

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Ovysmen<sup>®</sup> oral contraceptive tablets

Norethisterone/ethinylestradiol

Ovysmen is a registered trademark

### Five important things to know about the Pill.

- The Pill is a reliable contraceptive and may reduce your risk of cancer of the ovary and womb if used for a long time.
- The Pill will not protect you against sexually transmitted diseases.
- This medicine can increase your risk of problems such as blood clots and breast cancer.
- Some women should not take the Pill because of current medical problems or illnesses. Please read the leaflet to make sure Ovysmen is right for you.
- To prevent pregnancy it is important to take Ovysmen as instructed and start each strip on time. Please make sure that you understand what to do if you miss a pill or think you are pregnant.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, family planning nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- **If you get any side effects**, talk to your doctor, family planning nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

- 1 What Ovysmen is and what it is used for
- 2 What you need to know before you take Ovysmen3 How to take Ovysmen
- 3.3 A missed pill
- 4 Possible side effects
- 5 How to store Ovysmen
- 6 Contents of the pack and other information

## 1 What Ovysmen is and what it is used for

Ovysmen is a combined oral contraceptive pill ('the Pill'). **You take it to stop getting pregnant.**

This contraceptive contains two types of female sex hormones, oestrogen and progestogen. These hormones prevent an egg being released from your ovaries so you can't get pregnant. Also, Ovysmen makes the fluid (mucus) in your cervix thicker which makes it more difficult for sperm to enter the womb.

Ovysmen is a 21-day Pill - you take one each day for 21 days, followed by 7 days when you take no pills.

**The benefits of taking the Pill include:**

- it is one of the most reliable reversible methods of contraception if used correctly
- it doesn't interrupt sex
- it usually makes your periods regular, lighter and less painful
- it may help with pre-menstrual symptoms.

Ovysmen will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

**Ovysmen needs to be taken as directed to prevent pregnancy.**

## **2 What you need to know before you take Ovysmen**

It's important that you understand the benefits and risks of taking the Pill before you start taking it, or when deciding whether to carry on taking it. Although the Pill is suitable for most healthy women it isn't suitable for everyone.

→ Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.

### **Before you start taking the Pill**

- Your doctor will ask about you and your family's medical problems and check your blood pressure. You may also need other checks, such as a breast examination but only if these are necessary for you or you have any special concerns.

### **While you're on the Pill**

- You will need **regular check-ups** with your doctor or family planning nurse, usually when you need another prescription of the Pill.
- You should go for **regular cervical smear tests**.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking the Pill, because the Pill can affect the results of some tests.
- **If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking the Pill about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking the Pill again.

### **2.1 The Pill and blood clots**

The Pill may slightly increase your risk of having a blood clot (called a thrombosis), especially in the first year of taking it.

A clot in a leg vein – a deep vein thrombosis (or DVT) – is not always serious. However, if it moves up the veins to the lungs, it can cause chest pain, breathlessness, collapse or even death. This is called a 'pulmonary embolism' and is very rare.

**Your chances of having a blood clot are only increased slightly by taking the Pill.**

- Of 100,000 women who are **not on the Pill** and not pregnant, about **5** will have a blood clot in a year.

- Of 100,000 women **taking a Pill** such as Ovysmen, about **15** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around **60** will have a blood clot in a year.

**You are more at risk of having a blood clot in your veins:**

- as you get **older**
- if you are **seriously overweight**
- if you **smoke**
- if you or any of your close family have had **blood clots**
- if you have any **blood clotting problem** that needs treatment with a medicine such as warfarin
- if you're **off your feet for a long time** because of major surgery, injury or illness
- if you have had one or more **miscarriages**
- if you have **recently had a baby**

→**Tell your doctor** if any of these risk factors apply to you. Taking the Pill may add to this risk so Ovysmen may not be suitable for you.

**Signs of a blood clot include:**

- **painful swelling in your leg**
- sudden **chest pain, difficulty breathing**
- sudden **changes in eyesight** (such as loss of vision or blurred vision)

→**See a doctor as soon as possible. Do not take any more Ovysmen** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a **heart attack**) or the brain (causing a **stroke**). In healthy young women the chance of having a heart attack or stroke is extremely small.

**You are more at risk of having a heart attack or stroke:**

- as you get **older**
- if you have **high blood pressure**
- if you **smoke** or **drink** too much **alcohol**
- if you **have high levels of fat** in your blood or are **seriously overweight**
- if you **have an irregular heartbeat** (atrial fibrillation), problems with **heart valves** or **heart failure**
- if you or someone in your close family has had a **heart attack** or **stroke** at a young age
- if you have **migraines**
- if you have **diabetes**
- if you have a blood problem called **sickle cell anaemia**

→**Tell your doctor** if any of these risk factors apply to you. Taking the Pill may add to this risk so Ovysmen may not be suitable for you.

**Signs of a heart attack or stroke include:**

- sudden **crushing pains in your chest** which may reach your left arm
- sudden **weakness** or **numbness** in one side or part of your body
- **severe headache or migraine** for the first time or worse than normal
- **slurred speech** or any other difficulties affecting your speech

- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)

→**See a doctor as soon as possible. Do not take any more Ovysmen** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

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## 2.2 The Pill and cancer

The Pill reduces your risk of cancer of the ovary and womb if used for a long time. However, it also seems to slightly increase your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than the Pill. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take the Pill. The Pill slightly increases your risk of breast cancer. This risk goes up the longer you're on the Pill, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Pill users are small. For example:

- Of 10,000 women who have **never taken the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who **take the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take the Pill for 5 years in their early thirties**, about **111** will have breast cancer by the time they are 45 years old.

**Your risk of breast cancer is higher:**

- as you get older
- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight

→**See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.

→**See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes** (jaundice). You may need to stop taking Ovysmen.

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## 2.3 Ovysmen should not be taken by some women

→Tell your doctor or family planning nurse if you have any medical problems or illnesses.

**Do not take Ovysmen if any of the following apply to you:**

- If you are **breast feeding** and **your baby is less than 6 weeks old**

- If you have **breast** or **liver cancer**
  - If you have an **irregular heartbeat** (atrial fibrillation), problems with **heart valves** or **heart failure**
  - If you have ever had a problem with your blood circulation. This includes **blood clots**, for example in the legs (**deep vein thrombosis**) or lungs (**pulmonary embolism**), or a **heart attack** or **stroke**
  - If you have any conditions which make you **more at risk of a blood clot** (thrombosis – see section 2.1), such as having an operation and being **off your feet for a long time**
  - **If you have very high blood pressure**
  - If you **smoke** 15 or more cigarettes a day and you are 35 years old or more
  - If you have **migraines** which affect your vision
  - If you have had **diabetes** for more than 20 years or have diabetes with secondary problems
  - If you have or have recently had a **severe liver disease**
  - If you have the disease **Systemic Lupus Erythematosus** (SLE) with or without Raynaud's disease
  - If you are **allergic** (hypersensitive) to any of the ingredients in Ovysmen.
- If you suffer from any of these**, or get them for the first time while taking Ovysmen, contact your doctor as soon as possible. Do not take Ovysmen as it may put your health at risk.

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#### 2.4 Ovysmen can make some illnesses worse

Some of the conditions listed below can be made worse by taking the Pill. Or they may mean it is less suitable for you. You may still be able to take Ovysmen but you need to take special care and have check-ups more often.

**Tell your doctor or family planning nurse if any of these apply to you:**

- If you have problems with your heart, circulation or blood clotting, such as **high blood pressure**
- If you have **diabetes** without secondary problems
- If you have **gall bladder problems**
- If you have **porphyria**
- If you have a history of **migraines**
- If you have **brown patches on your face or body** (chloasma) as you may need to keep out of the sun
- If you have had any of the following **problems while pregnant** or during **previous Pill use**, such as itchy skin or blister-like rash, yellowing of skin or eyes, hearing problem, systemic lupus erythematosus (SLE), severe headaches

→**Tell your doctor or family planning nurse if any of these apply to you.**

**Also tell them if you get any of these for the first time while taking the Pill**, or if any get worse or come back, because you may need to stop taking Ovysmen and use another method of contraception, such as condoms.

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#### 2.5 Other medicines and Ovysmen

If you ever need to take another medicine at the same time as being on the Pill, always tell your doctor, pharmacist or dentist that you're taking Ovysmen.

Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

**Some medicines can stop Ovysmen from working properly** – for example:

- **some medicines used to treat epilepsy** (such as topiramate, carbamazepine, phenytoin, oxcarbazepine, felbamate, eslicarbazepine acetate, rufinamide)
- **bosentan** (for high blood pressure in the blood vessels of your lungs)
- **rifampicin and rifabutin** (for treatment of TB)
- **anti-HIV medicines**
- **boceprevir and telaprevir** (for treatment of Hepatitis C infections)
- **aprepitant and fosaprepitant** (for prevention of nausea and vomiting caused by certain cancer drug treatments)
- **griseofulvin** (for fungal infections)
- **modafinil** (for excessive daytime sleepiness)
- **certain sedatives** (called ‘barbiturates’)
- **St. John’s Wort** (a herbal remedy)
- **colesevelam** (to treat high cholesterol levels)
- **etoricoxib** (to help with pain and inflammation of arthritis)

If you do need to take one of these medicines, Ovysmen may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

**Ovysmen can also affect other medicines** for example:

- **ciclosporin** (to prevent transplant rejection and for rheumatoid arthritis or some skin problems)
- **lamotrigine** (for epilepsy)
- **prednisolone** (a steroid to reduce inflammation)
- **selegiline** (for Parkinson’s disease)
- **theophylline** (for asthma, bronchitis and emphysema)
- **tizanidine** (used to relax muscles)

Talk to your doctor before having Ovysmen if you are taking any of these medicines. They may have to change how much of these medicines you are taking.

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## 2.6 Ovysmen with food and drink

There are no special instructions about food and drink while on Ovysmen.

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## 2.7 Pregnancy and breast-feeding

**Do not start to use Ovysmen** if you are pregnant. If you think you might be pregnant while taking Ovysmen, do a pregnancy test to confirm that you are before you stop taking it.

**If you are breast-feeding**, your doctor or family planning nurse may advise you not to take Ovysmen. Talk to them about alternative contraception. Breast-feeding may not stop you getting pregnant.

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## **2.8 Driving and using machines**

Ovysmen has no known effect on the ability to drive or use machines.

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## **2.9 Ovysmen contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using Ovysmen.

# **3 How to take Ovysmen**

## **3.1 How to take it**

To prevent pregnancy, always take Ovysmen as described below. Check with your doctor or family planning nurse if you are not sure.

### **Take Ovysmen every day for 21 days**

Ovysmen comes in a strip of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

### **Then have seven pill-free days**

After you have taken all 21 pills in the strip, you have seven days when you take no pills. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

You don't need to use extra contraception during these seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time.

### **Then start your next strip**

Start taking your next strip of Ovysmen after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

As long as you take Ovysmen correctly, you will always start each new strip on the same day of the week.

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## **3.2 Starting Ovysmen**

### **As a new user or starting the Pill again after a break**

**Either** take your first Ovysmen pill up to and including day 5 of your next period (counting the first day of your period as day 1). This way, you will have contraceptive protection with your first pill.

**Or** start taking Ovysmen at any time, if you are sure you are not already pregnant. But then you must use extra contraception, such as condoms, until you have taken the first 7 pills correctly.

### **Changing to Ovysmen from another contraceptive**

If you are currently taking another Pill and you are taking it correctly, you can start Ovysmen at any time, if you are sure you are not already pregnant.

There is no need to wait for your next period to start and you don't need extra contraception. If you are currently using a non-hormonal method and your period started more than 5 days ago, you must use extra contraception, such as condoms, until you have taken the first 7 pills correctly.

**Starting Ovysmen after a miscarriage or abortion**

If you have had a miscarriage or an abortion, your doctor may tell you to start taking Ovysmen straight away. This means that you will have contraceptive protection with your first pill.

**Contraception after having a baby**

If you have just had a baby, your doctor may tell you to start taking Ovysmen 21 days after the birth. This means that you will have contraceptive protection with your first pill.

If you start Ovysmen after this, you must use extra contraception, such as condoms, until you have taken the first 7 pills correctly.

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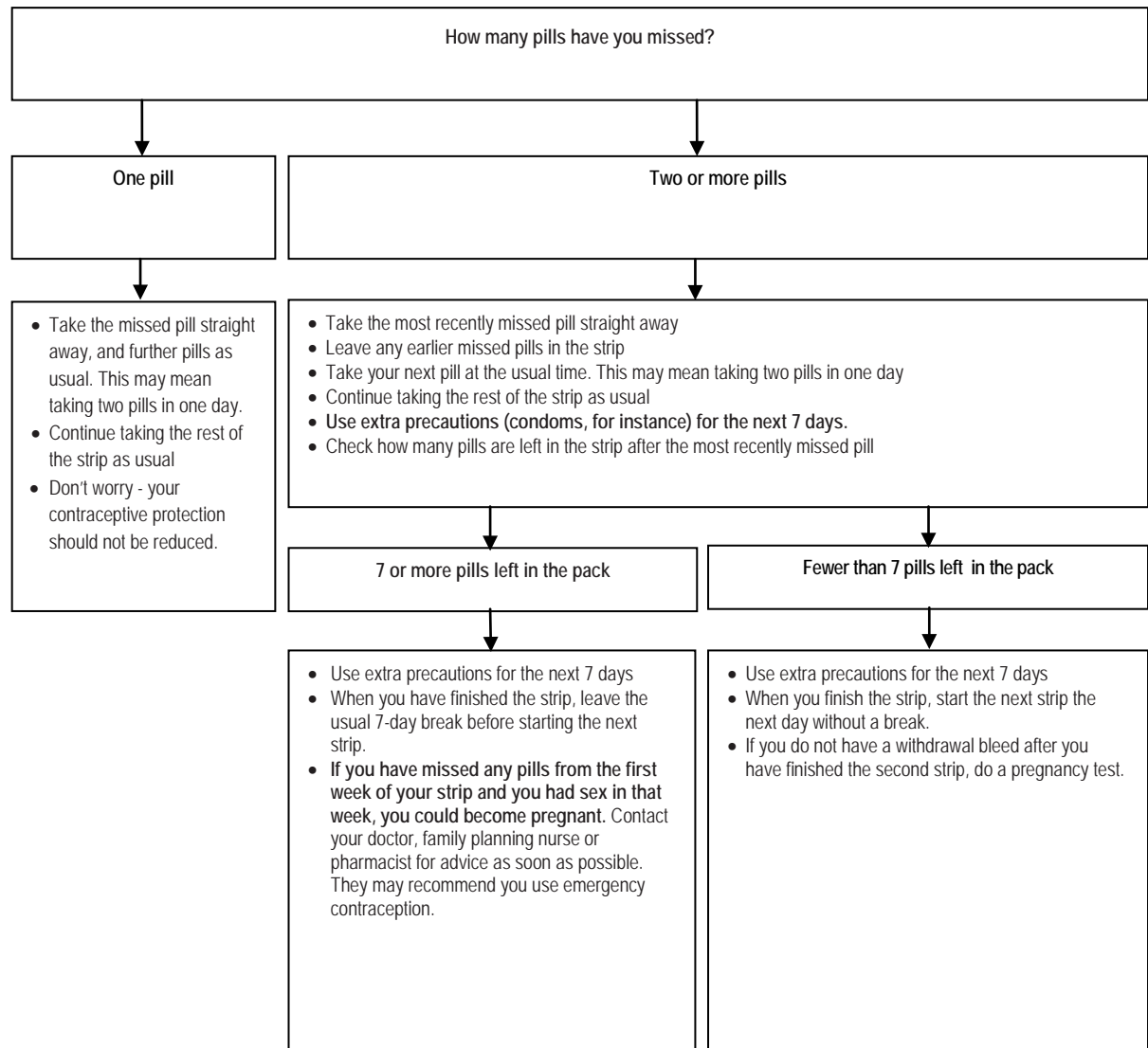


### 3.3 A missed pill

Missing pills or starting a strip late may make your pill less effective. The chance of pregnancy after missing pills depends on **when** pills are missed and **how many** pills are missed.

Missing one pill anywhere in your strip or starting a new strip one day late is **not** a problem. Missing **more than one** or starting a strip **more than one day late** may affect your contraceptive cover.

It is more risky to start a strip late and miss more than one pill.



If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant. Contact your doctor or family planning clinic, or do a pregnancy test yourself.

**If you start a new strip of pills late**, or make your 'week off' longer than eight days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor, family planning nurse or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

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### **3.4 A lost pill**

If you lose a pill, just take a pill from a spare strip. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

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### **3.5 If you are sick or have diarrhoea**

If you are sick or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. If you have been sick **within 2 hours of taking Ovysmen**, just take a pill from a spare strip. Carry on taking your pills as normal if you can. You won't need to use extra contraception.

If you are still sick or have diarrhoea for **more than 1 day**, follow the instructions for a missed pill – see section 3.3, *A missed pill*.

→**Talk to your doctor if your stomach upset carries on or gets worse.** He or she may recommend another form of contraception.

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### **3.6 Missed a period – could you be pregnant?**

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your family planning clinic or doctor's surgery. If you are pregnant, stop taking Ovysmen and see your doctor.

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### **3.7 Taking more than one pill should not cause harm**

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

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### **3.8 You can delay a period**

If you want to delay having a period, finish the strip of pills you are taking. Start the next strip the next day without a break. Pill taking should then continue as usual.

When you use the second strip, you may have some unexpected bleeding or spotting on the days that you take the pill, but don't worry. Take the next strip after the usual 7 day break even if you are still bleeding or spotting.

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### **3.9 When you want to get pregnant**

If you are planning a baby, it's best to use another method of contraception after stopping Ovysmen until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

## 4 Possible side effects

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

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Ovysmen.

### 4.1 Serious side effects – see a doctor straight away

**Signs of a blood clot in a vein include:**

- **painful swelling in your leg**
- sudden **chest pain, difficulty breathing**
- sudden **changes in eyesight** (such as loss of vision or blurred vision).

**Signs of heart attack or stroke include:**

- a **severe headache or migraine** for the first time, or worse than normal
- sudden **changes in eyesight** (such as loss of vision or blurred vision)
- sudden **weakness or numbness** in one side or part of your body
- **slurred speech** or any other difficulties affecting your speech
- sudden **crushing pains in your chest** which may reach your left arm.

**Signs of breast cancer include:**

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

**Signs of severe liver problems include:**

- severe **pain** in your **upper abdomen**
- **yellow skin or eyes** (jaundice).

**Other serious side effects include:**

- **increased blood pressure**
- **hives (urticaria), swelling** of the face, lips, mouth, tongue or throat which may cause **difficulty in swallowing or breathing**. These may be signs of **allergy**.

→ **If you think you may have any of these, see a doctor straight away.**

You may need to stop taking Ovysmen.

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### 4.2 Other possible side effects – tell your doctor

**Very common side effects** (affects more than 1 in 10 patients)

- **Headache** (but if severe, unusual or long lasting, see a doctor as soon as possible)
- **Vomiting** (being sick)
- **Painful or unusual periods**
- **Bleeding and spotting between your periods** for the first few months (though this usually stops when your body adjusts to Ovysmen) – see section 4.3, *Bleeding between periods should not last long*
- **Premenstrual syndrome (PMS)**

**Common side effects** (affects more than 1 in 100 patients)

- **Depression**, feeling **nervous**
- Feeling **dizzy**
- **Stomach ache** and **bloating**
- **Diarrhoea**
- **Acne**
- **Tender** or **painful breasts**
- **Gynaecological problems:**
  - Vaginal problems, such as more secretions or discharge, itchiness
  - Heavy or missing periods
  - **Withdrawal bleed** when product is stopped
- **Muscle spasms**
- **Back pain; pelvic pain**

**Uncommon side effects** (affects fewer than 1 in 100 patients)

- **Migraine** (see a doctor as soon as possible if this is your first migraine or it's worse than usual)
- **Mood swings** or **changes**
- Feeling **irritable** or **anxious**
- **Skin problems** such a **rash**, **redness** and **itchiness**
- Changes in **skin colour**
- **Hair thinning** (alopecia)
- **Nausea** (feeling sick)
- **Reduced appetite**
- **Weight gain**
- **Swollen hands, ankles or feet**
- **Reduced sex drive**
- **Thrush** (fungal infection), including in the vagina
- Feeling **tired**
- Feeling **weak** or **unwell**

**Rare side effects** (affects fewer than 1 in 1,000 patients)

- **Abnormal cells** in the **cervix** (identified by a smear test)
- **Increased appetite**
- **Difficulty losing weight**
- **Weight loss**
- **Gallstones**
- **Excessive hair growth**
- **Contact lenses** feel uncomfortable

**Very rare side effects** (affects fewer than 1 in 10,000 patients)

- **Cancer of the cervix** (vaginal discharge that smells and contains blood, unusual vaginal bleeding, pelvic pain, painful sex)
- **Breast problems** such as fuller breasts; producing a milky fluid from the nipples
- **Vaginal dryness**

**Frequency not known**

- **Raised blood sugar levels**
- **Gynaecological problems:**

- Very **heavy** bleeding
- Irregular or late periods
- **Reduced** amount of **breast milk** (if breast feeding)
- **Red painful lumpy swellings on the legs**
- Changes in **fat levels** in the blood (seen by blood tests)
- **Pancreatitis** (inflammation of the pancreas, which causes severe pain in the abdomen and back)
- **Sensitivity to light**

#### → **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or family planning nurse. This includes any possible side effects not listed in this leaflet. Also tell them if any existing conditions get worse while you are taking Ovysmen. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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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#### **4.3 Bleeding between periods should not last long**

Usually you should only have a withdrawal bleed like a period during the seven pill-free days. However, a few women have a little unexpected bleeding or spotting while they are taking Ovysmen, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Ovysmen as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

→ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Ovysmen for a while
- carries on even after you've stopped taking Ovysmen.

## **5 How to store Ovysmen**

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

Store Ovysmen below 30°C. Store it in the original package to protect it from light.

Do not use Ovysmen after the expiry date which is stated on the carton and on the strip. The expiry date refers to the last day of that month.

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

## **6 Contents of the pack and other information**

### **What Ovysmen contains**

Active substances:

Each pill contains 500 micrograms norethisterone and 35 micrograms ethinylestradiol.

Other ingredients:

Ovysmen also contains anhydrous lactose (a type of sugar), magnesium stearate and pregelatinised starch.

### **What Ovysmen looks like and contents of the pack**

Each box of Ovysmen contains three strips each containing 21 tablets. The tablets are white and engraved 'C535'.

### **Marketing Authorisation holder:**

Janssen-Cilag Ltd, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

### **Manufacturer:**

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

OR

McGregor Cory Ltd, Middleton Close, Banbury, Oxfordshire OX16 4RS, UK

**For information in large print, tape, CD or Braille, telephone 0800 7318450.**

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