Package leaflet: Information for the user
MINESSE 60 micrograms/15 micrograms, film-coated tablets

Gestodene/Ethinylestradiol

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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What MINESSE is and what it is used for

- MINESSE is an oral contraceptive pill and is used to prevent pregnancy.
- Each of the 24 pale yellow tablets contains a small amount of two different female hormones, namely gestodene and ethinylestradiol.
- The 4 white tablets contain no active substances and are called placebo tablets.
- Contraceptive pills that contain two hormones are called "combination" pills.

2. What you need to know before you take MINESSE

General notes

Before you can begin taking MINESSE, 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.

Before you start using MINESSE 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").

In this leaflet, several situations are described where you should stop using MINESSE, or where the reliability of MINESSE may be decreased. In such situations you should either not have 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 MINESSE alters the monthly changes of the body temperature and of the cervical mucus.

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

Do not take MINESSE

You should not use MINESSE 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 are allergic to gestodene or ethinylestradiol or any of the other ingredients of this medicine (listed in section 6).
- 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 ever had a disorder of certain blood vessels of the heart (coronary arteries);
- 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 benign (called focal nodular hyperplasia or hepatic adenoma) or malignant tumour of the liver or if you have recently had a liver disease. In those cases, your doctor will ask you to stop taking the tablets until your liver is working normally;
- If you have vaginal bleeding of unknown cause;
- If you have breast cancer or cancer of the womb or a cancer that is sensitive to female sex hormones or if you are suspected of having such cancers.
- If you have Hepatitis C and are taking certain anti-viral medicinal products such as ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section 'Other medicines and MINESSE').

Warnings and precautions

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 clot' (thrombosis) 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 using MINESSE, you should also tell your doctor.

- If a blood test has shown that you have a high level of sugar, a high level of cholesterol and fats or a high level of prolactin (hormone that stimulates milk production).
- If you are obese;
- If you have a benign breast tumour or if a close relative has ever had breast cancer;

- If you have a disease of the uterus (uterine dystrophy);
- If you suffer from epilepsy (see also 'Taking or using other medicines');
- If you suffer from migraine;
- If you have loss of hearing due to a disorder known as otosclerosis;
- If you suffer from asthma;
- 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 in 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 MINESSE;
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- If you have varicose veins;
- If you or a close relative (parents, grandparents, brothers, sisters…) has ever suffered from a disease with a tendency to develop blood clots (in the leg, lung or elsewhere, heart attack, stroke);
- If, during a pregnancy or when using another contraceptive pill, you had a skin condition which caused itching and red patches and blisters (herpes gestationis);
- If you have had patches of discolouration on your face (chloasma) during pregnancy or when using another contraceptive pill. In this case, avoid direct exposure to the sun while you are using MINESSE.
- If you have gallstones;
- If you suffer from heart, liver or kidney disease;
- If you suffer from depression;
- If you have high blood pressure;
- If you suffer from a disease known as chorea characterized by irregular, sudden, involuntary movements;
- If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

Psychiatric disorders
Some women using hormonal contraceptives including MINESSE 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.

Do not hesitate to ask your doctor or pharmacist for advice if you have any doubts about the use of MINESSE.

BLOOD CLOTS
Using a combined hormonal contraceptive such as MINESSE 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 MINESSE 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. turning 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	Stroke

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.	
• 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 a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) 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 MINESSE 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 MINESSE 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 levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains gestodene such as MINESSE between about 9 and 12 women will develop a blood clot in a year.
- 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 **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10,000 women
Women using MINESSE	About 9-12 out of 10,000 women

Factors that increase your risk of a blood clot in a vein

The risk of a blood clot with MINESSE is small but some conditions will increase the risk. Your risk is higher:

- If you are very overweight (body mass index or BMI over 30kg/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). 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 MINESSE may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop MINESSE 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 MINESSE needs to be stopped.

If any of the above conditions change while you are using MINESSE, 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 MINESSE is very small but can increase:

- With increasing age (beyond about 35 years);
- **If you smoke.** When using a combined hormonal contraceptive like MINESSE you are advised to stop smoking. If you are unable to stop smoking and are older than 35 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 immediate family has had a heart attack or stroke at a young age (less than about 50). 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 MINESSE, 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.

MINESSE and cancer

Breast cancer has been detected slightly more often in women using combination pills, but it is not known whether this is caused by the pill. It is possible that these women were simply examined more thoroughly and more frequently, meaning that the breast cancer was detected earlier.
In women using combination pills for a relatively long time, studies have reported cases of cervical cancer. It is currently unknown whether it is caused by the pill or connected with sexual behaviour (e.g. more frequent changes of partner) and other factors.

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

Bleeding between periods

During the first few months that you are taking MINESSE, you may have unexpected bleeding (bleeding outside the placebo days). If this bleeding lasts longer than a few months, or if it begins after some months, your doctor must investigate the cause.

What you must do if no bleeding occurs in the placebo days

If you have taken all the pale yellow 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.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next blister pack until you are sure that you are not pregnant.

If you have no bleeding after you stop taking MINESSE

When you stop taking MINESSE it may take some time for your periods to return. If this continues for a prolonged time please see your doctor.

Other medicines and MINESSE

Always tell your doctor which medicines or herbal products you are already using including any medicines obtained without a prescription. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use MINESSE. They can tell you if you need to take

additional contraceptive precautions (for example condoms) and if so, for how long.

Some medicines can have an influence on the blood levels of MINESSE, can make it **less effective in preventing pregnancy** and can cause unexpected bleeding.

These include:
- medicines used for treatment of:
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
  - epilepsy (e.g. phenobarbital, phenytoin, primidone, carbamazepine, topiramate, felbamate)
  - tuberculosis (e.g. rifabutin, rifampicin)
  - fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole)
  - bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
  - certain heart diseases, high blood pressure (calcium channel blockers e.g. verapamil diltiazem)
  - arthritis, arthrosis (etoricoxib)
  - sleep disorders (modafinil)
  - the herbal remedy St. John's wort, which is used to treat certain types of depression
  - grapefruit juice

Troleandomycin may increase the risk for intrahepatic cholestasis (retention of bile in the liver) during co-administration with combined oral contraceptives (COCs).

MINESSE may **influence the effect** of other medicines, e.g.
- lamotrigine
- cyclosporine
- theophylline
- tizanidine

Do not use MINESSE if you have Hepatitis C and are taking certain Hepatitis C medicinal products such as those containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir as these products may cause increases in liver function blood test results (increase in ALT liver enzyme).
Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.
MINESSE can be restarted approximately 2 weeks after completion of this treatment. See section Do not take MINESSE.

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

Pregnancy
If you are pregnant, the doctor has no reason to prescribe any contraception.

If you discover that you are pregnant while taking MINESSE, stop taking this pill and consult your doctor.
If you are planning a pregnancy, tell your doctor.

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

Breast-feeding
It is not recommended to use MINESSE if you are breast-feeding.

If you want to breast-feed, your doctor will recommend you a suitable form of contraception.

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

Driving and using machines

The effect of MINESSE on the ability to drive or operate machinery has not been studied. MINESSE is not likely to impact your ability to drive or operate machinery. Dizziness has been reported as a side-effect. If you experience dizziness do not drive or operate machinery until it has resolved.

MINESSE contains lactose.
If you suffer from intolerance to certain sugars, consult your doctor before taking MINESSE.

3. How to take MINESSE

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

Dosage
- Begin taking MINESSE with the tablet number 1 which is located next to the word "START".
- Perforate the empty cell in the centre of the blister pack corresponding to the day of the week on which you have taken the first tablet. This will be the start day for every new blister pack. This will also be the day of the week you will take tablets number 8, 15 and 22 with a coloured border. This will help you to check that you are taking the tablets correctly.
- Each blister pack contains 28 tablets. Take one pill at the same time every day, on 28 consecutive days following the direction indicated by the arrows without fail as follows: take one pale yellow active tablet on each of the first 24 days and then one white placebo tablet on each day of the last 4 days.
- After taking the last tablet, continue taking MINESSE the following day starting another blister pack with no free interval between the blisters. You will always start a new blister pack on the same day of the week. As there are no breaks in taking the medication it is important that you already have the next blister pack ready before finishing one.
- Bleeding usually starts two to three days after you have taken the last pale yellow tablet of the blister pack and may not have finished before the next blister pack is started.

Method and route of administration
Swallow each tablet with a large glass of water.

If you have not used a contraceptive with hormones in the previous month
Take the first tablet on the first day of your period.

If you are changing from another contraceptive pill
Finish the blister pack you are on (if your present pill pack also contains hormone-free tablets, do not take them). Then start the MINESSE blister pack the next day without leaving any pill-free break.

If you were using a progestogen-only method (progestogen-only pill, an injectable method or an implant)
- changing from a progestogen-only pill: you can start MINESSE at any time during your menstrual cycle, the day after stopping the progestogen-only pill
- changing from an implant: start MINESSE the day the implant is removed
- changing from an injectable contraceptive: start MINESSE on the day your next injection was due

In all cases you must use a barrier contraceptive method (for example: a condom) during the first 7 days of taking the pill.

If you are starting MINESSE after a termination of pregnancy that occurred during the first trimester
You can normally start immediately but should follow the advice of your doctor before doing so.

If you are starting MINESSE after giving birth or after a termination of pregnancy that occurred during the second trimester
As with any other contraceptive pill, MINESSE should not be started less than 21 to 28 days after giving birth or after termination of pregnancy because you are at an increased risk of blood clots. If you start later,

you are advised to use a barrier contraceptive method during the first 7 days of taking the pill. If you have had sex before starting MINESSE be sure you are not pregnant or wait until your next period.

Always ask your doctor for advice.

Duration of use
Your doctor will tell you for how long you should use this pill.

If you take more MINESSE than you should
Overdose may produce gastrointestinal problems (e.g. nausea, vomiting, abdominal pain), breast tenderness, dizziness, drowsiness/fatigue and upset the menstrual cycle (bleeding).
Ask your doctor for advice.

If you forget to take MINESSE

If you forget to take a tablet there is a risk you could become pregnant

If you realise you have missed a pale yellow tablet within 12 hours of the time you normally take your tablet, take the missed tablet immediately and continue as normal, taking the next tablet at the usual time until the end of the blister pack.

If you realise you have missed a pale yellow tablet more than 12 hours after you normally take it, there is a risk you could become pregnant. In this case:
- take the last missed tablet immediately, even if this means taking 2 tablets on the same day
- continue taking the contraceptive until the end of the blister pack
- in addition, use a barrier method of contraception (condoms, spermicides...) for the next 7 days
- if this 7-day period extends beyond the last pale yellow tablet, discard any remaining tablets and start the next blister pack

If you have forgotten pale yellow tablet(s) in a blister pack and you do not have the expected bleeding that should start while taking the white tablets, you may be pregnant.
If you have forgotten one or more white tablets, you are still protected provided that the time between the last pale yellow tablet of the current blister pack and the first pale yellow tablet of the next blister pack is not greater than 4 days.
Ask your doctor for advice.

Vomiting or severe diarrhoea within 4 hours of taking the pill is similar to if you forget a tablet. After vomiting or diarrhoea, you must take another tablet from a reserve blister pack as soon as possible. If possible take it *within 12 hours* of when you normally take your pill. If this is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take MINESSE”.

If these episodes of vomiting or severe diarrhoea recur over several days, you should use a barrier method of contraception (condoms, spermicides...) until the beginning of the next blister pack. Ask your doctor for advice.

4. Possible side effects

Like all medicines, MINESSE 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 MINESSE, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism [VTE]) or blood clots in your arteries (arterial thromboembolism [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 Minesse.”

If you experience any of the following serious side effects, seek medical help immediately:

- A serious allergic reaction - **it is not known how frequently this occurs**
  Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat, skin rash, hives.

- Angioedema – **it is not known how frequently this occurs**
  Symptoms include swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section "Warnings and precautions").

- Retinal vein thrombosis – **it is not known how frequently this occurs**
  - Symptoms most commonly occur in one eye
  - painless blurring of vision which can progress to loss of vision
  - immediate loss of vision

- Haemolytic uraemic syndrome (a condition which affects your blood and kidneys) – **it is not known how frequently this occurs**
  Symptoms include vomiting, diarrhoea (which may be bloody), fever, feeling weak, passing less urine than usual.

- Pancreatitis **- this occurs rarely** (may affect between 1 and 10 users in 10,000)
  Symptoms include severe upper abdominal pain which may spread to your back.

- Erythema multifome - **it is not known how frequently this occurs**
  Symptoms include a skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister. You may also have ulcers in the mouth, eyes or genitals and have a fever.

Very common (may affect more than 1 in 10 people):
- headache, including migraine
- abdominal pain
- breast pain
- breast tenderness
- very light or no periods

Common (may affect up to 1 in 10 people):
- a vaginal infection including vaginal thrush
- bleeding between periods
- altered mood swings including depression or altered sexual appetite
- nervousness or dizziness
- nausea, vomiting
- feeling bloated
- acne
- painful periods
- change in blood flow during your period
- changes to vaginal discharge or change to the cervix (ectropion)
- water retention in tissue or oedema (severe fluid retention)
- weight loss or gain
- skin rash
- hair loss

Uncommon (may affect up to 1 in 100 people):
- increased appetite
- decreased appetite
- excessive growth of body hair

- discoloured patches on the face (chloasma)
- changes in laboratory test results: increase in cholesterol, triglyceride levels or increased blood pressure
- discharge from the nipple
- increased breast size
- worsening of varicose veins

Rare (may affect up to 1 in 1,000 people):
- harmful blood clots in a vein or artery 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 conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

- liver or biliary disorders (such as hepatitis or abnormal function of the liver)
- gallbladder disease including gallstones or worsening of this condition

Not known: frequency cannot be estimated from the available data
- benign liver tumour (called focal nodular hyperplasia or hepatic adenoma) or malignant liver tumour
- worsening of an immune system disease (lupus), of a liver disease (porphyria) or of a disease known as chorea characterized by irregular, sudden, involuntary movements
- obstruction of the bile flow in the liver or worsening of this condition
- ischaemic bowel disease, possible aggravation of inflammatory bowel disease - symptoms include abdominal cramps and pain, diarrhoea (which may be bloody), weight loss.
- intolerance to a sugar called glucose
- contact lens intolerance
- abdominal cramps
- jaundice (yellowing of the skin or eyes)
- tender red lumps under the skin (erythema nodosum)
- inflammation of the optic nerve which can lead to partial or total loss of vision

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.

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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MINESSE

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

No particular 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 to protect the environment.

6. Contents of the pack and other information

What MINESSE contains

Pale yellow tablet:
The active substances are: 60 micrograms gestodene and 15 micrograms ethinylestradiol.
The other ingredients are: lactose monohydrate, microcrystalline cellulose, magnesium stearate, polacrilin potassium, polyethylene glycol 1450, purified water, montanglycol wax, Opadry Yellow [hydroxypropylmethylcellulose, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172)].

White tablet:
There is no active substance.
The other ingredients are: lactose monohydrate, microcrystalline cellulose, magnesium stearate, polacrilin potassium, polyethylene glycol 1500, purified water, montanglycol wax, Opadry White [hydroxypropylmethylcellulose, hydroxypropylcellulose, titanium dioxide (E171), polyethylene glycol].

What MINESSE looks like and contents of the pack

MINESSE comes in the form of film-coated tablets.

Each box contains 1, 3 or 6 blisterstrips, each containing 28 tablets (24 pale yellow active tablets with “60” embossed on one face and “15” on the other face of the tablet and 4 white inactive tablets). Each blister strip is packed inside an aluminium foil pouch together with a silica gel desiccant sachet. After opening each blister pouch the desiccant sachet can be disposed of.

Not all pack sizes may be marketed.

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Manufacturer
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Detailed information on this medicine is available on the website of: www.medicines.ie

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