

RA 0550 GB P11 (REF 5.1)

NuvaRing, 0.120 mg/0.015 mg per 24 hours,

vaginal delivery system

Etonogestrel/Ethinylestradiol

Please read all of this package leaflet carefully before you start using NuvaRing.

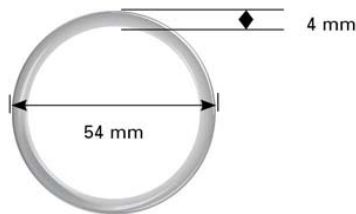
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor, or pharmacist.
- Read the leaflet also regularly if you are already using NuvaRing. This is important because the information in the leaflet may change.

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1. WHAT IS NUVARING AND WHAT IS IT USED FOR?

NuvaRing is a contraceptive vaginal ring used to prevent pregnancy. Each ring contains a small amount of two female sex hormones – etonogestrel and ethinylestradiol. The ring slowly releases these hormones into the blood circulation. Because of the low amount of hormones that is released, NuvaRing is considered a low-dose hormonal contraceptive. Since NuvaRing releases two different types of hormones it is a so-called combined hormonal contraceptive.



NuvaRing works just like a combined contraceptive pill (the Pill) but instead of taking a pill every day, the ring is used for 3 weeks in a row. NuvaRing releases two female sex hormones that prevent the release of an egg cell from the ovaries. If no egg cell is released you cannot become pregnant.

2. BEFORE YOU START TO USE NUVARING

General notes

In this leaflet, several situations are described where you should stop using NuvaRing, or where NuvaRing may be less reliable. In such situations you should not have intercourse or you should take extra non-hormonal contraceptive precautions – such as using a condom or another barrier method. Do **not** use rhythm or temperature methods. These methods can be unreliable because NuvaRing alters the monthly changes of the body temperature and of the cervical mucus.

NuvaRing, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

2.1 When you should not use NuvaRing

In some situations **you should not use** a combined hormonal contraceptive.

Tell your doctor if any of the following conditions applies to you. Your doctor may then advise you to use a different (non-hormonal) method of birth control.

- You have (or have ever had) a blood clot (venous thrombosis) in a blood vessel of your legs, lungs (embolus) or other organs. **For possible signs of a blood clot see section 2.2 ‘Blood clots (Thrombosis)’.**
- You have ever had a heart attack, or a stroke; or if you have (or have ever had) a condition that may be a first sign of a heart attack (such as angina pectoris or severe chest pain) or stroke (such as a transient ischemic attack [a TIA – a slight temporary stroke]).
- You have a serious risk factor, or several risk factors, for developing a blood clot – see also section 2.2 ‘Blood clots (Thrombosis)’.
- You have a disorder affecting your blood clotting – for instance protein C deficiency.
- You have (had) a type of migraine called ‘migraine with aura’.

- You have diabetes with damaged blood vessels.
- You have (had) inflammation of the pancreas (pancreatitis) associated with high levels of fat in your blood.
- You have (had) severe liver disease and your liver is not yet working normally.
- You have (had) a benign or malignant tumour in the liver.
- You have (had), or if you may have, cancer of the breast or the genital organs.
- You have any unexplained vaginal bleeding.
- You are allergic to ethinylestradiol or etonogestrel, or any of the other ingredients of NuvaRing.

If any of these conditions appear for the first time while using NuvaRing, remove the ring immediately and contact your doctor. In the meantime, use non-hormonal contraceptive measures.

2.2 When to take special care with NuvaRing

In some situations **you need to take special care** while using a combined hormonal contraceptive.

Tell your doctor if any of the following conditions apply to you. Also if the condition develops or gets worse while you are using NuvaRing you must tell your doctor.

- A close relative has or has ever had breast cancer.
- You have epilepsy (see section 2.2 ‘Using Other Medicines’).
- You have liver disease (for instance jaundice) or gallbladder disease (for instance gallstones).
- You have Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease).
- You have SLE (systemic lupus erythematosus; a disease affecting your natural defense system).
- You have HUS (haemolytic uremic syndrome; a disorder of blood clotting causing failure of the kidneys).
- You have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, porphyria [a disease of the blood], herpes gestationis [skin rash with vesicles during pregnancy], Sydenham’s chorea [a disease of the nerves in which sudden movements of the body occur], hereditary angioedema [*you should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing*]).
- You have (or have ever had) chloasma (yellowish-brown pigment patches, so called ‘pregnancy patches’, particularly on the face). If so, avoid too much exposure to the sun or ultraviolet light.
- You have a medical condition that makes it difficult to use NuvaRing – for example, if you are constipated, have a prolapse of the uterine cervix or have pain during intercourse.
- You have an operation, or if you are off your feet for a long time (see section 2.2 ‘Blood clots (Thrombosis)’).

Blood clots (Thrombosis)

Blood clots in a vein

A blood clot in a vein (known as a ‘venous thrombosis’) can block the vein. This can happen in veins in the leg, the lung (a lung embolus), or other organs.

Using any combined hormonal contraceptive, including NuvaRing, increases a woman’s risk of developing such clots compared with a woman not taking any combined hormonal contraceptive.

The risk is not as high as the risk of developing a blood clot during pregnancy. It is not yet known how NuvaRing influences the risk of getting a blood clot compared with contraceptive pills.

If you use a combined hormonal contraceptive your risk of a blood clot in a vein increases further:

- the older you are;
- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age;
- if you are overweight;
- if you must have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a plaster cast.

If this applies to you, it is important to tell your doctor that you are using NuvaRing, as the treatment may have to be stopped. Your doctor may tell you to stop using your hormonal contraception several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using NuvaRing again after you are back on your feet.

Blood clots in an artery

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart causes a heart attack, or in the brain causes a stroke.

The use of a combined hormonal contraceptive has been connected with an increased risk of clots in the arteries. This risk increases further:

- the older you are;
- **if you smoke. When using a hormonal contraceptive like NuvaRing you are strongly advised to stop smoking, especially if you are older than about 35 years;**
- if you are overweight;
- if you have high blood pressure. If you develop high blood pressure while using NuvaRing, you may be told to stop using it.
- if a close relative has had a heart attack or stroke at a young age;
- if you have a high level of fat in your blood (cholesterol or triglycerides);
- if you have diabetes;
- if you get migraines;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm).

For symptoms of a blood clot in a vein or artery see the blue box at the next page.

Symptoms of blood clots

Remove NuvaRing and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- unusual pain and/or swelling in one of your legs.
- severe pain in the chest which may reach the left arm;
- sudden breathlessness;
- sudden cough without an obvious cause;
- any unusual, severe or long-lasting headache or worsening of migraine;
- partial or complete blindness or double vision;
- difficulty in speaking or inability to speak;
- giddiness or fainting;
- weakness, strange feeling, or numbness in any part of your body.

Following a blood clot, recovery is not always complete. Very occasionally serious permanent disabilities may occur or the blood clot may even be fatal.

Cancer

The information given below was obtained in studies with combined oral contraceptives and it may also apply to NuvaRing. Information about vaginal administration of contraceptive hormones (as in NuvaRing) is not available.

Breast cancer has been found slightly more often in women using combined pills, but it is not known whether this is caused by the treatment. For example, it may be that tumours are found more in women on combined pills because they are examined by the doctor more often. The increased occurrence of breast cancer becomes gradually less after stopping the combined pill.

It is important to regularly check your breasts and you should contact your doctor if you feel any lump. You should also tell your doctor if a close relative has, or ever had breast cancer (see section 2.2 '*When to take special care with NuvaRing*').

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusual severe abdominal pain.

For users of the combined Pill it has been reported that cancer of the endometrium (the lining of the womb) and cancer of the ovaries occur less frequently. This may also be the case for NuvaRing but this has not been confirmed.

Using other medicines

Always tell the doctor who prescribes NuvaRing which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use NuvaRing. They can tell you if you need to take additional contraceptive precautions and, if so, for how long.

Some medicines may cause particular problems when you are using hormonal contraceptives, such as NuvaRing.

- There are medicines that can make NuvaRing less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used to treat:
 - ~ epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine, topiramate, felbamate);
 - ~ tuberculosis (e.g. rifampicin);
 - ~ HIV infections (e.g. ritonavir);
 - ~ other infectious diseases (antibiotics with the exception of amoxicillin and doxycycline, which have been shown not to influence the hormone release from NuvaRing).
- The herbal product St. John's wort may also stop NuvaRing from working properly. If you want to use herbal products containing St. John's wort while you are already using NuvaRing you should consult your doctor first.
- NuvaRing may also interfere with the working of other medicines – such as ciclosporin and the anti-epileptic lamotrigine.

You can use tampons while using NuvaRing. Insert NuvaRing before inserting a tampon. You should be careful when removing a tampon to be sure that the ring is not accidentally pulled out. If the ring does come out, simply rinse the ring in cool to lukewarm water and immediately reinsert it.

Using spermicides or vaginal yeast products will not reduce the contraceptive efficacy of NuvaRing.

Laboratory tests

If you are having any blood or urinary test, tell your health care professional that you are using NuvaRing as it may affect the results of some tests

Pregnancy

NuvaRing must not be used by women who are pregnant, or who think they may be pregnant. If you get pregnant while using NuvaRing you should remove the ring and contact your doctor.

If you want to stop NuvaRing because you want to get pregnant, see section 3.5 '*When you want to stop using NuvaRing*'.

Breast-feeding

NuvaRing is not usually recommended for use during breast-feeding. If you wish to use NuvaRing while breast-feeding, please seek the advice of your doctor.

Driving and using machines

NuvaRing is unlikely to affect your ability to drive or use machines.

3. HOW DO YOU USE NUVARING?

You can insert and remove NuvaRing yourself. Your doctor will tell you when to start using NuvaRing for the first time. The vaginal ring must be put in on the correct day in your monthly cycle (see section 3.3 '*When to start with the first ring*') and left in place for 3 weeks in a row. It is a good habit to regularly check whether the ring is still in your vagina. After the third week, you take NuvaRing out and have a one week break. You will usually have your monthly period during this ring-free interval.

3.1 How to insert and remove NuvaRing

1. Before inserting the ring, check it is not out of date (see section 5 '*How to store NuvaRing*').
2. Wash your hands before inserting or removing the ring.
3. Choose the position for inserting that is most comfortable to you, like standing with one leg up, squatting, or lying down.
4. Remove NuvaRing from its sachet.
5. Hold the ring between your thumb and index finger, press the opposite sides together and insert the ring into the vagina (see Figures 1– 4). When NuvaRing is in place you should not feel anything. If you feel uncomfortable, gently push NuvaRing a bit further into the vagina. The exact position of the ring inside the vagina is not important.
6. After 3 weeks you remove NuvaRing from the vagina. You can do this by hooking your index finger under the front rim of the ring or by grasping the rim and pulling it out (see Figure 5). If you locate the ring in your vagina, but are unable to remove it, you should contact your doctor.
7. Dispose of the used ring with the normal household waste, preferably inside the reclosable sachet. Do not flush NuvaRing down the toilet.



Figure 1
Take NuvaRing out of the sachet



Figure 2
Compress the ring

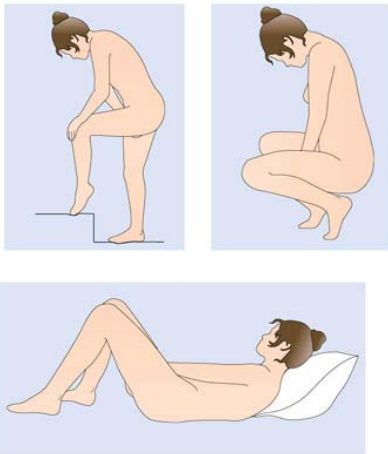


Figure 3
Choose a comfortable position to insert the ring

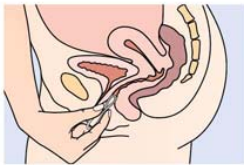


Figure 4A



Figure 4B



Figure 4C

Insert the ring into the vagina with one hand (Figure 4A), if necessary the labia may be spread with the other. Push the ring into the vagina until the ring feels comfortable (Figure 4B). Leave the ring in place for 3 weeks (Figure 4C).



Figure 5

NuvaRing can be removed by hooking the index finger under the ring or by grasping the ring between the index and middle finger and pulling it out.

3.2 Three weeks in, one week out

1. Starting with the day you put it in, the vaginal ring must be left in place **without interruption** for 3 weeks.
2. After 3 weeks you remove the ring on the same day of the week and at approximately the same time as it was put in. For example, if you put NuvaRing in on a Wednesday at about 22.00 h, you should remove the ring 3 weeks later, on Wednesday, at about 22.00 h.
3. After you have removed the ring, you do not use a ring for 1 week. During this week a vaginal bleed should occur. Usually this starts 2–3 days after removal of NuvaRing.
4. Start a new ring exactly after the 1 week interval (again on the same day of the week and approximately the same time), even if you have not stopped bleeding.
If the new ring is inserted more than 3 hours too late, the protection from pregnancy may be reduced. Follow the instructions in section 3.4 *'What to do if... You have forgotten to insert a new ring after the ring-free interval'*.

If you use NuvaRing as described above, your vaginal bleed will take place every month on roughly the same days.

3.3 When to start with the first ring

- *You have not used a hormonal contraceptive during the last month*

Insert the first NuvaRing on the first day of your natural cycle (i.e. the first day of your menstrual period). NuvaRing starts working straight away. You don't need to take any other contraceptive precautions.

You can also start NuvaRing between day 2 and day 5 of your cycle, but if you have sexual intercourse during the first 7 days of NuvaRing use make sure that you also use an additional contraceptive method (such as a condom). You only have to follow this advice when you use NuvaRing for the first time.

- *You have used a combined Pill during the last month*

Start using NuvaRing at the latest the day following the tablet-free period of your present Pill. If your Pill pack also contains inactive tablets, start NuvaRing at the latest on the day after the last inactive tablet. If you are not sure which tablet this is, ask your doctor or pharmacist. Never extend the hormone-free interval of your current Pill pack beyond its recommended length. If you have used the Pill consistently and correctly and if you are sure that you are not pregnant, you can also stop taking the Pill on any day of your current Pill pack and start using NuvaRing immediately.

- *You have used a transdermal patch during the last month*

Start using NuvaRing at the latest the day following your usual patch-free break. Never extend the patch-free break beyond its recommended length. If you have used the patch consistently and correctly and if you are sure that you are not pregnant, you can also stop using the patch on any day and start using NuvaRing immediately.

- *You have used a minipill (progestagen-only pill) during the last month.*

You can stop taking the minipill any day and start NuvaRing the next day, at the same time you would normally have taken your pill. But make sure you also use an additional contraceptive method (such as a condom) for the first 7 days of ring use.

- *You have used an injectable or implant or a progestagen-releasing IUD during the last month.*

Start using NuvaRing when your next injection is due or on the day that your implant or your progestagen-releasing IUD is removed. But make sure you also use an additional contraceptive method (such as a condom) for the first 7 days of ring use.

- *After having a baby.*

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start using NuvaRing. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to use NuvaRing, you should discuss this first with your doctor.

- *After a miscarriage or an abortion.*

Your doctor will advise you.

3.4 What to do if....

Your ring is accidentally expelled from the vagina

NuvaRing may accidentally be expelled from the vagina – for example, if it has not been inserted properly, while removing a tampon, during sexual intercourse, during constipation, or if you have a prolapse of the womb. Therefore, you should regularly check whether the ring is still in your vagina.

If the ring is out for less than 3 hours it will still protect you from pregnancy. You can rinse the ring with cold to lukewarm water (do not use hot water) and put it back in. If the ring is out for more than 3 hours, it may not protect you from pregnancy, see the advice in section 3.4 ‘*What to do if... Your ring has temporarily been out of the vagina*’.

Your ring has temporarily been out of the vagina

When it is in the vagina, NuvaRing slowly releases hormones into the body to prevent pregnancy. If the ring has been out of the vagina for more than 3 hours, it may not protect you from pregnancy. So, the ring must not be outside the vagina for longer than 3 hours in every twenty-four hour period.

- If the ring has been out of the vagina for **less than 3 hours**, it will still protect you from pregnancy. You should put the ring back in as soon as possible but at the latest within 3 hours.
- If the ring has been out of the vagina, or you suspect that the ring has been out of the vagina, for **more than 3 hours during the 1st and 2nd week**, it may not protect you from pregnancy. Put the ring back in the vagina as soon as you remember, and leave the ring in place without interruption for at least 7 days. Use a condom if you have sexual intercourse during these 7 days. If you are in your 1st week, and you had sexual intercourse during the past 7 days, there is a possibility you may be pregnant. In that case contact your doctor.

- If the ring has been out of the vagina, or you suspect that the ring has been out of the vagina, for **more than 3 hours in the 3rd week** it may not protect you from pregnancy. You should discard that ring and choose between one of the following two options:

1 - Insert a new ring immediately

This will start the next three-week use period. You may not have your period, but breakthrough bleeding and spotting may occur.

2 - Do not insert the ring again. Have your period first and insert a new ring no later than 7 days from the time the previous ring was removed or fell out.

You should only chose this option if you have used NuvaRing continuously during the previous 7 days.

Your ring breaks

Very rarely NuvaRing may break. If you notice that your NuvaRing has broken, discard it and start with a new ring as soon as possible. Use extra contraceptive precautions (e.g. a condom) during the next 7 days. If you had sexual intercourse before you noticed the ring breakage, please contact your doctor.

You have inserted more than one ring

There have been no reports of serious harmful effects due to an overdose of the hormones in NuvaRing. If you have accidentally inserted more than one ring, you may feel sick (nausea) or have vomiting or vaginal bleeding.

Remove excess rings and contact your doctor if these symptoms persist.

You have forgotten to insert a new ring after the ring-free interval

If your **ring-free interval** was **longer than 7 days**, put a new ring as soon as you remember. Use extra contraceptive precautions (such as a condom) if you have sexual intercourse during the next 7 days. **If you had sexual intercourse in the ring-free interval, there is a possibility you may be pregnant.** In that case contact your doctor immediately. The longer the ring-free interval, the higher the risk that you have become pregnant.

You have forgotten to remove the ring

- If your ring has been left in place for between 3 and **4 weeks**, it will still protect you from pregnancy. Have your regular ring-free interval of one week and subsequently insert a new ring.
- If your ring has been left in place for **more than 4 weeks** there is a possibility of becoming pregnant. Contact your doctor before you start with a new ring.

You have missed a menstrual period

- **You have followed the instructions for NuvaRing**

If you have missed a menstrual period but you followed the instructions for NuvaRing, and have not used other medicines, it is very unlikely that you are pregnant. Continue to use NuvaRing as usual. If you miss your menstrual period twice in a row, however, you may be pregnant. Tell your doctor immediately. Do not start the next NuvaRing until your doctor has checked you are not pregnant.

- **If you have not followed the instructions for NuvaRing**

If you have missed a menstrual period and you did not follow the instructions, and you do not have your expected period in the first normal ring-free interval, you may be pregnant. Contact your doctor before you start with a new NuvaRing.

You have unexpected bleeding

While using NuvaRing, some women have unexpected vaginal bleeding between menstrual periods. You may need to use sanitary protection. In any case, leave the ring in the vagina and continue to use the ring as normal. If the irregular bleeding continues, becomes heavy or starts again, tell your doctor.

You want to change the first day of your menstrual period.

If you follow the instructions for NuvaRing, your menstrual period (withdrawal bleed) will begin in the ring-free interval. If you want to change the day it starts, you can make the ring-free interval shorter (but never longer!).

For example, if your period usually begins on a Friday, you can change this to a Tuesday (3 days earlier) from next month onwards. Simply insert your next ring 3 days earlier than usual.

If you make your ring-free interval very short (for example, 3 days or less), you may not have your usual bleeding. You may have spotting (drops or flecks of blood) or breakthrough bleeding while using the next ring.

If you are not sure how to proceed, contact your doctor for advice.

You want to delay your menstrual period

Although it is not the recommended regimen, delay of your menstrual period (withdrawal bleed) is possible by inserting a new ring immediately after removing the current ring, with no ring-free interval between rings. You can leave the new ring inserted for up to a maximum of 3 weeks. You may experience spotting (drops or flecks of blood) or breakthrough bleeding while using this new ring. When you want your period to begin, just remove the ring. Have your regular ring free interval of one week and subsequently insert a new ring.

You can ask your doctor for advice before deciding to delay your menstrual period.

3.5 When you want to stop using NuvaRing

You can stop using NuvaRing any time you want.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

If you stop using NuvaRing because you want to get pregnant, you should wait until you have had a natural period before trying to conceive. This helps you calculate when the baby will be due.

4. POSSIBLE SIDE EFFECTS

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

Serious reactions seen with NuvaRing, as well as the related symptoms, are described in section 2.2 under ‘Blood clots (Thrombosis)’ (main symptoms of a blood clot include: unusual

pain or swelling in a leg, chest pain or problems breathing. If you think you have signs of a blood clot, remove NuvaRing, and contact your doctor immediately) and ‘Cancer’.

If you are allergic to one of the ingredients of NuvaRing (hypersensitivity) you may experience the following symptoms: angioedema [swollen face, tongue and/or throat and/or difficulty swallowing] or hives together with difficulty breathing. If this happens, remove NuvaRing and contact your doctor immediately.

Users of NuvaRing have reported the following side effects.

Common side effects (*affecting more than 1 in 100, but less than 1 in 10 women*)

- abdominal pain, feeling sick (nausea)
- yeast infection of the vagina (such as ‘thrush’); discomfort in the vagina due to the ring; genital itching; secretion from the vagina
- headache or migraine; depressive moods; lower sex drive
- breast pain; painful menstrual periods
- acne
- weight gain
- the ring falling out

Uncommon side effects (*affecting more than 1 in 1000, but less than 1 in 100 women*)

- disturbed vision; dizziness
- swollen abdomen; vomiting, diarrhoea or constipation
- feeling tired, unwell or irritable; mood changes; mood swings
- extra fluid in the body (oedema)
- bladder or urinary tract infection
- difficulty or pain when passing urine; strong desire or need to pass urine; passing urine more often
- problems during intercourse, including pain, bleeding or partner feeling the ring
- increased blood pressure
- increased appetite
- back pain; muscle spasms; pain in legs or arms
- less sensitive skin
- sore or larger breasts; fibrocystic breast disease (cysts in the breasts which may become swollen or painful)
- inflammation of the cervix; cervical polyps (growths in the cervix); rolling outward of the margin of the cervix (ectropion)
- changes to menstrual periods (e.g. periods can be heavy, long, irregular or stop altogether); pelvic discomfort; premenstrual syndrome; spasm of the uterus
- vaginal infection (fungal and bacterial); burning feeling, smell, pain, discomfort or dryness in the vagina or vulva
- hair loss, eczema, itching, rash or hot flushes.
- ring breakage

The following rare side effects have been reported during market use of NuvaRing: hives, penis discomfort of the partner (such as irritation, rash, itching).

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 NUVARING

Keep NuvaRing out of the reach and sight of children!

If you discover that a child has been exposed to the hormones from NuvaRing, ask your doctor for advice.

Store your NuvaRing in the original package below 30°C in order to protect from light and moisture.

You should not use a NuvaRing if it was dispensed to you more than 4 months ago, or if the expiry date has passed. The dispensing date and expiry date are both shown on the carton and sachet.

Do not use the ring if you notice a colour change in the ring or any visible signs of deterioration.

6. FURTHER INFORMATION

What NuvaRing contains

- The active substances are: etonogestrel (11.7 mg) and ethinylestradiol (2.7 mg)
- The other substances are: ethylene vinylacetate copolymer (a type of plastic that will not dissolve in the body) and magnesium stearate.

Etonogestrel and ethinylestradiol are released from the ring at a rate of 0.120 mg/day and 0.015 mg/day, each for 3 weeks.

What NuvaRing looks like and the content of the package

NuvaRing is a flexible, transparent, colourless to almost colourless ring, 54mm wide.

Each ring is packed in a reclosable foil sachet. The sachet is packed in a cardboard box together with this package leaflet. Each box contains 1 or 3 rings.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

UK MAH: Organon Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge, CB4 0FL, United Kingdom.

Malta MAH: NV Organon, PO Box 20, 5340 BH Oss, The Netherlands.

Manufacturers:

NV Organon, PO Box 20, 5340 BH Oss, The Netherlands.

Organon Ireland Ltd., Drynam Road Swords, Co. Dublin, Ireland.

This medicinal product is authorized in the Member States of the EEA under the following name:

NuvaRing
0.120 mg/0.015 mg per 24 hours, vaginal delivery system

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The

Netherlands, Norway, Romania, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom.

Last revision of this package leaflet

This leaflet was last revised in June 2012