Package leaflet: Information for the user

Drovelis® 3 mg/14.2 mg film-coated tablets
drospirenone/estetrol

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Important things to know about combined hormonal contraceptives (CHCs):
- They are one of the most reliable reversible methods of contraception if used correctly.
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 'Blood clots').

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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Drovelis is and what it is used for

Drovelis is a contraceptive pill that is used to prevent pregnancy.
- The 24 pink film-coated tablets are active tablets that contain a small amount of two different female hormones, namely estetrol and drospirenone.
- The 4 white film-coated tablets are inactive tablets that do not contain hormones and are called placebo tablets.
- Contraceptive pills that contain two different hormones, like Drovelis, are called 'combination' or 'combined' pills. They work together to prevent ovulation (release of an egg from the ovary) and to reduce the chance of any released egg being fertilised and making you pregnant.

2. What you need to know before you take Drovelis

General notes
Before your start taking Drovelis, you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see section 2 'Blood clots'.

Before you can begin taking Drovelis, 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 taking the pill, or where the reliability of the pill may be decreased. In such situations, you should not have sexual intercourse 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 the pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

Drovelis, like other hormonal contraceptives, does not prevent against human immunodeficiency virus (HIV) infection (acquired immunodeficiency syndrome, AIDS) or any other sexually transmitted disease.

Do not take Drovelis
You should not take Drovelis if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- If you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots');
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage;
  - very high blood pressure;
  - a very high level of fat in the blood (cholesterol or triglycerides);
  - a condition known as hyperhomocysteinaemia;
- if you have (or have ever had) a type of migraine called 'migraine with aura';
- if you have (or have ever had) a tumour in the liver (benign or malignant);
- if you have (or have ever had) a 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) 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 estetrol or drospirenone, or any of the other ingredients of this medicine (listed in section 6).

If any of these conditions appear for the first time while using Drovelis, stop taking it immediately and tell your doctor. In the meantime, use a non-hormonal contraceptive. See also 'General notes' in section 2 above.

Warnings and precautions
Talk to your doctor or pharmacist before taking Drovelis.

When should you contact your doctor?

Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clots' section below).

For a description of the symptoms of these serious side effects please go to 'How to recognise a blood clot'.

Tell your doctor if any of the following conditions apply to you
If the condition develops, or gets worse while you are taking Drovelis, you should also tell your doctor:

- if a close relative has or has ever had breast cancer;
- if you have hereditary or acquired angioedema. Medicines containing oestrogens may induce or worsen symptoms of angioedema. 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;
- if you have a liver disease or the gallbladder disease;
- if you have a kidney disease;
- if you have diabetes;
- if you have depression;
- if you have epilepsy (see section 2 'Other medicines and Drovelis');
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (SLE – a disease affecting your natural defence system);
- if you have haemolytic uraemic syndrome (HUS – a disorder of blood clotting causing failure of the kidneys);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- if you need an operation, or you are off your feet for a long time (see section 2 'Blood clots');
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Drovelis;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins;
- if you have or have ever had chloasma (a discolouration of the skin especially of the face or neck known as 'pregnancy patches'). In this case, avoid direct exposure to sunlight or ultraviolet light.
- 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]).

BLOOD CLOTS

Using a combined hormonal contraceptive such as Drovelis increases your risk of developing a blood clot compared with not using one. In rare cases, a blood clot can block blood vessels and cause serious problems.

Blood clots can develop

- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to Drovelis is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?

- swelling of one leg or along a vein in the leg or foot especially when accompanied by:
  - pain or tenderness in the leg which may be felt only when standing or walking
  - increased warmth in the affected leg
  - change in colour of the skin on the leg e.g. turing pale, red or blue
	Deep vein thrombosis

- sudden unexplained breathlessness or rapid breathing; - sudden cough without an obvious cause, which may bring up blood; - sharp chest pain which may increase with deep breathing; - severe light headedness or dizziness; - rapid or irregular heartbeat; - severe pain in your stomach; If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	Pulmonary embolism
Symptoms most commonly occur in one eye: - immediate loss of vision or painless blurring of vision which can progress to loss of vision;	Retinal vein thrombosis (blood clot in the eye)
- chest pain, discomfort, pressure, heaviness; - sensation of squeezing or fullness in the chest, arm or below the breastbone; - fullness, indigestion or choking feeling; - upper body discomfort radiating to the back, jaw, throat, arm and stomach; - sweating, nausea, vomiting or dizziness; - extreme weakness, anxiety, or shortness of breath; - rapid or irregular heartbeats.	Heart attack
- sudden weakness or numbness of the face, arm or leg, especially on one side of the body; - sudden confusion, trouble speaking or understanding; - sudden trouble seeing in one or both eyes; - sudden trouble walking, dizziness, loss of balance or coordination; - sudden, severe or prolonged headache with no known cause; - loss of consciousness or fainting with or without seizure; Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Stroke

- swelling and slight blue discolouration of an extremity; - severe pain in your stomach (acute abdomen).	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?
- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?
The risk of developing a blood clot in a vein is highest during the first year of taking combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same medicine or a different medicine) after a break of 4 weeks or more. After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.
When you stop Drovelis your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?
The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.
The overall risk of a blood clot in the leg or lung (DVT or PE) with Drovelis is small.
- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains low-dose ethinylestradiol (<50 microgram ethinylestradiol) combined with levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- It is not yet known how the risk of a blood clot with Drovelis compares to the risk with a combined hormonal contraceptive that contains levonorgestrel.
- The risk of having a blood clot will vary according to your personal medical history (see 'Factors that increase your risk of a blood clot' below).

	Risk of developing a blood clot in a year
Women who are **not using** a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing low-dose ethinylestradiol(<50 microgram ethinylestradiol) combined with **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10,000 women
Women using Drovelis	Not yet known

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with Drovelis is small but some conditions will increase the risk. Your risk is higher:
- if you are very overweight (body mass index or BMI over 30 kg/m^2);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50 years). In this case you could have a hereditary blood clotting disorder;

- if you need to 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 cast. The use of Drovelis may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Drovelis ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.
Air travel (> 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.
It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Drovelis needs to be stopped.
If any of the above conditions change while you are using Drovelis, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?
Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery
It is important to note that the risk of a heart attack or stroke from using Drovelis is very small but can increase:
- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Drovelis, you are advised to stop smoking. If you are unable to stop smoking and are older than 35 years your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immeddiate family has had a heart attack or stroke at a young age (less than about 50 years). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using Drovelis, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

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 tumours are detected more in women on combination pills because they are examined by their doctor more often. After stopping the combination pill, the increased risk gradually reduces. It is important to check your breasts regularly 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 ‘Warnings and precautions’).

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

Cervical cancer is caused by an infection with the human papilloma virus (HPV). It has been reported to occur more often in women using the pill for more than 5 years. It is unknown if this finding is due to the use of homonal contraceptives or to other factors, such as difference in sexual behaviour.

Psychiatric disorders
Some women using hormonal contraceptives including Drovelis have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Bleeding between periods
Your period will normally start while you are taking the white placebo tablets in the Drovelis pack. During the first few month that you are taking Drovelis, you may have unexpected bleeding (bleeding outside the placebo days). Mostly this bleeding is mild and usually not requiring any sanitary protection. 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 you must do if no bleeding occurs during the placebo days
If you have taken all the pink active 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. Keep taking Drovelis as usual.
If you have not taken all the tablets correctly, or if the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Only start the next strip if you are sure that you are not pregnant. See also in section 3 'If you vomit or have severe diarrhoea' or in section 2 'Other medicines and Drovelis'.

Children and adolescents
Drovelis is only indicated after menarche (the first menstrual period).

Other medicines and Drovelis
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you take Drovelis. They can tell you if you need to take additional contraceptive precautions (for example using condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.
Some medicines can have an influence on the blood levels of Drovelis and can make it less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used for the treatment of:
- epilepsy (e.g. barbiturate, carbamazepine, phenytoin, primidone, felbamate, oxcarbazepine, topiramate);
- tuberculosis (e.g. rifampicin);
- HIV and hepatitis C virus (HCV) infections (e.g. so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as, ritonavir, nevirapine, efavirenz);
- fungal infections (e.g. griseofulvin);
- high blood pressure in the blood vessels in the lungs (e.g. bosentan).

The herbal product St. John's wort (*Hypericum perforatum*) may also stop Drovelis from working properly. If you want to use herbal products containing St. John's wort while you are already using Drovelis you should consult your doctor first.

If you are taking these medicines or herbal products that might make Drovelis less effective, a barrier contraceptive method should also be used. The barrier method must be used during the whole time of the concomitant medicine therapy and for 28 days after its discontinuation If the concomitant medicine therapy runs beyond the end of the pink active tablets in the current pack, the white placebo tablets must be discarded and the next pack of Drovelis should be started right away.

If long-term treatment with the above mentioned medicines is necessary, you should use non-hormonal contraceptive methods. Ask your doctor or pharmacist for advice.

Drovelis may influence the effect of other medicines, e.g.:
- ciclosporin (medicine used for the treatment of suppression of tissue rejection following transplant surgery);
- lamotrigine (medicine used for the treatment of epilepsy).

The HCV combination therapeutic regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin as well as regimen glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. Drovelis contains estetrol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Drovelis with these HCV combination therapeutic regimens. Your doctor will advise you.

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

Laboratory tests
If you are having any blood or urinary test, tell your doctor that you are using Drovelis as it may affect the results of some tests.

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

Pregnancy and breast-feeding
Drovelis must not be taken by women who are pregnant, or think they may be pregnant.
If you become pregnant while taking Drovelis you should stop taking Drovelis immediately and contact your doctor.

If you want to become pregnant, you can stop taking Drovelis at any time (see section 3 'If you stop taking Drovelis').

Drovelis is not recommended during breast-feeding. If you wish to take the pill while breast-feeding, you should contact your doctor.

Driving and using machines
Drovelis has no or negligible effect on the ability to drive and use machines.

Drovelis contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
The pink active tablet contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Drovelis

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

When and how to take the tablets
The Drovelis blister contains 28 film-coated tablets: 24 pink active tablets with the active substances (number 1-24) and 4 white placebo tablets without active substances (number 25-28).
Each time you start a new blister of Drovelis, take the number 1 pink active tablet (see 'Start'). Choose from the 7 weekday stickers, the one that begins with your starting day. For example, if you start on a Wednesday, use the day label sticker that starts with 'Wed'. Place it in the frame on the front of the

blister card on the "⇨" symbol. Each day will line up with a row of pills. This allows you to check whether you took your daily tablet.

Take one tablet each day at about the same time, with some water if necessary.

Follow the direction of the arrows on the blister, so take the pink active tablets first and then the white placebo tablets.

Your period will start during the 4 days that you take the white placebo tablets (so-called withdrawal bleeding). Usually it will start 2 to 4 days after the last pink active tablet intake and may not have finished before the next blister is started.
Start taking your next blister immediately after the last white placebo tablet, even if your period has not finished. This means that you will always start a new blister on the same day of the week, and also that you have your period on roughly the same days each month.

Some users may not have their period every month during the intake of the white placebo tablets. If you have taken Drovelis every day according to these instructions, it is unlikely that you are pregnant.

Starting your first pack of Drovelis

If you have not used a contraceptive with hormones in the previous month
Begin with Drovelis on the first day of the cycle (that is the first day of your period). If you start Drovelis on the first day of your menstruation 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 of tablet-taking.

Changing from a combined hormonal contraceptive, or combined contraceptive vaginal ring or patch
You can start Drovelis preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill finish (or after the last inactive 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 Intra-Uterine Device [IUD])
You may switch any day from the progestogen-only pill (from an implant or an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 consecutive days of tablet-taking.

After a miscarriage or an artificial abortion
Follow the advice of your doctor.

After having a baby
You can start Drovelis between 21 and 28 days after having a baby. If you start later than day 28, you must use a barrier method (for example, a condom) during the first 7 days of Drovelis use. If, after having a baby, you have had sex before starting Drovelis, 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 Drovelis (again) after having a baby
Read the section on "Breast-feeding".

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

If you take more Drovelis than you should
There are no reports of serious harmful results of taking too many Drovelis tablets.
If you take several tablets at once, then you may feel sick or vomit or bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

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

If you forget to take Drovelis
The last 4 white tablets of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of Drovelis. Throw away the forgotten white placebo tablet.

If you miss a **pink, active tablet** (tablets 1-24 of your blister-strip), you must do the following:

- if you are **less than 24 hours late** taking a pink active tablet, the protection against pregnancy is not reduced. Take the tablet as soon as possible and then take the following tablets again at the usual time.

- if you are **more than 24 hours late** taking a pink active tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a pink active tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules (see also the diagram):

More than one tablet forgotten in this strip:
Contact your doctor.

One pink active tablet forgotten between days 1-7
Take the forgotten tablet as soon as possible, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use extra precautions, for example, a condom, for the next 7 days while taking the tablets correctly. If you have had sex in the week before forgetting the tablet you must realize that there is a risk of a pregnancy. In that case, contact your doctor.

One pink active tablet forgotten between days 8-17
Take the forgotten tablet as soon as possible, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

One pink active tablet forgotten between days 18-24
You can choose between two possibilities:

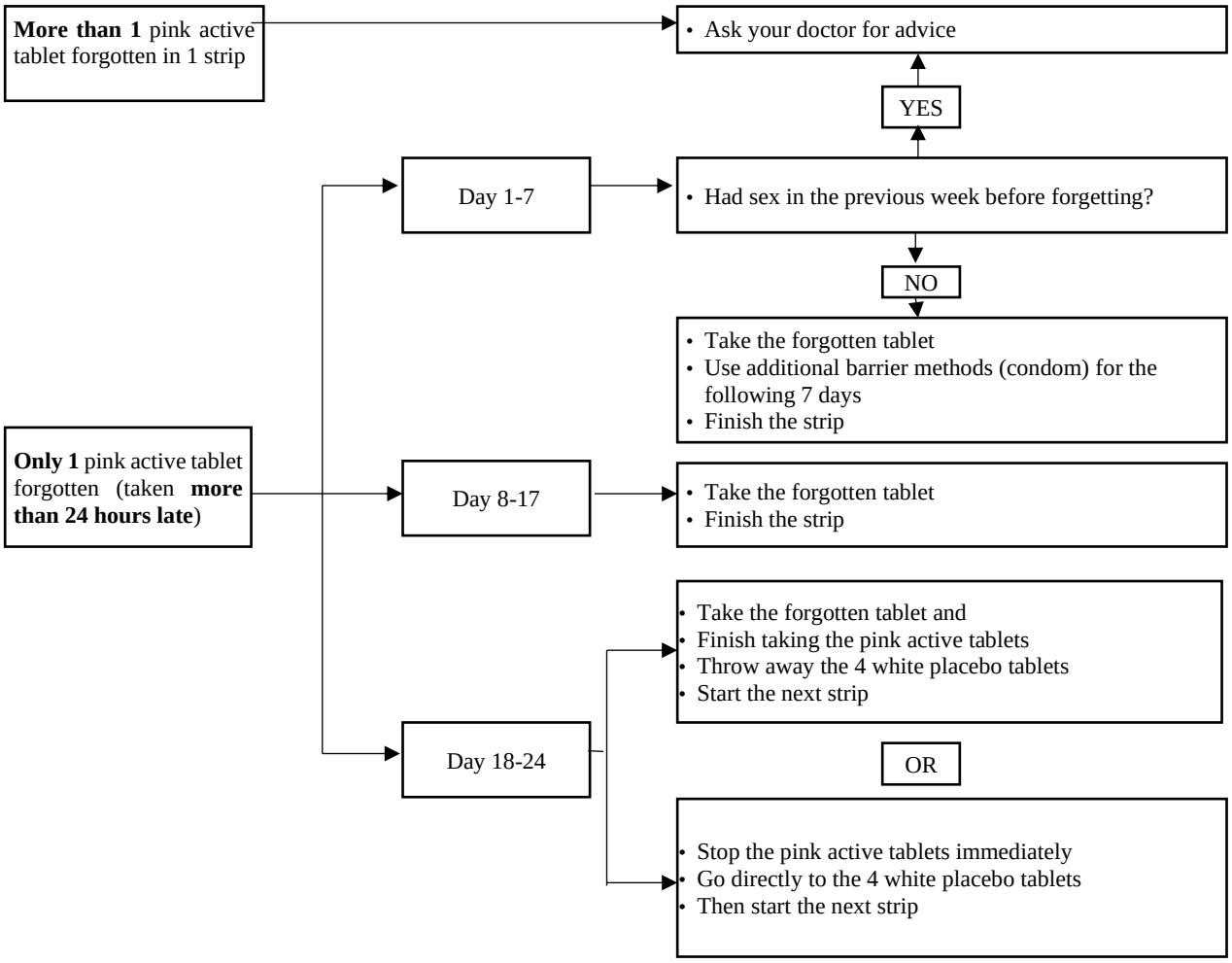
1. Take the forgotten tablet as soon as possible, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the white placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different).
   Most likely, you will have a period at the end of the second strip - while taking the white placebo tablets - but you may have light or menstruation-like bleeding during the second strip.

2. You can also stop the pink active tablets and go directly to the 4 white placebo tablets. Before taking the white placebo tablets, record the day on which you forgot your tablet. The placebo period should not exceed 4 days. If you want to start a new strip on the day you always start, take the white placebo tablets for less than 4 days.

If you follow one of these two recommendations, you will remain protected against pregnancy.

If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the placebo days, this may mean that you are pregnant. You must contact your doctor before you start the next strip.

Schedule if you are more than 24 hours late taking pink active tablets



More than one tablet forgotten in this strip
Follow the advice of your doctor.

If you vomit or have severe diarrhoea
If you vomit within 3-4 hours of taking a pink active 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, you must take another pink active tablet from a reserve strip 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, you should follow the advice given under 'If you forget to take Drovelis'.

Delaying your period: what you need to know
Even if it is not recommended, you can delay your period by not taking the white placebo tablets from the 4th row and going straight to a new strip of Drovelis and finishing it. You may experience light or menstruation-like bleeding while using this second strip. Finish this second strip by taking the 4 white placebo tablets. Then start your next strip. You might ask your doctor for advice before deciding to delay your menstrual period.

If you want to change the starting day of your period
If you take the tablets according to the instructions, then your period will begin during the placebo days. If you have to change this day, reduce the number of placebo days – when you take the white placebo tablets – but never increase them (4 is the maximum). For example, if you start taking the white placebo tablets on Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new blister 3 days earlier than usual. You may not have any bleeding during the shortened

period of white placebo tablet intake. While using the next blister you may have some spotting (drops or flecks of blood) or breakthrough bleeding on pink active tablet -taking days.

If you are not sure what to do, speak with your doctor or pharmacist.

If you stop taking Drovelis
You can stop taking Drovelis at any time. If you do not want to become pregnant, first ask your doctor about other methods of birth control.
If you stop taking Drovelis because you want to get pregnant, it is best to wait until you have had a natural period before trying to become pregnant. This will help you to calculate the expected delivery date more easily.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Drovelis, please talk to your doctor.

An increased risk of blood clots in your veins (VTE) or blood clots in your arteries (ATE) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 'What you need to know before you take Drovelis'.

The followig side effects have been linked with the use of Drovelis:

Common (may affect up to 1 in 10 people):
- mood disorder and disturbance, libido disorder;
- headache;
- abdominal pain, nausea;
- acne;
- breast pain, painful periods, vaginal bleeding (during or outside periods, heavy irregular bleeding);
- weight fluctuation.

Uncommon (may affect up to 1 in 100 people):
- fungal infection, vaginal infection, urinary tract infection;
- changes in appetite (appetite disorder);
- depression, emotional disorder, anxiety disorder, stress, problems sleeping;
- migraine, dizziness, 'pins and needles', drowsiness;
- hot flush;
- abdominal (belly) swelling, vomiting, diarrhoea;
- hair loss, excessive sweating (hyperhidrosis), dry skin, rash, skin swelling;
- back pain;
- swollen breasts, lumps in the breast, abnormal genital bleeding, pain with intercourse, fibrocystic breast disease (presence of one or more cysts in a breast), heavy periods, no periods, menstrual disorders, premenstrual syndrome, contractions of the uterus, uterine or vaginal bleeding including spotting, vaginal discharge, vulvovaginal disorder (dryness, pain, odour, discomfort);
- fatigue, swelling of parts of your body e.g. ankles (oedema), chest pain, feeling abnormal;
- blood tests showing increased liver enzymes, changes in certain blood fats (lipids).

Rare (may affect up to 1 in 1,000 people):
- breast inflammation;
- benign breast mass;

- hypersensitivity (allergy);
- fluid retention, increased potassium levels in the blood;
- nervousness;
- forgetfulness;
- dry eye, visual blurring, visual impairment;
- giddiness;
- high or low blood pressure, inflammation of a vein with the formation of a blood clot (thrombophlebitis), varicose vein;
- constipation, dry mouth, indigestion, lip swelling, flatulence, bowel inflammation, gastric reflux, abnormal bowel contractions;
- allergic skin reactions, golden brown pigment patches (chloasma) and other pigmentation disorders, male pattern hair growth, excessive hair growth, skin conditions such as dermatitis and itchy dermatitis, dandruff and oily skin (seborrhoea) and other skin disorders;
- muscle and joint cramps, pain and discomfort;
- urinary tract pain, abnormal urine smell;
- pregnancy that occurs outside the womb (ectopic pregnancy);
- ovarian cyst, increased spontaneous milk flow, pelvic pain, breast discolouration, bleeding during intercourse, endometrial disorders, nipple disorders, abnormal uterine bleeding;
- malaise and feeling generally unwell, increase in body temperature, pain;
- incease in blood pressure, changes in blood tests (abnormal kidney function test, increased blood potassium, increased blood glucose, decreased haemoglobin, decresed iron stores in blood, blood in urine);
- harmful blood clots in a vein for example:
  - in a leg or foot (i.e. DVT)
  - in a lung (i.e. PE)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - blood clots in the liver, stomach/intestine, kidneys or eye

  The chance of having a blood clot may be higher if you have any other condition that increase this risk (see section 2 for more information on the conditions that increase the risk for blood clots and the symptoms of a blood clot).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Drovelis

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 blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Drovelis contains
The active substances are drospirenone and estetrol.
Each pink active tablet contains 3 mg drospirenone and estetrol monohydrate equivalent to 14.2 mg estetrol.
Each white placebo tablet does not contain active substances.

The other excipients are:

Pink active film-coated tablets:
Tablet core:
Lactose monohydrate (see section 2 'Drovelis contains lactose and sodium'), sodium starch glycolate (see section 2 'Drovelis contains lactose and sodium '), maize starch, povidone K30, magnesium stearate (E470b).
Tablet coating:
Hypromellose (E464), hydroxypropylcellulose (E463), talc (E553b), cottonseed oil, hydrogenated, titanium dioxide (E171), iron oxide red (E172).

White placebo film-coated tablets:
Tablet core:
Lactose monohydrate (see section 2 'Drovelis contains lactose and sodium'), maize starch, magnesium stearate (E470b).
Tablet coating:
Hypromellose (E464), hydroxypropylcellulose (E463), talc (E553b), cottonseed oil, hydrogenated, titanium dioxide (E171).

What Drovelis looks like and contents of the pack
The active film-coated tablets are pink, 6 mm diameter, round, biconvex with a drop-shaped logo embossed on one side.
The placebo film-coated tablets are white to off-white, 6 mm diameter, round, biconvex with a drop-shaped logo embossed on one side.

Drovelis is presented in blisters of 28 film-coated tablets (24 pink active tablets and 4 white placebo tablets) packed in a carton. In addition to the blister(s), the Drovelis box contains an etui-storage bag and 1, 3, 6, or 13 self-adhesive sticker(s) marked with days of the weeks. The numbers of self-adhesive stickers depend on the number of blisters.

Pack sizes: 28 (1 × 28), 84 (3 × 28), 168 (6 × 28) and 364 (13 × 28) film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest
Hungary

Manufacturer
Haupt Pharma Münster GmbH
Schleebrüggenkamp 15
48159 Münster
Germany

Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest
Hungary

This leaflet was last revised in January 2025.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.