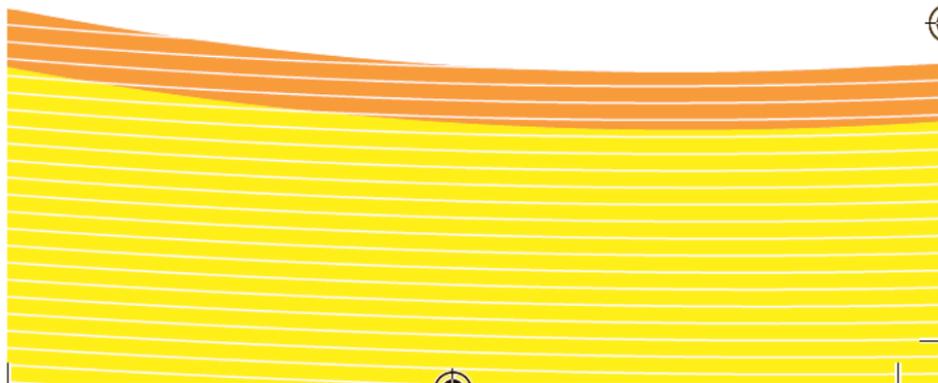


Nuvelle™ *Continuous*



Estradiol and norethisterone acetate

PACKAGE BOOKLET: INFORMATION FOR THE USER



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Package booklet: Information for the user

Nuvelle™ Continuous

Estradiol and norethisterone acetate

1

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Page 1

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5

Read all of this booklet carefully before you start taking this medicine because it contains important information for you.

- ▶ Keep this booklet. 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 signs of illness are the same as yours.
- ▶ If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this booklet. See section 4.

| What is in this booklet | |
|---|-----------|
| 1. WHAT NUVELLE CONTINUOUS IS AND WHAT IT IS USED FOR | 6 |
| 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NUVELLE CONTINUOUS | 9 |
| Medical history and regular check-ups | 9 |
| Do not take Nuvelle Continuous | 11 |
| Warnings and precautions | 14 |
| HRT and cancer | 19 |
| Effect of HRT on heart or circulation | 25 |
| Blood clots in a vein (thrombosis) | 25 |

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Page 3

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code-no.: **33**

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colors: **Black / PANTONE 151 C /**

version: **03.08.2017/02**

Restricted Document

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| | |
|--|-----------|
| Heart disease (heart attack) | 28 |
| Stroke | 28 |
| Other conditions | 29 |
| Other medicines and Nuvelle Continuous | 30 |
| Laboratory tests | 33 |
| Pregnancy and breast-feeding | 33 |
| Driving and using machines | 33 |
| Nuvelle Continuous contains lactose monohydrate | 34 |
| 3. HOW TO TAKE NUVELLE CONTINUOUS | 35 |
| About the pack | 36 |

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Page 4

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| | |
|--|-----------|
| When to start | 38 |
| If you take more Nuvelle Continuous than you should | 39 |
| If you forget to take Nuvelle Continuous | 39 |
| If you stop taking Nuvelle Continuous | 40 |
| If you need to have surgery | 40 |
| 4. POSSIBLE SIDE EFFECTS | 42 |
| 5. HOW TO STORE NUVELLE CONTINUOUS | 49 |
| 6. CONTENTS OF THE PACK AND OTHER INFORMATION | 50 |

1. WHAT NUVELLE CONTINUOUS IS AND WHAT IT IS USED FOR

What Nuvelle Continuous is

Nuvelle Continuous is a Hormone Replacement Therapy (HRT). It contains two types of female hormone, an oestrogen and a progestogen. Your ovaries no longer make these hormones after the menopause. Nuvelle Continuous is used in postmenopausal women with at least 12 months (1 year) since their last natural period.

6

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Page 6

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What Nuvelle Continuous is used for

Relief of symptoms occurring after menopause

During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). Nuvelle Continuous alleviates these symptoms after menopause. You will only be prescribed Nuvelle Continuous if your symptoms seriously hinder your daily life.



Prevention of osteoporosis

After the menopause, some women may develop fragile bones (osteoporosis). You should discuss all available options with your doctor.

If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use Nuvelle Continuous to prevent osteoporosis after menopause.



2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NUVELLE CONTINUOUS

Medical history and regular check-ups

The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.



Before you start (or restart) HRT, your doctor will ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Once you have started on Nuvelle Continuous, you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with Nuvelle Continuous.

- ▶ Go for regular breast screening, as recommended by your doctor.



Do not take Nuvelle Continuous

If any of the following applies to you. If you are not sure about any of the points below, **talk to your doctor** before taking Nuvelle Continuous,

Do not take Nuvelle Continuous

- ▶ If you have or have ever had **breast cancer**, or if you are suspected of having it
- ▶ If you have **cancer which is sensitive to oestrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- ▶ If you have any **unexplained vaginal bleeding**



- ▶ If you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated
- ▶ If you have or have ever had a **blood clot in a vein** (thrombosis) such as in the legs (deep vein thrombosis) or the lungs (pulmonary embolism)
- ▶ If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency)
- ▶ If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**

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Page 12

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- ▶ If you have or have ever had a **liver disease** and your liver function tests have not returned to normal
- ▶ If you have a rare blood problem called “porphyria” which is passed down in families (inherited)
- ▶ If you are **allergic** to estradiol and norethisterone acetate or any of the other ingredients of this medicine (listed in section 6)
- ▶ If you have been told to **avoid lactose**, that you have a rare hereditary condition called **Lapp lactase deficiency** or **glucose-galactose malabsorption**

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- 
- ▶ If any of the above conditions appear for the first time while taking Nuvelle Continuous, stop taking it at once and consult your doctor immediately.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nuvelle Continuous



Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with Nuvelle continuous. If so, you should see your doctor more often for check-ups:



- ▶ fibroids inside your womb

14



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- ▶ growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- ▶ increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)")
- ▶ increased risk of getting an oestrogen-sensitive cancer (such as a mother, sister or grandmother who has had breast cancer)
- ▶ high blood pressure
- ▶ a liver disorder, such as a benign liver tumour
- ▶ diabetes
- ▶ gallstones
- ▶ migraine or severe headaches

15

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Page 15

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- ▶ a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- ▶ epilepsy
- ▶ asthma
- ▶ a disease affecting the eardrum and hearing (otosclerosis)
- ▶ a very high level of fat in your blood (triglycerides)
- ▶ fluid retention due to cardiac or kidney problems
- ▶ hereditary angioedema (episodes of swelling of body parts)

16

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Page 16

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Stop taking Nuvelle Continuous and see a doctor immediately

If you notice any of the following when taking HRT:

- ▶ any of the conditions mentioned in the 'DO NOT take Nuvelle Continuous' section
- ▶ yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- ▶ a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- ▶ migraine-like headaches which happen for the first time
- ▶ if you become pregnant
- ▶ if you notice signs of a blood clot, such as:

17

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Page 17

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- ▷ painful swelling and redness of the legs
- ▷ sudden chest pain
- ▷ difficulty in breathing

for more information, see 'Blood clots in a vein (thrombosis)'

Note: Nuvelle Continuous is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

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Page 18

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HRT and cancer

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)

Taking oestrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer).

The progestogen in Nuvelle Continuous protects you from this extra risk.

In women who still have a womb and who are not taking HRT, on average, 5 in 1000 will be diagnosed with endometrial cancer between the ages of 50 and 65.

19

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Seite 19

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For women aged 50 to 65 who still have a womb and who take oestrogen-only HRT, between 10 and 60 women in 1000 will be diagnosed with endometrial cancer (i.e. between 5 and 55 extra cases), depending on the dose and for how long it is taken.

Irregular bleeding

You may have irregular bleeding or drops of blood (spotting) during the first 3–6 months of taking Nuvelle Continuous. However, if the irregular bleeding:

- ▶ Carries on for more than the first 6 months
- ▶ Starts after you have been taking Nuvelle Continuous for more than 6 months

20

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Page 20

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- 
- Carries on after you have stopped taking Nuvelle Continuous
see your doctor as soon as possible.

Breast cancer



Evidence suggests that taking combined oestrogen-progestogen and possibly also oestrogen-only HRT increases the risk of breast cancer. The extra risk depends on how long you take HRT. The additional risk becomes clear within a few years. However, it returns to normal within a few years (at most 5) after stopping treatment.



21



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Compare

Women aged 50 to 79 who are not taking HRT, on average, 9 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period. For women aged 50 to 79 who are taking oestrogen-progestogen HRT over 5 years, there will be 13 to 23 cases in 1000 users (i.e. an extra 4 to 6 cases).

Regularly check your breasts. See your doctor if you notice any changes in your breast, such as:

- ▶ dimpling of the skin
- ▶ changes in the nipple
- ▶ any lumps you can see or feel



Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

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Ovarian cancer

Ovarian cancer is rare - much rarer than breast cancer. The use of oestrogen-only or combined oestrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).



Effect of HRT on heart or circulation

Blood clots in a vein (thrombosis)

The risk of **blood clots in the veins** is about 1.3 to 3-times higher in HRT users than non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations apply to you:

25

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Page 25

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- ▶ you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, “If you need to have surgery”)
- ▶ you are seriously overweight (BMI >30 kg/m²)
- ▶ you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- ▶ if any of your close relatives has ever had a blood clot in the leg, lung or another organ
- ▶ you have systemic lupus erythematosus (SLE)
- ▶ you have cancer

For signs of a blood clot, see “Stop taking Nuvelle Continuous and see a doctor immediately”.

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Seite 26

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Compare

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein. For women in their 50s who are taking oestrogen-progestogen HRT for over 5 years, there will be 9 – 12 cases in 1000 (i.e. an extra 5 cases).





Heart disease (heart attack)

There is no evidence that HRT will prevent a heart attack.

Women over the age of 60 years who use oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.



Stroke

The risk of getting a stroke is about 1.5-times higher in HRT users than in non-users. The number of extra cases of stroke due to HRT use will increase with age.



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Page 28

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Compare

Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).



Other conditions

- ▶ HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.



- 
- If you have a tendency to develop **blotchy brown patches** (chloasma) on the face you should avoid exposure to the sun or ultraviolet light whilst using Nuvelle Continuous

Other medicines and Nuvelle Continuous

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may interfere with the effect of Nuvelle Continuous. This might lead to irregular bleeding. This applies to the following medicines



medicines for **epilepsy** (such as barbiturates, phenytoin, primidone carbamazepine and possibly oxcarbazepine, topiramate and felbamate)

- ▶ medicines for **tuberculosis** (such as rifampicin, rifabutin)
- ▶ medicines for **HIV and Hepatitis C Virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as nevirapine, efavirenz, ritonavir and nelfinavir)
- ▶ Herbal remedies containing **St. John's wort** (*Hypericum perforatum*)



- ▶ Medicines for **treatment of fungal infections** (such as griseofulvin, fluconazole, itraconazole, ketoconazole and voriconazole)
- ▶ Medicines for **treatment of bacterial infections** (such as clarithromycin and erythromycin)
- ▶ Medicines for **treatment of certain heart diseases, high blood pressure** (such as verapamil and diltiazem)
- ▶ Grapefruit juice

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Page 32

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Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking Nuvelle Continuous, because this medicine can affect the results of some tests.

Pregnancy and breast-feeding

Nuvelle Continuous is for use in post menopausal women only. If you become pregnant, stop taking Nuvelle Continuous and contact your doctor.

Driving and using machines

No effects on ability to drive and use machines have been observed in users of Nuvelle Continuous.



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Page 33

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There is nothing to suggest that the use of Nuvelle Continuous affects driving or use of machines.

Nuvelle Continuous contains lactose monohydrate

Nuvelle Continuous contains lactose (a type of sugar). If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicinal product.



3. HOW TO TAKE NUVELLE CONTINUOUS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not take Nuvelle Continuous until at least 12 months after your last natural period.

Your doctor will aim to prescribe the lowest dose to treat your symptom for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

Nuvelle Continuous is **not** for use in children or adolescents.

35

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Seite 35

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About the pack

This pack is designed to help you remember to take your medicine. Each tablet is placed in a section marked with the day of the week on which it should be taken. The arrows between tablets show the order in which they must be taken. Your doctor may tell you when to start (see “when to start” for further information).

On the day you start, take your first pink tablet from the top row of tablets marked with the correct day. For instance, if you start on a Tuesday, press out the tablet from the blister marked 'TUE'.

36

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Take one tablet each day, following the directions of the arrows, until you have finished all 28 tablets in the memo strip. It is best to take your tablet at the same time each day. You can take Nuvelle Continuous with or without food. The tablet should be swallowed whole with a glass of water or milk.



When you have finished each memo strip, start the next memo strip on the following day. Do not leave a break between memo strips. Tablet taking should be continuous and each memo strip will therefore be started on the same day of the week.



When to start

If you are not currently using an HRT preparation:
start taking Nuvelle Continuous on any day.

If you have been taking other HRT preparations:
carry on until you have finished your current pack
and have taken all the tablets for that month. Take
your first Nuvelle Continuous tablet the next day. Do
not leave a break between your old tablets and the
Nuvelle Continuous tablets.

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Page 38

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If you take more Nuvelle Continuous than you should

Overdose may cause nausea and vomiting and irregular bleeding. No specific treatment is necessary but you should consult your doctor or pharmacist if you are concerned.

If you forget to take Nuvelle Continuous

If you forget to take a tablet at your usual time and you are less than 12 hours late, take it as soon as possible. Take the next tablet at the usual time.

If you are more than 12 hours late, leave the forgotten tablet in the pack. Continue to take the rest of the tablets at the usual time every day. You may experience irregular bleeding.

39



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Page 39

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If you stop taking Nuvelle Continuous

You may begin to feel the usual symptoms of menopause again, which may include hot flushes, trouble sleeping, nervousness, dizziness or vaginal dryness. Consult your doctor or pharmacist if you want to stop taking Nuvelle Continuous tablets.



If you need to have surgery

If you are going to have surgery, tell the surgeon that you are taking Nuvelle Continuous. You may need to stop taking Nuvelle Continuous about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, “Blood clots in a vein (thrombosis)”).



40



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Seite 40

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Ask your doctor when you can start taking Nuvelle Continuous again.

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

41

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Seite 41

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PZ: **2675A-4A**

code-no.: **33**

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4. POSSIBLE SIDE EFFECTS

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

The following diseases are reported more often in women using HRT compared to women not using HRT:

Serious side effects

- ▶ breast cancer
- ▶ abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer)
- ▶ ovarian cancer
- ▶ blood clots in the veins of the legs or lungs (venous thromboembolism)

42

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Side 42

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- ▶ heart disease
- ▶ stroke
- ▶ probable memory loss if HRT is started over the age of 65

For more information about these side effects see section 2.

Other side effects that have been linked to the use of Nuvelle Continuous and other oral hormone replacement therapies:

- ▶ During the first few months of treatment you may experience some vaginal bleeding at unexpected times (breakthrough bleeding and spotting). These symptoms normally lessen with continued

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Page 43

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material-no.: **86000334**

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treatment. If they don't, contact your doctor (see section 2 'HRT and cancer/ Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)' for more information).

- ▶ breast pain, tenderness or enlargement, breast discharge
- ▶ painful periods, changes in vaginal secretions, pre-menstrual symptoms, increased size of fibroids in the womb, thrush, changes to the neck of the womb

- ▶ indigestion, a feeling of being bloated, passing wind, feeling or being sick, abdominal pain, gall bladder disease
- ▶ skin rashes or discolouration, itching, eczema, acne, unusual hair loss or hair growth, increased skin pigment especially on the face (chloasma – see section 2 'other conditions' for more information), some rare skin problems
- ▶ headache, migraine, dizziness, anxiety or depressive symptoms, fatigue
- ▶ fast or irregular heartbeat (palpitations), high blood pressure, inflammation of veins usually in the legs

45

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Page 45

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material-no.: **86000334**

PZ: **2675A-4A**

code-no.: **33**

name: **LF-BRO-Nuvelle Continuous FTB GB**

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- ▶ fluid retention leading to swelling of parts of the body
- ▶ changes in body weight and sex drive, increased appetite
- ▶ muscle cramps, leg pains
- ▶ nose bleeds, visual disturbances (such as blurred vision), discomfort with contact lenses, allergic-type reactions, a worsening of glucose tolerance, bladder inflammation, rare disorders (porphyria, chorea).
- ▶ worsening of hereditary angioedema, with rapid swelling of the skin and/or mucous membranes such as swollen hands, face (eyes, lips, nose),

46

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Seite 46

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tongue and/or pharynx. Swollen tongue/pharynx may lead to difficulty swallowing. Possible hives together with difficulty breathing.

The following side effects have been reported with other HRTs:

- ▶ various skin disorders:
 - ▷ painful reddish skin nodules (erythema nodosum)
 - ▷ rash with target-shaped reddening or sores (erythema multiforme)

▷ Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this booklet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

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5. HOW TO STORE NUVELLE CONTINUOUS

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.



6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nuvelle Continuous contains

The **active substances** are estradiol (as hemihydrate) and norethisterone acetate.

The **other ingredients** are lactose monohydrate, maize starch, pre-gelatinized maize starch, povidone 25 000, talc, magnesium stearate (E572), methylhydroxypropyl cellulose, macrogol 6000, titanium dioxide (E171) and red ferric oxide pigments (E172).

50

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Seite 50

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PZ: 2675A-4A

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What Nuvelle Continuous looks like and contents of the pack

Nuvelle Continuous tablets are pink film-coated tablets.

They are supplied in a blister pack (memo strip) containing 28 tablets with the days of the week printed on the blister.

Boxes containing three blister packs are available

51

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Page 51

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client: **JS86**

material-no.: **86000334**

PZ: **2675A-4A**

code-no.: **33**

name: **LF-BRO-Nuvelle Continuous FTB GB**

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1.3.2

55

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder

Bayer PLC
400 South Oak Way,
Reading
RG2 6AD

Manufacturer

Bayer AG, Berlin, Germany or Bayer Weimar GmbH und
Co. KG, 99427 Weimar, Germany.

This booklet was last revised in August 2017.

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52

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Page 52

Bayer AG

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material-no.: **86000334**

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