

Package Leaflet: Information for the patient

ALESSE[®] 100 micrograms/20 micrograms film-coated tablets levonorgestrel/ethinylestradiol

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, 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 ALESSE is and what it is used for
2. What you need to know before you take ALESSE
3. How to take ALESSE
4. Possible side effects
5. How to store ALESSE
6. Contents of the pack and other information

1. What ALESSE is and what it is used for

ALESSE is a combined oral contraceptive pill for the prevention of pregnancy. It contains two different female hormones, levonorgestrel and ethinylestradiol.

Each of the 21 round pink tablets contains 100 micrograms of levonorgestrel and 20 micrograms ethinylestradiol.

2. What you need to know before you take ALESSE

Before you can start taking ALESSE your doctor will ask you some questions around your personal health history and that of your close relatives. Your doctor will also measure your blood pressure and may also carry out some other tests.

In this leaflet some situations are described where you should stop using ALESSE or where the reliability of ALESSE may be decreased and there is a higher risk of pregnancy. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions (e.g. use a condom or other barrier method). Do not use the rhythm or temperature methods. These methods can become unreliable because ALESSE alters the monthly changes in body temperature and cervical mucus.

ALESSE like other oral contraceptive products does not protect against HIV infection (AIDS) or any other sexually transmitted diseases

Do not take ALESSE:

- If you are allergic to either of the active substances (levonorgestrel or ethinylestradiol) or any of the other ingredients of this medicine (listed in section 6)
- If you have, or have ever had heart disease or diseases of the blood vessels, in particular;
 - a heart attack (myocardial infarction), a heart rhythm disorder or a heart valve disorder
 - a blood clot including in the legs (deep vein thrombosis) or in the lungs (pulmonary embolism) or a ruptured blood vessel in the brain (stroke), 'mini-stroke' or a general tendency to form blood clots (venous or arterial thrombosis)
 - chest pain caused by angina pectoris

- If you have high blood pressure not stabilised by treatment
- If you suffer from certain types of migraines (migraine with focal neurological symptoms)
- If you have breast cancer or cancer of the womb, or a type of cancer that is sensitive to female sex hormones, or you are suspected of having any of these cancers
- If you have vaginal bleeding of unknown cause
- If you have high levels of sugar in your blood (diabetes) associated with a disease of the blood vessels
- If you are pregnant or suspect you may be pregnant
- If you have or have ever had a benign or malignant tumour of the liver, or if you have recently had liver disease. In these cases your doctor will ask you to stop taking ALESSE until your liver is working properly again.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking ALESSE.

In some situations you may need to take special care when taking ALESSE or any other combined oral contraceptive. Your doctor will check you regularly. Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use. This risk increases with age and with the extent of smoking and is quite marked in women over 35 years of age. Women who use combined oral contraceptives should not smoke. Other methods of contraception should be considered for those women over 35 years old who smoke.

If any of the following conditions applies to you, you must tell your doctor before starting to take ALESSE. If any of the conditions listed below develops or gets worse while taking ALESSE, you must consult your doctor so that they can decide whether ALESSE is still suitable for you.

Tell your doctor if :

- You have high blood pressure
- You have high levels of cholesterol or abnormal levels of lipids (fats) in the blood (dyslipoproteinemia)- this is picked up in blood tests
- You are obese
- You have diabetes
- You have a disease of the heart valves or heart rhythm disorder (atrial fibrillation)
- You or a close relative (parent, brother or sister) has ever suffered from a disease with a tendency to develop blood clots (in the leg, lung or elsewhere in the body or have a history of heart attack or stroke)
- You have varicose veins or have suffered from inflammation of the superficial veins in your legs
- You experience any sudden unexplained changes in your vision
- You have gallstones, gallbladder disease or have problems caused by a blockage of the bile ducts (cholestasis) - this may cause intense itching
- You develop migraine for the first time or suffer worsening of existing migraine headaches
- You have or develop liver disease, jaundice, an inflamed pancreas or kidney disease
- You suffer from depression
- You have a loss of hearing due to a disorder known as otosclerosis
- You have had during a pregnancy or when using another contraceptive pill a skin condition which caused itching, red patches and blisters (herpes gestationis)
- You have had during a pregnancy temporary brown patches on your skin (chloasma). The pill can make this recur so you should avoid strong sunlight or sunbeds while taking ALESSE.
- You suffer from a disorder affecting your immune system (systemic lupus erythematosus)
- You suffer from a disease known as Sydenham's Chorea. The symptoms include irregular, sudden involuntary movements.
- You have ever had a blood disease associated with a kidney disease (haemolytic uremic syndrome)
- You have ever had a blood disease called porphyria
- You have ulcerative colitis or Crohn's disease (inflammation of the gut which causes pain in the abdomen, frequent diarrhoea and tiredness).

- You have a blood disease called sickle cell disease

If you have hereditary angioedema, products containing oestrogens may cause or worsen the symptoms of angioedema. 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 in breathing.

ALESSE and thrombosis (blood clots)

Venous thrombosis (blood clots)

The use of any combination pill, including ALESSE, increases a woman's risk of developing a venous thrombosis (formation of a blood clot in vessels) compared with a woman who does not take any (contraceptive) pill.

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

- with increasing age
- if you are overweight
- if one of your close relatives has developed a blood clot in a vessel at an early age
- with prolonged immobilization (for example, when you have your leg or legs in plaster or splints), major surgery, any surgery to the legs, major trauma. In these situations it is better to stop taking ALESSE (if the surgery is planned you should stop at least four weeks beforehand) and not to start again until two weeks after you are fully on your feet again.
- Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking a combined pill.

Arterial thrombosis (blood clots)

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

The risk of arterial thrombosis in users of combined pills increases:

- **If you smoke. You are strongly advised to stop smoking when you use ALESSE, especially if you are older than 35 years.**
- With increasing age even if you don't smoke
- if you have an increased fat content in your blood (cholesterol or triglycerides)
- if you are overweight
- if one of your close relatives has had a heart attack or stroke at a young age
- if you have high blood pressure
- if you have migraine
- if you have a problem with your heart (valve disorder, a disturbance of the heart rhythm)

Stop taking ALESSE and consult your doctor immediately or go to the emergency department of the nearest hospital if you experience possible signs of thrombosis, such as:

- any unusual, severe or long-lasting headache, or more frequent or severe migraine attack
- an increase in blood pressure
- severe pain and/or swelling in one of your legs
- sudden severe pain in the chest which may spread to the left arm
- difficulty breathing, sudden breathlessness
- sudden unusual cough with no obvious cause
- changes to your eyesight, partial or complete blindness, or double vision

- difficulty in speaking, or inability to speak
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness, strange feeling, or numbness in any part of your body
- sudden severe stomach ache

ALESSE and cancer

Breast cancer has been detected slightly more often in women using combined 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 combined 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 ALESSE, you may have unexpected bleeding (bleeding or spotting outside the tablet free week). If this bleeding lasts longer than a few months, or if it begins after some months, your doctor must investigate the cause.

What to do if no bleeding occurs in the tablet free week

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.

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.

Other medicines and ALESSE

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. There are some medicines that may interact with ALESSE.

Medicines can sometimes interfere with each other. If you receive treatment from any other doctor, nurse or qualified healthcare professional make sure they are aware that you are using ALESSE as a contraceptive. They can advise if it will be necessary to take any additional precautions (e.g. using a condom or other barrier contraceptive) while you are taking other medicines while you are taking ALESSE.

Some medicines can make ALESSE less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used for treatment of:

- HIV infections (ritonavir, nevirapine)
- epilepsy (e.g. phenobarbital, phenytoin, primidone, felbamate, carbamazepine, oxcarbazepine or topiramate)
- infections (e.g. rifabutin, rifampicin, griseofulvin, ampicilline or other penicillins or tetracycline)
- sleep disorders (modafinil)
- gout (phenylbutazone)
- the herbal remedy St. John's Wort (*Hypericum perforatum*), which is used to treat certain types of depression

If you have been told to take additional contraceptive precautions while taking any of the above medicines

follow your doctor's instructions carefully. If you need to take the medicine beyond the end of your current tablet pack, miss your tablet-free week and start the next pack straight away. In some cases you may need to continue to use additional barrier contraception for several weeks after you have stopped taking the medicine.

Alesse may interfere with the following medicines:

- Cyclosporin (to reduce the body's immune response)
- Lamotrigin (for epilepsy)

Taking an antibiotic medicine called troleandomycin may increase the risk for intrahepatic cholestasis (retention of bile in the liver) while taking the combined pill.

Taking a medicine called flunarazine used for preventing migraine may increase the risk of galactorrhoea. This is a condition where your breasts spontaneously leak milk when you have not been breastfeeding or recently had a baby.

Pregnancy

Do not take ALESSE if you are pregnant. If you think you may have become pregnant while using ALESSE tell your doctor immediately.

Breastfeeding

It is not recommended that you take the combined pill while you are breastfeeding as the hormones can affect your milk. If you wish to breastfeed, your doctor will be able to advise you on suitable alternative methods of contraception.

Always ask your doctor, nurse, or healthcare professional for advice before taking any medicine.

Driving and using machines

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

ALESSE contains lactose

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

3. How to use ALESSE

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

Each blister strip of ALESSE contains 21 tablets. Take your first tablet from the blister showing the correct day of the week. You must take one tablet every day, with water if necessary, at the same time each day until the pack is finished. You will then have a tablet free-week before you start your next pack of tablets. You will always start your next pack on the same day of the week.

During the tablet free week you will have bleeding similar to a period. This bleeding will usually start after two or three days, and may not finish before you start the next pack of tablets.

If this is the first time you are starting the pill or you have not used a hormonal contraceptive for the past month

Take the first tablet on the first day of your period.

Starting later than the first day of bleeding (from days 2-7 of the cycle) will mean you will have to use additional barrier contraception (e.g. condom) for the first 7 days.

If you are changing from another combined contraceptive pill

Changing from pills containing 21 tablets in each pack

Finish the pack of the current pill before starting ALESSE the next day without a break.

Changing from 'every day' pills containing 28 tablets in each pack

If your current pill contains any inactive tablets (placebo tablets), do not take these, and start ALESSE straight away the next day without leaving any tablet-free break.

If you are changing from a progestogen-only pill, an injectable method or an implant

- When changing from a progestogen-only pill you can start ALESSE at any time during your menstrual cycle, the day after stopping the progestogen-only pill
- When changing from an implant, start ALESSE the day after the implant is removed
- When changing from an injectable contraceptive start ALESSE on the day after your next injection was due

In all cases you must use a barrier contraceptive method during the first 7 days of taking the pill.

If you are starting ALESSE after a termination that occurred during the first trimester (three months) of pregnancy

You can start taking ALESSE immediately but should follow the advice of your doctor before doing so. No additional barrier contraception is needed.

If you are starting ALESSE after giving birth or after a termination of pregnancy that occurred during the second trimester

As with any other contraceptive pill, ALESSE should not be started less than 28 days after giving birth or after termination of a second trimester 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 ALESSE be sure you are not pregnant or wait until your next period.

Always ask your doctor for advice if you are not sure.

If you forget to take ALESSE

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

If you realise you have missed a 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 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 tablets until the end of the blister pack
- in addition, use a barrier method of contraception (e.g. condom) for the next 7 days
- if this 7-day period extends beyond the last tablet in the pack, start the next blister pack straight away without a tablet free break. You may have some spotting or bleeding while taking the second pack, this is nothing to worry about.

If you have forgotten one or more tablets in a blister pack and you do not have any bleeding in the tablet-free week, you may be pregnant and you should ask your doctor for advice.

If you have vomiting or diarrhoea

Vomiting or severe diarrhoea within 4 hours of taking the pill is similar to if you forget to take 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 above given under “*If you realise you have missed a tablet more than 12 hours after you normally take it*”.

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

How to delay a period

You can delay your period by starting another pack of ALESSE without any tablet-free week. You may have some spotting or bleeding while taking the second pack, this is nothing to worry about. You should have a normal bleed after finishing the second course of tablets.

If you take more ALESSE than you should

If you accidentally take more ALESSE than you should, you may have symptoms including gastrointestinal problems (e.g. nausea, vomiting, abdominal pain), breast tenderness, dizziness, drowsiness/fatigue and vaginal bleeding. These symptoms will reduce naturally as your body deals with the excess hormones. If you are worried ask your doctor for advice.

4. Possible side effects

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

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.
- **A blood clot in the eye - it is not known how frequently this occurs**
Symptoms include loss of vision, pain and swelling of the eye especially if sudden.
- **Haemolytic uremic 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 - it is not known how frequently this occurs**
Symptoms include severe upper abdominal pain which may spread to your back.
- **Erythema multiforme - 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.

Other side effects include:

Very common (may affect more than 1 in 10 people)

- Headache, including migraines
- Breakthrough bleeding and spotting
- Nausea
- Abdominal pain
- Painful periods

Common (may affect up to 1 in 10 people)

- Vaginal irritation and infection, including thrush
- Mood changes, including feeling depressed
- Decreased sexual feeling
- Feeling nervous
- Feeling dizzy
- Vomiting
- Diarrhoea
- Feeling bloated
- Acne (spots)
- Skin rash
- No periods (amenorrhoea)
- Changes in the amount of blood loss and length of periods
- Breast pain/tenderness or breast enlargement or discharge from the nipple
- Changes in your cervix which might get picked up during a smear test
- Fluid retention (e.g. getting swollen ankles)
- Increases or decreases in your weight
- Changes in levels of fats in your blood (picked up through blood tests)

Uncommon (may affect up to 1 in 100 people)

- Increased appetite
- Decreased appetite
- Hives (urticaria)
- Unusual hairiness (hirsutism)
- Hair loss
- Dark patches on your skin (you may have had these in a previous pregnancy)
- Increased blood pressure
- Gallstones
- Intolerance to a sugar called glucose
- Aggravation of varicose veins

Rare (may affect up to 1 in 1,000 people)

- Yellowing of the skin or eyes (jaundice caused by abnormal bile flow in the liver)
- Tender red lumps under the skin (erythema nodosum)

Not known: frequency cannot be estimated from the available data

- Benign or malignant cancer of the liver
- Worsening of an autoimmune condition called systemic lupus erythematosus
- Worsening of an inherited blood condition called porphyria
- Worsening of uncontrolled or jerky body movements (chorea)
- Inflammation of the optic nerve (symptoms include blurred vision and may lead to partial or complete loss of sight)
- Intolerance to contact lenses

- Gallbladder disease, or worsening of this condition
- Ischaemic or inflammatory bowel disease - symptoms include abdominal cramps and pain, diarrhoea (which may be bloody), weight loss
- Stomach cramps
- Vaginal discharge
- Decrease in folate levels in the blood

If you are at all worried about any new symptoms or other aspects of your health while taking ALESSE, please tell your doctor.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ALESSE

- Keep this medicine out of the sight and reach of children.
- Do not store above 25° C
- Do not use this medicine after the expiry date stated on the blister pack and the carton after EXP. The expiry date refers to the last day of that month.

If you stop taking ALESSE: 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 ALESSE contains

The active substances are 100 micrograms levonorgestrel and 20 micrograms ethinylestradiol.

The other ingredients are : lactose monohydrate, microcrystalline cellulose, polacrillin potassium, magnesium stearate, hydroxypropyl methylcellulose, macrogol 1500, titanium dioxide (E171), red iron oxide (E172).

What ALESSE looks like and contents of the pack

ALESSE tablets are packed in aluminium foil/pvc blister packs containing 21 round pink biconvex film coated tablets with 'W' embossed on one side and '912' embossed on the other.

Blister strips are contained in an outer cardboard carton or in a vinyl wallet inside a cardboard carton. Each blister strip is packed inside an aluminium foil pouch together with a silica gel desiccant sachet. After opening each blister pouch the desiccant can be disposed of.

Each pack may contain either:

- 1 x 21 tablets or
- 3 x 21 tablets or
- 6 x 21 tablets or
- 13 x 21 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pfizer Healthcare Ireland
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National Digital Park
Citywest Business Campus
Dublin 24
Ireland

Manufacturer

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Germany

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	ALESSE Film coated tablets
Spain	LOETTE Film coated tablets
Denmark	LOETTE

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