

Flexyess PIL

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flexyess 0.02 mg / 3 mg film-coated tablets

Ethinylestradiol / Drospirenone

Read all of this leaflet carefully before you start taking this medicine.

- *Keep this leaflet, 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, do not pass it on to others. It may harm them.*
- *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.*

In this leaflet

1. WHAT FLEXYESS IS AND WHAT IT IS USED FOR.....	2
2. BEFORE YOU TAKE FLEXYESS.....	2
General notes	2
When you should not use Flexyess	2
When do you need to take special care with Flexyess	3
Flexyess and venous and arterial blood clots	3
Flexyess and cancer	5
Bleeding between periods.....	5
What to do if no bleeding occurs during the 4-day tablet-free interval.....	5
Flexyess and using other medicines	5
Taking Flexyess with food and drink	6
Laboratory tests	6
Pregnancy	6
Breast-feeding.....	6
Driving and using machines	6
Important information about some of the ingredients of Flexyess.....	6
3. HOW TO TAKE FLEXYESS.....	6
Preparing the Clyk tablet dispenser for use.....	7
Replacing an empty cartridge with a new cartridge	8
When can you start with Flexyess?	8
If you take more Flexyess than you should.....	9
If you forget to take Flexyess	9
What to do in the case of vomiting or severe diarrhoea	10
If you want to stop taking Flexyess	10
4. POSSIBLE SIDE EFFECTS	10

Flexyess PIL

5. HOW TO STORE FLEXYESS	11
Expiry date.....	12
6. FURTHER INFORMATION	12
What Flexyess contains	12
What Flexyess looks like and contents of the pack.....	12
Marketing Authorisation Holder	12
Manufacturer	12

1. WHAT FLEXYESS IS AND WHAT IT IS USED FOR

- Flexyess is a contraceptive pill and is used to prevent pregnancy
- Each tablet contains a small amount of two different female hormones, namely drospirenone and ethinylestradiol.
- Contraceptive pills that contain two hormones are called “combination” pills.

2. BEFORE YOU TAKE FLEXYESS

General notes

Before you can begin taking Flexyess, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using Flexyess, or where the reliability of Flexyess may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Flexyess alters the monthly changes of body temperature and of cervical mucus.

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

When you should not use Flexyess

- If you have (or have ever had) a blood clot in a blood vessel of the leg (thrombosis), of the lung (pulmonary embolism) or other organs
- if you have (or have ever had) a heart attack or stroke
- if you have (or have ever had) a disease that can be an indicator of a heart attack in the future (for example, angina pectoris, which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects)
- if you have a disease that may increase the risk of a clot in the arteries. This applies to the following diseases:
 - diabetes with damaged blood vessels
 - very high blood pressure
 - a very high level of fat in the blood (cholesterol or triglycerides)

Flexyess PIL

- if you have a disturbance of blood clotting (for example, protein C deficiency)
- if you have (or have ever had) a certain form of migraine (with so-called focal neurological symptoms)
- if you have (or have ever had) liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of Flexyess. This may cause itching, rash or swelling.

When do you need to take special care with Flexyess

In some situations you need to take special care while using Flexyess or any other combination pill, and your doctor may need to examine you regularly. Also, if any of the following conditions applies to you, you must inform your doctor before starting to use Flexyess. If any of the following conditions develops or worsens, while you are using Flexyess you must consult your doctor:

- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or the gallbladder
- if you have diabetes
- if you have depression
- if you have Crohn's disease or inflammatory bowel disease (ulcerative colitis)
- if you have a blood disease called HUS (haemolytic uraemic syndrome) that causes kidney damage
- if you have a blood disease called sickle cell anaemia
- if you have epilepsy (see page X "Flexyess and using other medicines")
- if you have a disease of the immune system, called SLE (systemic lupus erythematosus)
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's chorea)
- If you have or have ever had golden brown pigment patches (chloasma), so called "pregnancy patches", especially on the face. If this is the case, avoid direct exposure to sunlight or ultraviolet light.
- if you have hereditary angioedema, products containing oestrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.

Flexyess and venous and arterial blood clots

The use of any combination pill, including Flexyess, increases a woman's risk of developing a **venous blood clot (venous thrombosis)** compared with women who do not take any contraceptive pill.

The risk of venous thrombosis in users of combination pills increases:

- with increasing age
- if you are overweight
- if one of your close relatives ever had a blood clot in the leg, lung (pulmonary embolism), or other organ at a young age
- if you must have surgery, if you have had a serious accident or if you are immobilized for a long time. It is important to tell your doctor in advance that you are using Flexyess as the treatment may

Flexyess PIL

have to be stopped. Your doctor will tell you when to start Flexyess again. This is usually about two weeks after you are back on your feet

Your chances of having a blood clot are increased by taking the pill.

- Of 100,000 women who are not on the pill and not pregnant, about 5-10 may have a blood clot in a year.
- Of 100,000 women taking a pill like Flexyess, 30-40 may have a blood clot in a year, the exact number is unknown.
- Of 100,000 women who are pregnant, around 60 may have a blood clot in a year.

A blood clot in the veins may travel to the lungs and may block blood vessels (called a lung embolus). Formation of blood clots in the veins may be fatal in 1-2% of cases.

The level of risk may vary according to the type of pill you take. Discuss with your doctor the available options.

The use of combination pills has been connected with an increase of the risk of an **arterial blood clot (arterial thrombosis)**, for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of an arterial blood clot in users of combination pills increases:

- **if you smoke. You are strongly advised to stop smoking when you use Flexyess, especially if you are older than 35 years**
- if you have high levels of blood cholesterol or triglycerides
- if you are overweight
- if one of your close relatives had a heart attack or stroke at a young age
- if you have high blood pressure
- if you suffer from migraine
- if you have a problem with your heart (valve disorder, a disturbance of the cardiac rhythm)

Stop taking Flexyess and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- severe pain and/or swelling in one of your legs
- sudden 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 the body

Flexyess PIL

Flexyess and cancer

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often.

The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in contraceptive pill users. In isolated cases, these tumors have led to life-threatening internal bleeding. Contact your doctor if you have unusually severe abdominal pain.

Some studies suggest that long-term use of the pill increases a woman's risk of developing cervical cancer. However, it is not clear to what extent sexual behaviour or other factors such as Human Papilloma Virus (HPV) increases this risk.

Bleeding between periods

During the first few months that you are taking Flexyess, you may have unexpected bleeding (bleeding outside the tablet-free days). If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

What to do if no bleeding occurs during the 4-day tablet-free interval

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. Continue to take Flexyess as usual.

If you have taken the tablets incorrectly, or, if you have taken tablets correctly but the expected bleeding does not happen twice in a row, you may be pregnant. Contact your doctor immediately.

Bleeding under treatment with Flexyess normally does not occur every 4 weeks but at reduced frequency with intervals of up to 120 days. Unexpected pregnancy may be difficult to recognize. If for some reason you think you may be pregnant, do a pregnancy test. If the test is positive, or you are still unsure contact your doctor.

Do not continue with tablet-taking until you are sure that you are not pregnant. In the meantime, use non-hormonal contraceptive measures. See also under 'Pregnancy'.

Flexyess and using other medicines

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

Some medicines can make Flexyess less effective in preventing pregnancy, or can cause unexpected bleeding. These include:

- medicines used for the treatment of:
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
 - tuberculosis (e.g. rifampicin)
 - HIV infections (ritonavir, nevirapine) or other infections (antibiotics such as griseofulvin, penicillin, tetracyclines)
 - high blood pressure in the blood vessels in the lungs (bosentan)

Flexyess PIL

- the herbal remedy St. John's wort

Flexyess may influence the effect of other medicines, e.g.

- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)

Ask your doctor or pharmacist for advice before taking any medicine.

Taking Flexyess with food and drink

Flexyess may be taken with or without food, if necessary with a small amount of water.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormonal contraceptives can affect the results of some tests.

Pregnancy

If you are pregnant, you must not take Flexyess. If you become pregnant while taking Flexyess you must stop immediately and contact your doctor.

If you want to become pregnant, you can stop taking Flexyess at any time (see also 'If you want to stop taking -Flexyess 'on page X).

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Use of Flexyess is generally not advisable when a woman is breast-feeding. If you want to take the pill while you are breast-feeding you should contact your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There is no information suggesting that use of Flexyess affects driving or use of machines.

Important information about some of the ingredients of Flexyess

Flexyess contains lactose.

If you cannot tolerate certain sugars, contact your doctor before you take Flexyess.

3. HOW TO TAKE FLEXYESS

General advice

Always use Flexyess exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The Clyk tablet dispenser will guide you through the regimen.

Take one tablet of Flexyess every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

Flexyess PIL

Tablet intake

1) Mandatory phase (day 1-24):

When starting Flexyess, tablets must be taken continuously for a minimum of 24 days, after which you can either:

- stop taking tablets for a 4-day tablet-free interval
- or continue taking them for up to 120 days (see flexible phase).

During the first 24 days the Clyk tablet dispenser does not allow a 4-day tablet-free interval.

2) Flexible phase (day 25-120):

During days 25-120, the tablets can be taken continuously up to a maximum of 120 days. Within this period, you may decide yourself when to take the 4-day tablet-free interval. This will usually cause bleeding.

During the flexible phase, the Clyk tablet dispenser allows you to initiate a 4-day tablet-free interval at any time.

If you do not initiate the 4-day tablet-free interval yourself, the Clyk dispenser automatically initiates a 4-day tablet-free interval after 120 days of continuous tablet intake.

In the event of continued bleeding (three consecutive days) during days 25-120, it is advisable to take the 4-day tablet-free interval. This will reduce the total number of days with bleeding.

Tablet-free interval

A tablet-free interval should never be longer than 4 days and it should only be started if tablet taking has been continuous for 24 days.

During the 4-day tablet-free interval bleeding usually occurs and may not have finished before you start the next tablet intake cycle.

After each 4-day tablet-free interval, you will start a new intake cycle of a minimum of 24 days to a maximum of 120 days. After the mandatory phase of 24 days of continuous tablet taking, you again may choose when to have the tablet-free 4 day interval between days 25 and 120.

Preparing the Clyk tablet dispenser for use

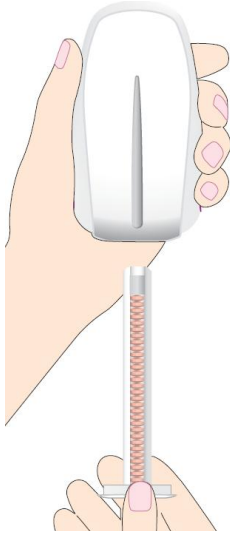
Flexyess can only be used in combination with the Clyk dispenser.

The separate document instructions for use of the Clyk dispenser should be carefully read before and during use.

1. Remove the OC dispenser from its package
2. Remove a cartridge (containing 30 tablets) from its blister immediately prior to insertion
3. Hold the dispenser in the palm of your hand so you see the viewing window for the tablets (see picture)
4. Hold the cartridge in your other hand so that you can see the tablets.
5. Insert the cartridge in the dispenser, pushing it in all the way and leave in. The tablets are now visible through the viewing window.

Flexyess PIL

- Turn the dispenser over to view the display screen on the front. This now tells you that your OC dispenser is turned on and ready to use.



Replacing an empty cartridge with a new cartridge

When the cartridge is empty release it from the tablet dispenser by pressing the cartridge release button (the button with a blue circle on it). Only remove the new cartridge from its blister immediately prior to insertion.

Dispose of the empty cartridge and insert a new one as described above.

When can you start with Flexyess?

- If you have not used a contraceptive with hormones in the previous month*
Begin with Flexyess on the first day of the cycle (that is, the first day of your period). If you start Flexyess on the first day of your period you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.
- Changing from another combined hormonal contraceptive, or combined contraceptive vaginal ring or patch*
You can start Flexyess preferably on the day after the last tablet-free interval or after the last hormone-free tablet of your previous pill. When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.
- Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing IUD)*
You may switch any day from the progestogen-only pill (from an implant or an IUS on the day of its removal, from an injectable when the next injection would be due) but in all of these cases use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.
- After a miscarriage or abortion*
Follow the advice of your doctor.
- After having a baby*

Flexyess PIL

You can start Flexyess between 21 and 28 days after having a baby. If you start later than day 28-you must use a so-called barrier method (for example, a condom) during the first seven days of Flexyess use.

If, after having a baby, you have had sex before starting Flexyess (again), you must first be sure that you are not pregnant or you must wait until your next period.

- *If you are breast-feeding and want to start Flexyess (again) after having a baby*
Read the section on “Breast-feeding” on page X.

Ask your doctor what to do if you are not sure when to start.

If you take more Flexyess than you should

There are no reports of serious harmful results of taking too many Flexyess tablets. If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina.

If you have taken too many Flexyess tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take Flexyess

IMPORTANT: If you have missed one or more pills, check if the ‘Use an additional method of contraception’ symbol (an exclamation mark in a box) is displayed on your Clyk dispenser’s home screen.

Whenever the home screen displays the exclamation mark, you should use an additional non-hormonal method of contraception (e.g. condoms). You should use an additional method of non-hormonal contraception until the exclamation mark disappears.

Management of missed tablets

- If you are **less than 24 hours** late when taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then continue taking the tablets again at the usual time.
- If you are **more than 24 hours** late in taking any tablet your protection against pregnancy may be reduced. The following advice can be given in daily practice:
 - More than one tablet forgotten
Check if the ‘Use an additional method of contraception’ symbol (an exclamation mark in a box) is displayed on your Clyk dispenser’s home screen and follow the above instructions. If you are unsure what to do, ask your doctor for advice.
 - **1 tablet missed during Day 1-7**

You should take the last missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take tablets at the usual time. In addition check if the ‘Use an additional method of contraception’ symbol (an exclamation mark in a box) is displayed on your Clyk dispenser’s home screen and follow the above instructions. If you have had sex in the week before forgetting the tablet you must realize that there is a risk of pregnancy. In that case, contact your doctor.

- **1 tablet missed during Day 8-24**

You should take the last missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take tablets at your usual time. If you have taken your tablets correctly in the 7 days preceding the first missed tablet, there is no need to use extra contraceptive precautions. However, if this is not the case or if you have missed more than 1 tablet, you should

Flexyess PIL

check if the ‘Use an additional method of contraception’ symbol (an exclamation mark in a box) is displayed on your Clyk dispenser’s home screen and follow the above instructions. If you are unsure what to do, ask your doctor for advice.

- **1 tablet missed during Day 25-120**

You may choose either of the following options, without the need for extra contraceptive precautions.

1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time until you have taken at least 7 tablets in a row without interruption.

or

2. Stop taking tablets, have a 4-day pill-free break (also count the day you missed your tablet) and continue with a new intake cycle of Flexyess

- If you have forgotten tablets, and you do not have a bleeding during your 4-day pill-free break, you may be pregnant. Contact your doctor before you continue to take the tablets, (see also section “*What to do if no bleeding occurs during the 4-day interval*”).

What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet as soon as possible. If possible take it within 24 hours of when you normally take your pill. If this is not possible or 24 hours have passed, use extra protection (e.g. a condom) for the next 7 days.

If you want to stop taking Flexyess

You can stop taking Flexyess whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking Flexyess and wait for a menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

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

4. POSSIBLE SIDE EFFECTS

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

The following is a list of the side effects that have been linked with the use of Flexyess:

Common side effects (affects 1 to 10 users in 100):

- mood swings, depression, decreased interest in or loss of interest in sex
- headache
- migraine
- nausea
- breast pain, **problems with your periods, such as irregular periods, absence of periods**

Flexyess PIL

Uncommon side effects (affects 1 to 10 users in 1,000)

- nervousness, sleepiness
- dizziness, ‘pins and needles’
- migraine, varicose veins, increased blood pressure
- stomach ache, vomiting, indigestion, intestinal gas, inflammation of the stomach, diarrhoea
- acne, itching, rash
- aches and pains, e.g. back pain, limb pain, muscle cramps
- vaginal fungal infection, pelvic pain, breast enlargement, benign breast lumps, uterine/vaginal bleeding (which usually subsides during continued treatment), genital discharge, hot flushes, inflammation of the vagina (vaginitis), problems with your periods, painful periods, reduced periods, very heavy periods, vaginal dryness, abnormal cervical smear
- lack of energy, increased sweating, fluid retention
- weight increase

Rare side effects (affects 1 to 10 users in 10,000):

- candida (fungal infection)
- anemia, increase in the number of platelets in the blood
- allergic reaction
- hormonal (endocrine) disorder
- increased appetite, loss of appetite, abnormally high concentration of potassium in the blood, abnormally low concentration of sodium in the blood
- failure to experience an orgasm, insomnia
- giddiness, tremor
- eye disorders, e.g. inflammation of the eyelid, dry eyes
- abnormally rapid heartbeat
- inflammation of a vein, nosebleed, fainting
- enlarged abdomen, bowel disorder, feeling bloated, stomach hernia, fungal infection of the mouth, constipation, dry mouth
- pain of bile ducts or the gallbladder, inflammation of the gallbladder
- yellow brown patches on the skin, eczema, hair loss, acne-like inflammation of the skin, dry skin, lumpy inflammation of the skin, excessive hair growth, skin disorder, stretch marks on the skin, skin inflammation, light-sensitive skin inflammation, skin nodules
- difficult or painful sex, inflammation of the vagina (vulvovaginitis), bleeding following intercourse, withdrawal bleeding, breast cyst, increased number of breast cells (hyperplasia), malignant lumps in the breast, abnormal growth on the mucosal surface of the neck of the womb, shrinkage or wasting of the lining of the womb, ovarian cysts, enlargement of the womb
- feeling generally unwell
- weight loss

The following side effects have also been reported, but their frequency cannot be estimated from the available data: hypersensitivity, erythema multiforme (rash with target-shaped reddening or sores).

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet or if you think that this may be the case, please tell your doctor or pharmacist.

5. HOW TO STORE FLEXYESS

Keep Flexyess out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Flexyess PIL

The tablet dispenser is not watertight and should always be kept dry.

Expiry date

Do not take Flexyess after the expiry date which is stated on the folding box and the blister of the cartridge (see “EXP”). Once you have removed the cartridge from the blister, insert it immediately into the dispenser and take the tablets within 40 days.

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

6. FURTHER INFORMATION

What Flexyess contains

- The active substances are ethinylestradiol (as betadex clathrate) and drospirenone. Each tablet contains 0.020 milligram ethinylestradiol (as betadex clathrate) and 3 milligram drospirenone.
- The other ingredients are
Tablet core: lactose monohydrate, maize starch, magnesium stearate (E470b),
Tablet film-coating: hypromellose (E464), talc (E553b), titanium dioxide (E171) and red iron oxide (E172).

What Flexyess looks like and contents of the pack

- The Flexyess tablet is light pink, round with convex surfaces; one side is embossed with the letters "DS" in a regular hexagon. The tablets are presented in a cartridge which is then packed in a blister.
- The Starter pack for Flexyess contains:
1 carton box with 1 blister containing 1 cartridge with 30 tablets and
1 carton box containing 1 dispenser.
- The refill packs for Flexyess contain 1, 3, 4 or 12 blisters, each containing a cartridge with 30 tablets

Marketing Authorisation Holder

Bayer Limited, The Atrium, Blackthorn Road, Dublin 18

In case of questions about the use of the tablet dispenser please contact the local BAYER subsidiary.

Manufacturer

Bayer Pharma AG
Berlin, Germany

and

Bayer Weimar GmbH and Co. KG
Weimar, Germany

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

Country	Proposed (invented) name, strength, and pharmaceutical form
Austria (AT)	Flexyess 0,02 mg/3 mg Filmtabletten
Belgium (BE)	Yvidually 0,02 mg/3 mg, filmomhulde tabletten
Bulgaria (BG)	Flexyess 0,02 mg/3 mg филмирани таблетки
Cyprus (CY)	Flexyess 0,02 mg/3 mg επικαλυμμένα με λεπτό υμένιο δισκία

Flexyess PIL

Czech Republic (CZ)	Flexyess 0,02 mg/ 3 mg potahované tablety
Denmark (DK)	Flexyess, 0,02 mg/3 mg, filmovertrukne tabletter
Estonia (EE)	Yvidually, 0,02 mg/ 3 mg õhukese polümeerikattega tabletid
Finland (FI)	Flexyess 0,02 mg/3 mg tabletti, kalvopäällysteinen
France (FR)	Flexyess 0,02 mg / 3 mg, comprimé pelliculé
Germany (DE)	Flexyess 0,02 mg/3 mg Filmtabletten
Greece (EL)	Flexyess 0,02 mg/3 mg επικαλυμμένα με λεπτό υμένιο δισκία
Hungary (HU)	Flexyess 0,02 mg/3 mg filmtabletta
Iceland (IS)	Flexyess, 0,02 mg/3 mg, filmuhúðaðar töflur
Ireland (IE)	Flexyess 0.02 mg/3 mg film-coated tablets
Italy (IT)	Yvidually 0,02 mg/3 mg compresse rivestite con film
Latvia (LV)	Yvidually 0,02 mg/3 mg apvalkotās tabletes
Lithuania (LT)	Flexyess 0,02 mg/3 mg plėvele dengtos tabletės
Luxembourg (LU)	Flexyess 0,02 mg/3 mg, comprimés pelliculés
Malta (MT)	Flexyess 0.02 mg / 3 mg film-coated tablets
The Netherlands (NL)	Yvidually 0,02 mg/3 mg, filmomhulde tabletten
Norway (NO)	Flexyess, 0,02 mg/3 mg, tabletter, filmdrasjerte
Poland (PL)	Flexyess, 0,02 mg/3 mg, tabletki powlekane
Portugal (PT)	Flexyess 3 mg + 0,02 mg comprimido revestido por película
Romania (RO)	Yvidually 0,02 mg/3 mg, comprimate filmate
Slovak Republic (SK)	Flexyess, 0,02 mg/3 mg filmom obalená tableta
Slovenia (SI)	Flexyess 0,02 mg/ 3 mg filmsko obložene tablete
Spain (ES)	Flexyess 0,02 mg/ 3 mg comprimidos recubiertos con película
Sweden (SE)	Flexyess, 0,02 mg/3 mg,, filmdragerade tabletter
United Kingdom (UK)	Flexyess 0.02 mg / 3 mg film-coated tablets

This leaflet was last approved in To be inserted upon approval