should be inserted by a qualified healthcare professional before the expiry date shown on the pouch label.

Insertion and removal/replacement
Your healthcare professional will inform you regarding the efficacy, risks and side-effects of Nova T 380 before insertion. You will be examined before insertion, which may include a pap smear, and other tests, e.g., for infections, including sexually transmitted diseases, as necessary. A gynaecological examination should be performed to determine the position and size of the womb. You should be re-examined 4 to 12 weeks after insertion and once a year thereafter, or more frequently if clinically indicated.
It is recommended that Nova T 380 should only be inserted by doctor/healthcare professionals who are experienced in Nova T 380 insertions and/or have undergone sufficient training for Nova T 380 insertion.

When should Nova T 380 be inserted?
Nova T 380 can be inserted at any time during the menstrual cycle, if it is confirmed that you are not pregnant. To minimise the risk of an undetected pregnancy, the best time of insertion is within seven days from the onset of the menstrual bleeding. Nova T 380 can also be inserted immediately after a first trimester abortion provided that there are no genital infections. Nova T 380 should not be inserted earlier than 6 weeks after delivery.

How is Nova T 380 inserted?
An instrument called a speculum is inserted into the vagina and the cervix is cleansed with an antiseptic solution. Nova T 380 is then inserted into the womb via a thin, flexible plastic tube. You can feel this, but it should not cause much pain.

For how long can Nova T 380 be used?
Nova T 380 offers protection against pregnancy for five years, after which the device has to be removed. A new device can be inserted immediately if you want to continue using Nova T 380.

How can I tell whether Nova T 380 is in place?
You can check yourself if the strings are in place after your period. Gently put your finger into your vagina after your period and feel for the strings near the opening of your uterus (cervix).

Do not pull the strings because you may accidentally pull out Nova T 380. If you cannot feel the strings, this may indicate that an expulsion or perforation has occurred. In this case you should avoid intercourse or use a barrier contraceptive (such as condoms) and contact your doctor.

What if I want to become pregnant or have Nova T 380 removed for another reason?
The device can be easily removed at any time by your doctor, after which pregnancy is possible. Removal is usually a painless procedure. Fertility returns to normal after removal of Nova T 380.

If pregnancy is not desired, the removal should be carried out during the menstrual bleeding. Intercourse within a week before removal of Nova T 380 in the mid-cycle may lead to pregnancy. Therefore, another contraceptive should be used for a few days before and after the removal.

Insertion and removal may be associated with some pain and bleeding. The procedure may cause fainting as a reaction or a seizure in an epileptic patient.

5. POSSIBLE SIDE EFFECTS

Not all side effects reported for Nova T 380 are included in this leaflet. Should your general health worsen after Nova T 380 IUD has been inserted, please consult your doctor, pharmacist or other healthcare professional for advice.

It is perfectly normal for you to experience disturbances in menstrual bleeding during the first few months. The number of bleeding and spotting days may increase. Additionally, bleeding may be heavier. For a short period after insertion, you may experience abdominal pain.
Prolonged pain and heavy bleeding may mean that the Nova T 380 IUD has been partially expelled, in which case the device must be removed and a new one inserted in the correct position.

Pregnancy in the case of the method failure may be ectopic. Pelvic inflammatory disease may occur during the use of the Nova T 380 IUD. Cases of sepsis (very severe systematic infection, which may be fatal) have been reported following IUD insertion (see section “Take special care – perforations”).
The risk of perforation is increased in breast-feeding women and in women who had a delivery up to 36 weeks before insertion (see “Take special care – perforations”).
Some women may experience pain and dizziness after insertion. If these do not pass within half an hour in the resting position, the device may not be correctly positioned. An examination should be carried out and the Nova T 380 IUD removed if necessary. Allergic skin reactions may be due to the device.
Nova T 380 may increase menstrual blood loss and thus increase the risk of anaemia.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF NOVA T 380

Keep all medicines out of the reach and sight of children.
Keep the product in carton until required for use.
Store Nova T 380 at or below 30 °C. Protect from direct sunlight and moisture.
Nova T 380 is supplied sterile. It is sterilised by irradiation. It is for single use only. It must not be re-sterilised. Do not use it if the pouch is damaged or open.
The device should be inserted by a qualified healthcare professional before the expiry date shown on the pouch label.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF NOVA T 380:

The device with accessories is packed in a heat-sealed sterilisation pouch of polyester/ polyethylene/polyamide.

8. IDENTIFICATION OF NOVA T 380:

A white plastic body – shaped as a modified T, with silver-cored copper wire wound around the vertical arm and removal threads tied to the loop of the vertical arm.

9. REGISTRATION NUMBER:

34/34/0132

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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