

VALETTE® (VAL·ette)

dienogest and ethinyloestradiol

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Valette. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Valette against the benefits they expect it will have for you.

If you have any concerns, or are unsure about taking this medicine, ask your doctor or pharmacist for more advice.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT VALETTE IS USED FOR

Valette is a combined oral contraceptive, commonly known as a 'birth control pill' or 'the Pill'.

Valette is used to prevent pregnancy.

It is also used to treat mild to moderate acne in women seeking oral contraception.

You may also experience the following benefits:

- more regular, and lighter periods potentially resulting in a decreased risk in anaemia (iron deficiency)
- a decrease in period pain
- reduction of greasiness in skin and hair

Some conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy, fibrocystic breast changes and cancer of the uterus (womb) and ovaries may be less common in women taking the Pill.

When taken correctly, it prevents you from becoming pregnant in several ways, including:

- inhibiting ovulation (egg release)
- changing the cervical mucus consistency, making it more difficult for the sperm to reach the egg

When the Pill is taken by women under close observation in clinical trials, it is more than 99% effective in preventing pregnancy. However, in real life the Pill is around 92% effective. This is because pills might be missed, or taken with medicines that may interfere with their effectiveness, or may not be absorbed due to vomiting and diarrhoea.

Like all oral contraceptives, Valette is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE VALETTE

When you must not take it

Do not take Valette if you have an allergy to:

- dienogest and/or ethinyloestradiol (the active ingredients in Valette)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take Valette if you are taking any of the following medicines:

- antiviral medicines which contain ombitasvir, paritaprevir, or dasabuvir, and combinations of these. These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus)

Do not take Valette if you have or have had a blood clot in:

- the blood vessels of the legs (deep vein thrombosis - DVT)
- the lungs (pulmonary embolism - PE)

- the heart (heart attack)
- the brain (stroke)
- other parts of the body

Do not take Valette if you are concerned about an increased risk of blood clots.

Blood clots are rare. Very occasionally blood clots may cause serious permanent disabilities, or may even be fatal.

You are more at risk of having a blood clot when you take the Pill. But the risk of having a blood clot when taking the Pill is less than the risk of having a blood clot during pregnancy.

Do not take Valette if you are concerned about an increased risk of blood clots because of age or smoking.

The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke. You should stop smoking when taking the Pill, especially if you are older than 35 years of age.

Do not take Valette if you have, or have had:

- angina (chest pain)
- mini-stroke (also known as TIA or transient ischaemic attack)
- migraine, accompanied by visual symptoms, speech disability, or weakness or numbness in any part of your body
- diabetes mellitus with blood vessel damage
- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- severe liver disease and your liver function has not returned to normal

- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- benign or malignant liver tumour
- unexplained vaginal bleeding

If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor.

In the meantime use non-hormonal (barrier) methods of contraception (such as condoms or a diaphragm).

Do not take Valette if you are pregnant or think you might be pregnant.

The possibility of pregnancy should be ruled out before starting Valette.

Do not give Valette to a child.

Do not take Valette after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take Valette if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- you smoke
- you or anyone in your immediate family has had blood clots in the legs (DVT) or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol

Tell your doctor if you have, or have had any of the following medical conditions:

- diabetes
- high blood pressure
- heart valve disorders or certain heart rhythm disorders
- inflammation of your veins (superficial phlebitis)
- varicose veins
- migraine

Ask your doctor to check if you:

- are overweight
- have high cholesterol or triglycerides
- have liver disease
- have gall bladder disease
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- have systemic lupus erythematosus (SLE – a disease affecting the skin all over the body)
- have haemolytic uraemic syndrome (HUS – a disorder of blood coagulation causing failure of the kidneys)
- have sickle cell disease
- have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called *herpes gestationis*, a neurological

disease called Sydenham's chorea)

- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid exposure to the sun or ultraviolet radiation
- have hereditary 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

If any of the above conditions appear for the first time, or recur or worsen while taking Valette, you should contact your doctor.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Valette is generally not recommended if you are breastfeeding.

Valette contains lactose.

If you have intolerance to some sugars, contact your doctor before you start taking Valette.

If you have not told your doctor about any of the above, tell him/her before you start taking Valette.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

There are some medicines that you must not take with Valette – see “*When you must not take it*”.

Some medicines/foods and Valette may interfere with each other. These include:

- medicines used to treat tuberculosis, such as rifampicin, rifabutin
- medicines used to treat epilepsy, such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- medicines used to treat HIV, such as ritonavir or nevirapine
- some medicines used to treat hepatitis C virus (HCV), such as boceprevir, telaprevir
- macrolide antibiotics (e.g. clarithromycin, erythromycin)
- medicines used to treat fungal infections, such as ketoconazole, itraconazole, voriconazole, fluconazole and griseofulvin
- medicines used to treat depression such as nefazodone, fluvoxamine
- antacids such as cimetidine
- blood pressure medication such as diltiazem, verapamil
- etoricoxib, an anti-inflammatory medicine used to treat pain
- tizanidine, melatonin or midazolam which are medicines that relax the body
- theophylline, a medicine that helps with breathing
- cyclosporin, an immunosuppressant medicine
- herbal medicines containing St John's Wort
- grapefruit juice

These medicines/foods may be affected by Valette, or may affect how well it works. Your doctor may need to alter the dose of your medicine, or prescribe a different medicine.

You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines with Valette and for some time after stopping them.

Your doctor will be able to advise you about how long you will need to use additional contraceptive methods.

Your doctor and pharmacist have more information on medicines that you need to be careful with or avoid while taking this medicine.

HOW TO TAKE VALETTE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, printed on the pharmacist label or in this leaflet, ask your doctor or pharmacist for help.

How to take it

Take one tablet daily at about the same time each day. You must take Valette every day regardless of how often you have sex. This will also help you remember when to take it.

Swallow the tablet whole with water.

It does not matter if you take it before or after food.

Each blister pack is marked with the days of the week.

Take your first tablet from the green area on the blister pack corresponding to the day of the week.

Follow the direction of the arrows on the blister pack until all the tablets have been taken.

A period should begin 2-3 days after starting to take the brown inactive tablets (last row) and may not have finished before the next pack is started

Always start a new blister pack on the same day of the week as your previous pack.

Taking Valette for the first time

If you are starting Valette after a natural cycle, and you have not used a hormonal contraceptive in the past month, start on the first day of your period, i.e. on the first day of your menstrual bleeding.

You may also start on days 2-5 of your period, but in that case make sure you also use additional barrier contraceptive precautions (e.g. condom) for the first 7 days of tablet-taking.

Your doctor will advise you when to start if you:

- are taking Valette after having a baby
- have had a miscarriage or an abortion

Changing from another contraceptive

Changing from a combined oral contraceptive:

Start taking Valette on the day after taking the last active tablet in your previous Pill pack. Bleeding may not occur until

the end of the first pack of Valette.

You can also switch to Valette after taking one or more inactive tablets in your previous Pill pack, but no later than the day after taking the last inactive tablet.

If you are not sure which were the active or inactive tablets in your previous Pill pack, ask your doctor or pharmacist. Your previous Pill pack may have different colour tablets to those of Valette.

Changing from a progestogen-only pill ('minipill'):

Stop taking the minipill on any day and start taking Valette at the same time the next day.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.

Changing from a progestogen-only injection, implant or intrauterine system (IUS):

Start taking Valette when your next injection is due, or on the day that your implant or IUS is removed.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.

Changing from a vaginal ring:

Start on the day of removal of the ring but at the latest when the next application would have been due.

Stopping Valette

You can stop taking Valette at any time. If you are considering becoming pregnant, it is

recommended that you begin taking a vitamin supplement containing folic acid. It is best that you start taking folic acid tablets before you stop taking Valette and not stop until your doctor advises this. Seek advice from your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

If you forget to take Valette

If you miss a tablet and take the missed tablet within 12 hours of missing it, you should still be protected against pregnancy.

If you are more than 12 hours late follow these detailed instructions.

For Valette to be most effective, white active tablets need to be taken uninterrupted for 7 days.

If you have been taking the white active tablets for 7 uninterrupted days and miss a white active tablet, take the missed tablet as soon as you remember, then go back to taking your medicine as you would normally, even if this means taking two tablets in one day.

You will not need to use additional barrier contraceptive precautions.

The chance of pregnancy after missing a white active tablet depends on when you missed the tablet. There is a higher risk of becoming pregnant if you miss a tablet at the beginning or end of a pack.

If after taking your missed tablet you have less than 7 days of white active tablets left in a row, you should finish the active tablets in your pack but skip the brown inactive tablets and start a

new pack with the white active tablets corresponding to the correct day of the week.

This is the best way to maintain contraceptive protection. However, you may not have a period until the end of the white active tablets of the second pack. You may have spotting or breakthrough bleeding on tablet-taking days.

If you have been taking the white active tablets for less than 7 days and miss a white active tablet, take the missed tablet as soon as you remember, then go back to taking your medicine as you would normally, even if this means taking two tablets in one day. In addition, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the next 7 days.

If you have had sexual intercourse during that time, there is a possibility of pregnancy and you may need emergency contraception.

If you forget to take more than one white active tablet, seek advice from your doctor or pharmacist about what to do.

If you have had sexual intercourse in the week before missing your tablets, there is a possibility of becoming pregnant.

If you forget to take a brown inactive tablet, take it as soon as you remember and take the next tablet at the usual time.

You should still be protected against pregnancy because the brown tablets do not contain any active ingredients.

Please refer to the diagram at the end of this leaflet for “Summary of advice if you missed an active tablet more than 12 hours ago”.

Ask your doctor or pharmacist to answer any questions you may have.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Valette.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take several white active tablets at once, you may feel sick or vomit or may bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

WHILE YOU ARE TAKING VALETTE

Things you must do

Tell any doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Have regular check-ups with your doctor.

When you are taking the Pill, your doctor will tell you to return for regular check-ups, including getting a Pap smear test. Your doctor will advise how often you need a Pap smear test. A Pap smear test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking Valette.

Stop taking Valette and see your doctor immediately if you notice possible signs of thrombosis. These include:

- an unusual cough
- severe pain or heaviness in the chest
- breathlessness
- any unusual, severe, or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your abdomen
- severe pain, swelling or discolouration in either of your legs

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking Valette.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have

your leg or legs in plaster or splints). In women who take the Pill, the risk may be higher.

Your doctor may tell you to stop taking the Pill several weeks before surgery, or at the time of immobilisation, and when you can start taking the Pill again. If you notice possible signs of a blood clot, stop taking the Pill and consult your doctor immediately.

Consult your doctor if you develop high blood pressure while taking Valette – you may be told to stop taking it.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you vomit within 3-4 hours or have severe diarrhoea after taking a white active tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.

If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor.

When taking these tablets for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill, usually after about 3 months.

If you have missed a period, but you have taken all your tablets, it is very unlikely that you are pregnant as long as:

- you have taken the white active tablets at the right time

- you have not been taking medicine(s) that may interfere with Valette
- you have not vomited or had severe diarrhoea during this cycle

If this is so, continue to take Valette as usual. If you have any concerns consult your doctor or pharmacist.

If you miss your period twice in a row, you may be pregnant even if you have taken the Pill correctly. Stop taking Valette and seek advice from your doctor. You must use a non-hormonal method of contraception (such as condoms or a diaphragm) until your doctor rules out pregnancy.

Valette will not protect you from HIV-AIDS or any other Sexually Transmitted Infections (STIs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.

To protect yourself from STIs, you will need to use additional barrier contraceptives (e.g. condoms).

Things you must not do

Do not take Valette to treat any other conditions, unless your doctor tells you to.

Do not give your medicine to anyone else.

Do not stop taking your medicine or change the dosage without checking with your doctor.

You may become pregnant if you are not using any other contraceptive and you stop taking Valette, or do not take a tablet every day.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Valette.

This medicine helps most women but it may have unwanted side effects in some women.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The following list includes the more common side effects of your Pill. These are usually mild and short-lived.

If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:

- nausea, vomiting or diarrhoea
- stomach pain (including abdominal discomfort / distention)
- changes in weight
- headache, including migraines
- acne
- hair loss
- mood changes, including depression
- changes in blood pressure
- breast pain (including breast discomfort and breast tenderness), breast enlargement, breast swelling
- unusual discharge from the vagina

- abnormal vaginal bleeding or irregular bleeding between periods
- fungal or yeast infection
- discharge and itching in the vagina or genitals due to infection (genital inflammation)
- vaginal thrush or other fungal infections of the genitals
- increased appetite
- rash (including patchy rash)
- itching (sometimes all over your body)
- abnormal periods or painful periods
- pelvic pain
- ovarian cysts
- fatigue (including weakness and tiredness)

The following list includes very serious but rare side effects. You may need urgent medical attention or hospitalisation.

If you experience any of the following, tell your doctor immediately, or go to the Emergency Department at your nearest hospital:

- pain in the chest, arm or below the breastbone
- discomfort radiating to the back
- breathlessness and/or difficulty breathing
- swelling, pain or tenderness of one leg or along a vein in the leg
- sudden weakness, numbness or bad ‘pins and needles’ of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- severe, sudden stomach pains

- a fainting attack, or you collapse
- unusual headaches or migraines that are worse than usual
- sudden problems with speech, understanding or eyesight

The side effects listed above are possible signs of a blood clot (thrombosis).

- allergic reaction
- rapid heartbeat
- darkening of the skin or pigment patches on the skin, particularly of the face
- breast lumps

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed may also occur in some people.

Thrombosis and the Pill

Thrombosis is the formation of a blood clot that may block a blood vessel.

Thrombosis sometimes occurs in the deep veins of the legs (DVT). If a blood clot breaks away from the veins where it has formed, it may reach and block the arteries of the lungs, causing pulmonary embolism (PE).

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking the Pill. They can also happen during pregnancy. The risk of having blood clots is higher in Pill users than in non-users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the Pill for the first time, or after having a break from the Pill for 4 weeks or more.

If you notice possible signs of a blood clot, stop taking Valette and consult your doctor immediately.

Cancer and the Pill

Breast cancer has been diagnosed slightly more often in women who take the Pill than in women of the same age who do not take the Pill.

This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop taking the Pill. It is not known whether the difference is caused by the Pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

It is important that you check your breasts regularly and contact your doctor if you feel any lump.

In rare cases benign liver tumours and, even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding.

Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer has been reported to occur more often in women who have been taking the Pill for a long time. This finding may not be caused by the Pill, but may be related to sexual behaviour and other factors.

AFTER TAKING VALETTE

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill. Do not leave medication in the car.

Heat and damp can destroy some medicines.

Keep Valette where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Valette comes in a box containing either 1 or 3 blister packs. Each blister pack contains 21 white active tablets and 7 brown inactive tablets.

The blister pack is marked with days of the week next to each tablet.

Ingredients

Each Valette white active tablet contains:

Active ingredients:

- 2 milligrams of dienogest
- 30 micrograms of ethinyloestradiol

Inactive ingredients:

- Lactose
- maize starch
- maltodextrin
- sucrose
- liquid glucose
- calcium carbonate
- povidone
- macrogol 35000
- carnauba wax
- magnesium stearate
- titanium dioxide

Each brown inactive tablet contains:

- lactose
- maize starch
- purified talc
- povidone
- magnesium stearate
- sucrose
- macrogol 6000
- calcium carbonate
- glycerol
- ferric oxide
- glycol montanate
- titanium dioxide

Valette tablets do not contain gluten, tartrazine or azo dyes.

Supplier

Made in Germany for:

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Australian Registration Number

Valette - AUST R 122788

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See Bayer Australia website (www.bayer.com.au) for latest Australian Consumer Medicine Information.

Missed a pill?

See the end of this leaflet

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Summary of advice if you missed an active tablet more than 12 hours ago

Before missing your tablet, did you take white active tablets for the previous 7 days?	No	Did you have sex in the 7 days before missing the tablet?	→	No Take the tablet missed AND use extra barrier precaution for 7 days. If there are fewer than 7 active tablets left in the pack, finish the active tablets and go straight to the white active tablets of the next pack. This means you skip the brown inactive tablets. Yes See your Doctor or Pharmacist for advice
	Yes	Does your pack still have 7 active white tablets in a row to follow?	→	No Take the tablet you missed AND complete taking the white active tablets. Skip the brown inactive tablets. Start your next pack with the white active tablets. Yes Take the tablet you missed AND complete the pack as normal