

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

OVRAL 28 500 µg /50 µg sugar-coated tablets

Norgestrel and ethinyl estradiol

Contains sugar (active tablet): Lactose monohydrate 32,60 mg and sucrose 22,023 mg

Contains sugar (inactive tablet): Lactose monohydrate 38,006 mg, sucrose 24,60 mg

Read all of this leaflet carefully before you start taking OVRAL 28

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other healthcare providers,
- OVRAL 28 has been prescribed for you only and you should not share your medicine with other people. It may harm them, even if their signs of illness are the same as yours.

What is in this leaflet:

1. What OVRAL 28 is and what it is used for
2. What you need to know before you take OVRAL 28
3. How to take OVRAL 28
4. Possible side effects
5. How to store OVRAL 28
6. Contents of the pack and other information

1. What OVRAL 28 is and what it is used for

OVRAL 28 belongs to a group of medicines called combined oral contraceptives (COCs) which is used to prevent you from falling pregnant. OVRAL 28 is also used to control irregular menstruation.

2. What you need to know before you take OVRAL 28

Do not take OVRAL 28:

- if you are hypersensitive (allergic) to norgestrel, ethinyl estradiol, or any of the other ingredients of OVRAL 28 (listed in section 6).
- if you have a previous condition, or currently have a condition where a clot plugs a blood vessel in your body (e.g. heart attack or stroke caused by a clot blocking a blood vessel).
- if you have risk factors for developing a clot in a blood vessel. These risk factors include:
 - if you smoke and are over the age of 35 years.
 - if you have ever had, or currently have a clot in your leg (or a vein deep in the body), in your lung or have a family history of these blood clots.
 - if you have an inherited disease where your blood clots easily (hypercoagulopathy).
 - if you have an obstruction in one or more blood vessels that supply blood to the brain (cerebrovascular insufficiency) or a disease that causes a narrowing in the blood vessels to the brain (cerebrovascular disease). These conditions may lead to a stroke.
 - if you have a disease causing narrowing of blood vessels supplying the heart with blood (coronary artery disease), heart rhythm diseases or problems with your heart valves. You should consult your doctor immediately if you experience unexplained chest pain.
 - if you have uncontrolled high blood pressure.
 - if you have diabetes mellitus with diseases of your blood vessels.

- if you have headaches or migraines with vision disturbances such as blurred or lost vision, weakness or speech difficulties. OVRAL 28 should be stopped immediately if you develop a migraine with vision loss.
- if you are over the age of 35 and you have migraine headaches.
- If you currently have or have a history of breast cancer or other cancer that is sensitive to hormones.
- if you have abnormal bleeding from your vagina.
- if you are known to have inherited genetic changes called “BRCA 1 and/or BRCA 2 genes.”
- if you started your menstrual periods before the age of 12 years.
- if you have a history of non-cancerous breast disease such as atypical hyperplasia or lobular carcinoma *in situ*.
- if you have had any treatment using radiation to your chest or breast.
- if you have been treated or exposed while in your mother’s womb to a medicine called diethylstilbestrol (DES).
- if you are taking medicines for hepatitis C containing ombitasvir/paritaprevir/ritonavir with or without dasabuvir.
- if you are pregnant or breastfeeding your baby.
- if you have depression, which is not well controlled with treatment.
- if you have had depression with previous use of hormonal contraceptives.

Warnings and precautions

Take special care with OVRAL 28

CIGARETTE SMOKING

CIGARETTE SMOKING INCREASES THE RISK OF SERIOUS CARDIOVASCULAR SIDE EFFECTS FROM THE USE OF ORAL CONTRACEPTIVES. THE RISK INCREASES WITH

AGE AND WITH HEAVY SMOKING (15 OR MORE CIGARETTES PER DAY) AND IS QUITE MARKED IN WOMEN OVER 35 YEARS OF AGE. YOU ARE THEREFORE STRONGLY ADVISED TO STOP SMOKING.

Under no circumstances should OVRAL 28 be stopped without having adopted a satisfactory alternative method of contraception.

Tell your doctor if any of the following conditions apply to you:

If these conditions develop or get worse while you are taking OVRAL 28, you should also tell your doctor.

- If you have stopped taking OVRAL 28 and you are not using an alternative method of contraception.
- If you miss a menstrual period, see your doctor. Discontinue OVRAL 28 until your doctor says you can resume.
- OVRAL 28 tablets are to be used only on the advice, or on the recommendation of your doctor, who will give you more complete information on the use of OVRAL 28 and will advise you about possible contraindications (conditions in which you should not take this type of medication).
- If you have epilepsy, asthma or conditions where you retain fluid in your body.
- If during your treatment with OVRAL 28 you develop unexplained loss of vision, double vision or swelling of the eye nerve that may cause pain in your eye and bleeding in the eye.
- If you are due to receive a surgery or if you are not going to be mobile for an extended period of time. OVRAL 28 should be stopped four weeks before you are due to undergo surgery or during periods where you are not mobile. OVRAL 28 can be restarted approximately 2 weeks following completion of treatment with the combination medicine regimen.

- If you have given birth and you are not breastfeeding, you should not start OVRAL 28 earlier than four weeks after delivery.
- If you have uncontrolled high cholesterol. You may be at a higher risk of developing inflammation in your pancreas and your doctor may consider prescribing an alternative medicine for you.
- If during your treatment with OVRAL 28, you develop consistent upper stomach pain.
- If you have high blood pressure but it is well controlled with medicine, your blood pressure should be monitored regularly while taking OVRAL 28.
- If you have diabetes mellitus as you may not tolerate glucose well while on OVRAL 28.
- If you have a tumour or cancer in your liver or any type of liver disease including gallbladder problems or if your skin or the whites of your eyes appear yellow.
- If, while on treatment with OVRAL 28, you start to develop new headaches or migraine that are recurring, persistent and severe, tell your doctor immediately.
- If you experience no menstrual bleeding, very light menstrual bleeding, breakthrough bleeding or spotting that lasts for longer than three months of using OVRAL 28 or occurs after previous regular cycles. You should tell your doctor so that he/she may test for pregnancy or another cause such as cancer.
- If you have experienced very light menstrual bleeding infrequent menstrual bleeding or no bleeding while on other contraceptives previously, tell your doctor.
- If you are on treatment for depression.
- If you have had depression with previous use of hormonal contraceptives.
- If you have a substance abuse problem.
- If you have underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder.
- If you have a family history of mental disorders.
- If you have a history of physical or sexual abuse.

- If you have a genetic condition called hereditary angioedema where you have swelling in various parts of your body, including your hands, feet, face and throat.
- If you develop brown patches on your face (chloasma). This may especially happen if you previously developed brown patches on your face while you were pregnant. If you have developed brown patches on your face before, you should avoid exposure to sunlight or ultraviolet light while on treatment with OVRAL 28.
- If you are overweight as OVRAL 28 may not work as well for you.
- If you are elderly, as OVRAL 28 is not indicated for use in women who have undergone menopause.
- If OVRAL 28 is prescribed in children who have not started their period as OVRAL 28 is not indicated in this age group.
- If you have a rare hereditary blood disorder called porphyria.
- If you are taking certain medicines that may decrease the effect of OVRAL 28. You will need to use alternative or additional contraception while taking these medicines and for up to 28 days after stopping these medicines. Some of these medicines include medicine for fits, antibiotics, antifungal medicines, medicine for vomiting, medicine for depression and medicine for high blood pressure caused by your lungs (see Other medicines and OVRAL 28).

Hormonal contraceptives including OVRAL 28, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behavior (eg. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self destructive things, personality changes) and suicide. If you experience mood changes and depression contact your doctor for advice.

OVRAL 28 does not protect you against sexually transmitted diseases and the virus that causes AIDS.

OVRAL 28 and breast cancer

Breast cancer has been diagnosed slightly more often in women who use contraceptives such as OVRAL 28 than in women of the same age who do not use contraceptives. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of contraceptives. When you are taking OVRAL 28, you must perform monthly breast self-examinations. Your doctor will advise you on when to report for breast examinations and any appropriate investigations.

Other medicines and OVRAL 28

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking or using any of the following medicine:

- Antiepileptic medicines (e.g. phenytoin, phenobarbitone, carbamazepine, oxcarbazepine, topiramate, felbamate, rufinamide, lamotrigine): medicine used to treat fits, epilepsy or seizures.
- Bosentan: medicine used to treat a specific type of high blood pressure caused by the blood vessels of the lungs.
- Antifungal medicine (e.g. griseofulvin, itraconazole, voriconazole, fluconazole, ketoconazole): medicine used to treat fungal infections.
- Aprepitant: medicine used to treat vomiting.
- St. John's wort: (herbal) medicine used to treat depression.
- Antibiotics (e.g. rifabutin, rifampicin, ampicillin): medicine used to treat bacterial infections including tuberculosis (TB).
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g. phenylbutazone, salicylic acid): medicine used to treat pain and inflammation.
- Anti-cholesterol medicines (e.g. colestevlam, atorvastatin, rosuvastatin, clofibrilic acid): medicine used to lower cholesterol.

- Ascorbic acid (vitamin C): medicine to supplement the amount of vitamin C in your body.
- Analgesic medicines (e.g. paracetamol, morphine): medicine used to treat pain.
- Anti-viral medicines (e.g. ombitasvir/paritaprevir/ritonavir with or without dasabuvir, nelfinavir, ritonavir, darunavir/ritonavir, fosamprenavir/ritonavir, lopinavir/ritonavir, tipranavir/ritonavir, indinavir, atazanavir/ritonavir, nevirapine, efavirenz, etravirine): medicine used to treat HIV or the liver virus, hepatitis C.
- Immune system inhibitors (e.g. ciclosporin, prednisolone): medicine used to suppress the immune system to prevent rejection of an organ after an organ transplant or to prevent inflammation.
- Theophylline: medicine used to treat asthma or diseases where there is an obstruction of the airways.
- Tizanidine: medicine used to treat muscle spasms after a spinal cord injury or because of a multiple sclerosis.
- Temazepam: medicine used to treat sleeplessness (insomnia).
- Thyroid hormone replacement medicine (e.g. levothyroxine): medicine used to treat a low level of thyroid hormone in the body.
- OVRAL 28 may interfere with the result of some laboratory tests, in particular hormones, glucose tolerance, thyroid function, binding proteins, blood coagulation factors, serum triglycerides and liver function tests.

OVRAL 28 with food and drink

Do not take OVRAL 28 with grapefruit juice as it may increase the level of hormones in your blood.

Pregnancy, breastfeeding and fertility

You should not take OVRAL 28 if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking OVRAL 28.

Driving and using machines

OVRAL 28 has no influence on the ability to drive and use machines.

It is not always possible to predict to what extent OVRAL 28 may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which OVRAL 28 affects you (see section 4).

OVRAL 28 contains lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking OVRAL 28.

3. How to take OVRAL 28

Do not share medicines prescribed for you with any other person.

Always take OVRAL 28 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult dose is one (1) tablet of OVRAL 28 daily.

1. Start by taking the white tablet in the circle on the package on the first day of your menstrual cycle (i.e. the day bleeding commences).
2. Take one white tablet each day immediately after the evening meal or at bedtime, as nearly as possible at the same time each day for 21 days, following the arrows until all 21 white tablets are finished.
3. Then start taking one red coloured tablet each day (again following the arrows) until all the red tablets are finished.

4. On the following day start a new package taking the first white tablet in the circle to commence the next course.

NOTE: There must be no interval between finishing one course and starting the next.

The changes you can expect:

You will probably have a menstrual period two to three days after taking the last white tablet in each package. The blood flow may be slightly less or more than you had before you started taking OVRAL 28.

If, while on OVRAL 28 you develop severe vomiting and diarrhoea the absorption of OVRAL 28 may be diminished and you should use additional methods of contraception. If vomiting or diarrhoea occurs within 3 to 4 hours after taking an active tablet of OVRAL 28, handle this as a missed tablet (see If you forget to take OVRAL 28).

If you take more OVRAL 28 than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take OVRAL 28

OVRAL 28 is designed to protect you from pregnancy. It will do this as long as you follow the schedule carefully. However, should you forget to take one or more tablets, your body may not have enough hormones left to prevent pregnancy. In such cases, use an additional birth control method (other than OVRAL 28).

If you miss taking 1 tablet of OVRAL 28, take it in the morning as soon as possible, then take the next tablet at the usual time and continue the course as before. Remember to use an additional contraceptive method until you finish the package.

Suppose you forget to take 2 tablets of OVRAL 28 in a row; take the 2 missed tablets when you remember, and the tablet for that day at the regular time. In this case you take 3 tablets on the day you remember. Continue your schedule until the package is finished. An additional contraceptive method is necessary until you finish the package. If you forget 3 or more tablets in a row, do NOT take them when you remember and do NOT finish the package. Wait 4 more days.

This makes 1 week without tablets. Then begin a new package on DAY 8, even if you are still bleeding. During the 7 days without tablets, and until you have taken a tablet daily for seven days from the new OVRAL 28 package, use an additional birth control method. If you omit any of the tablets in a package and do not menstruate when you expect to, see your doctor or healthcare provider. Do not take any more tablets until the doctor says you can.

If you stop taking OVRAL 28

You should not stop taking OVRAL 28 without talking to your healthcare provider first. You may need to use other contraceptive methods.

4. Possible side effects

OVRAL 28 can have side effects,

Not all side effects reported for OVRAL 28 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OVRAL 28, please consult your healthcare provider for advice.

If any of the following happens, stop taking OVRAL 28 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to OVRAL 28. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Cancer of the reproductive organs, breasts or liver,
- bleeding of the brain, a clot in the brain or a stroke with symptoms such as numbness of the face and limbs on one side of the body,
- a clot in the blood vessel that supplies the eye with blood with symptoms such as sudden onset of vision loss generally only in one eye,
- inflammation of the eye nerve which could lead to partial or complete loss of vision,
- heart attack with symptoms such as tightness or pain in the chest, abnormal heartbeat, anxiety, shortness of breath and light-headedness,
- a clot in a blood vessel (arterial or venous thromboembolism),
- a clot in the lung (pulmonary embolism) with symptoms such as shortness of breath, chest pain and cough,
- inflammation of the pancreas (pancreatitis) with symptoms such as severe nausea and stomach pain,
- a clot in the blood vessels supplying the small intestines with blood with symptoms such as severe stomach pain, nausea and vomiting,
- liver and gallbladder problems with symptoms such as yellowing of the skin and whites of the eyes (jaundice) or a very rare liver condition called Budd-Chiari syndrome that effects

the drainage of the liver, with symptoms such as liver enlargement, a build-up of fluid in the stomach and stomach pain,

- bleeding under the skin,
- suicidal thoughts/behavior and suicide.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Increased appetite,
- depression, nervousness,
- headache,
- worsening of varicose veins,
- nausea, stomach pain, cramps and bloating,
- acne, brown patches on the face,
- backache,
- vaginal infection, vaginal discharge, painful menstruation, breast discomfort, changes in menstrual flow,
- fatigue.

Side effects with an unknown frequency

- Unwanted male-pattern hair growth in women (hirsutism),
- fluid retention, decreased appetite, effects on the carbohydrates and fats (lipids),
- porphyria (an inherited blood disorder) or a worsening of existing porphyria,
- mood changes, mood swings, changes in sex drive (libido),
- migraine,
- lesions in the eye, change in the curve of your eye, intolerance to contact lenses,

- high blood pressure,
- irritation in the stomach and gut, inflammation of the inner lining of the colon,
- skin pigmentation, bull's-eye-shaped lesions on the skin, nodules or tender bumps under the skin,
- unscheduled menstrual bleeding (spotting or breakthrough bleeding), absence of menstrual flow, breast changes including tenderness, pain, enlargement and secretion from the breast, premenstrual syndrome (PMS), temporary infertility after discontinuation of treatment, thrush,
- mass gain, change in weight.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA**: via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0) 11 239-6200

By reporting side effects, you can help provide more information on the safety of OVRAL 28.

5. How to store OVRAL 28

Store all medicines out of reach of children.

Store at or below 25 °C, in a cool dry place.

Protect from light.

Keep in the original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OVRAL 28 contains

The active substances are 500 µg of norgestrel and 50 µg ethinyl estradiol

The other ingredients are:

Calcium carbonate, lactose monohydrate, magnesium stearate, maize starch, polyethylene glycol, povidone, sucrose, talc purified, wax.

Contains sugar: Lactose monohydrate 32,60 mg and sucrose 22,023 mg.

Each red, inactive sugar-coated tablet of OVRAL 28 contains calcium carbonate, colour FD&C Red no. 3 (C.I. 45430), colour FD&C yellow no. 6 (C.I. 15985:1), lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, ponceau 4R aluminum lake (C.I. 16255), povidone, quinoline yellow aluminum lake (C.I. 47005), sodium benzoate, sucrose, talc purified, wax.

Preservative:

Sodium benzoate 0,002 % *m/m*

Contains sugar: Lactose monohydrate 38,006 mg, sucrose 24,60 mg.

What OVRAL 28 looks like and the contents of the pack

OVRAL 28 active tablet is white, lustrous, round biconvex sugar-coated tablets.

OVRAL 28 inert tablet is red, biconvex sugar-coated tablets.

28 sugar-coated tablets (consisting of 21 white active tablets and 7 red inert tablets) are packed in a clear polyvinyl chloride film sealed with an aluminium foil backing. The blister strip is packed into an outer cardboard carton together with a leaflet.

100 x 28 sugar-coated tablets (consisting of 21 white active tablets and 7 red inert tablets) are packed in clear polyvinyl chloride films sealed with aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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H1644 (Act 101/1965)



Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: B9319940 S2

Namibia: NS2 12/18.8/0142

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