### NEW ZEALAND CONSUMER MEDICINE INFORMATION

### **ORALCON 30 ED**

### Levonorgestrel 0.15 mg and Ethinylestradiol 0.03 mg tablet



### What is in this leaflet

Please read this leaflet carefully before you start taking Oralcon 30 ED.

This leaflet answers some common questions about Oralcon 30 ED.

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 Oralcon 30 ED against the benefits they expect it will have for you.

#### If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

# What Oralcon 30 ED is used for

Oralcon 30 ED is used to prevent pregnancy.

You may also experience the following benefits:

- More regular and lighter periods

   potentially resulting in a decrease in anaemia (iron deficiency)
- A decrease in period pain

Some conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy (where the foetus is carried outside of your womb), lumpy breasts, acne and cancer of the uterus (womb) and ovaries may be less common in women taking the Pill. Oralcon 30 ED contains the active ingredients levonorgestrel and ethinylestradiol. It belongs to a group of medicines called combined oral contraceptives, commonly known as a 'birth control pill' or 'the pill'.

When taken correctly, Oralcon 30 ED 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
- changing the lining of the uterus, making it less suitable for implantation

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 have been missed, may have been taken with medicines that interfere with their effectiveness, or may not be absorbed due to vomiting or diarrhoea.

Like all oral contraceptives, Oralcon 30 ED is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

Your doctor may have prescribed this medicine for another reason.

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

This medicine is available with a doctor's prescription or from a trained pharmacist without a doctor's prescription if you meet certain criteria.

### Before you take Oralcon 30 ED

## When you must not take it

### Do not take Oralcon 30 ED if you have an allergy to:

- any medicine containing ethinylestradiol and/or levonorgestrel
- 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 breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

### Do not take Oralcon 30 ED 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 Oralcon 30 ED if you are concerned about an increased risk of blood clots. Blood clots are rare. Very occasionally blood clots may cause serious permanent disability, and may even be fatal.

You are more at risk of having a blood clot when you take the Pill. However, 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 Oralcon 30 ED 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 Oralcon 30 ED if you are taking any antiviral medicines which contain glecaprevir, pibrentasvir, sofosbuvir, velpatasvir, voxilaprevir, ombitasvir, paritaprevir and/or dasabuvir.

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 (HCV)).

### Do not take Oralcon 30 ED if you have, or have had:

- any blood clotting disorders such as Protein C deficiency, Protein S deficiency, Leiden Factor V mutation, Antithrombin III deficiency or other inherited blood clotting conditions
- a confirmed blood test showing:
  - increased levels of homocysteine
  - antiphospholipid antibodies (APLAs) e.g. anticardiolipinantibodies and lupus anticoagulant. These may increase your risk for blood clots or pregnancy losses (miscarriage)
- angina (chest pain)
- a 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
- high risk of blood clots due to conditions such as diabetes mellitus with blood vessel damage, severe high blood pressure or severe high or low level of fats in your blood
- 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)
- a benign or malignant liver tumour
- unexplained vaginal bleeding.
- major surgery after which you have not been able to move around for a period of time

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 this medicine if you are pregnant.

### Do not breastfeed if you are taking this medicine.

Oralcon 30 ED is generally not recommended if you are breastfeeding.

### Do not give this medicine to a child.

Oralcon 30 ED is not intended for use in females whose periods have not yet started.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or 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 are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

### Tell your doctor:

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
- hyperhomocysteinaemia, a condition characterised by high levels of the amino acid homocysteine in the blood
- high or low level of fats in your blood
- inflammation of your veins (superficial phlebitis)
- migraine
- cancer
- epilepsy
- varicose vein

### Ask your doctor to check if you:

- are overweight
- have any hereditary or acquired conditions that may make it more likely for you to get blood clots
- have high cholesterol or triglycerides
- have liver disease
- have gall bladder disease
- have jaundice (yellowing of the skin) and/or pruritus (itching of the skin) related to cholestasis (condition in which the flow of bile from the liver stops or slows)
- 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 (yellowishbrown 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, recur or worsen while taking Oralcon 30 ED, you should contact your doctor.

If you have not told your doctor about any of the above, tell them before you start taking Oralcon 30 ED.

### Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Oralcon 30 ED.

Some medicines may interfere with Oralcon 30 ED. These include:

- medicines used to treat tuberculosis such as rifampicin, rifabutin
- a class of antibiotics known as macrolides, such as clarithromycin, erythromycin
- medicines used to treat fungal infections, such as
- ketoconazole, griseofulvinmedicines used to treat HIV,
- such as ritonavir, nevirapine
  some medicines used to treat
- some medicines used to treat HCV, such as boceprevir, telaprevir, ombitasvir, paritaprevir, dasabuvir

- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- cyclosporin, an immunosuppressant medicine
- etoricoxib, a medicine used to treat painful joint disease
- melatonin, a hormone used as a sleep aid
- midazolam, a medicine used as a sedative
- theophylline, a medicine used to treat respiratory disease
- tizanidine, a medicine used as a muscle relaxant
- some medicines used to treat high blood pressure, chest pain or irregular heartbeats such as diltiazem, verapamil
- herbal medicines containing St John's Wort
- grapefruit juice.

These medicines may be affected by Oralcon 30 ED or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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 Oralcon 30 ED and for some time after stopping them.

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

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

# How to take Oralcon 30 ED

# 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 box, ask your doctor or pharmacist for help.

### How much to take

Take one tablet daily at about the same time every day. You must take Oralcon 30 ED every day regardless of how often you have sex. This will also help you remember when to take it.

### How to take it

### Swallow the tablet whole with a full glass of water.

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

Each blister pack is marked with the day of the week. **Take your first** white (active) tablet from the orange area of 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 to 3 days after starting to take the yellow 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 Oralcon 30 ED for the first time

If you are starting Oralcon 30 ED 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. the first day of 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. condoms or a cap or diaphragm with spermicide) for the first 7 days of tablet-taking. Your doctor will advise you when to start if you:

- are taking Oralcon 30 ED after having a baby
- have had a miscarriage or an abortion.

## Changing from another contraceptive

#### Changing from a combined oral contraceptive:

Start taking Oralcon 30 ED 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 Oralcon 30 ED.

You can also switch to Oralcon 30 ED 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/inactive tablets in your previous Pill pack, ask your doctor or pharmacist. Your previous Pill pack may have different colour tablets to those of Oralcon 30 ED.

#### Changing from a vaginal ring:

Start taking Oralcon 30 ED on the day of removal of the ring but at the latest when the next application would have been due.

#### Changing from a progestogenonly pill ('minipill'):

Stop taking the minipill on any day and start taking Oralcon 30 ED 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 tablettaking when having intercourse.

#### Changing from a progestogenonly injection, implant or intrauterine system (IUS):

Start taking Oralcon 30 ED 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 tablettaking when having intercourse.

### Stopping Oralcon 30 ED

You can stop taking Oralcon 30 ED 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 Oralcon 30 ED 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.

## Additional contraceptive precautions

When additional contraceptive precautions are required you should either abstain from sex, or use a barrier method of contraception, a cap (or diaphragm) plus spermicide, or a condom. Rhythm methods are not advised as the Pill disrupts the cyclical changes associated with the natural menstrual cycle e.g. changes in temperature and cervical mucus.

### If you forget to take it

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 Oralcon 30 ED 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 Pill as you would normally, even if this means taking two tablets in one **day, at the same time.** You should still be protected against pregnancy.

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 yellow inactive tablets. Start taking the white active tablets in your next pack 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 Pill as you would normally, even if this means taking two tablets in one day, at the same time. 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 in the preceding 7 days, there is a possibility of pregnancy and you may need emergency contraception. You should discuss this with your doctor or pharmacist.

#### 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 yellow inactive tablet, you do not need to take them later because they

### do not contain any active ingredients.

However, it is important that you discard the missed yellow tablet(s) to make sure that the number of days between taking active tablets is not increased as this would increase the risk of pregnancy. Continue with the next tablet at the usual time.

Please refer to the table at the end of this leaflet, "Summary of advice if you missed a white active tablet more than 12 hours ago".

### If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### While you are taking Oralcon 30 ED

### Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Oralcon 30 ED.

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

### If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this metcine.

The risk of having blood clots is temporarily increased as a result of major surgery, any surgery to the legs or pelvis, neurosurgery or major trauma. In women who take the Pill, the risk may be higher.

In women at risk of prolonged immobilisation (including major surgery, any surgery to the legs or pelvis, neurosurgery, or major trauma), your doctor may tell you to stop taking (in the case of elective surgery at least four weeks in advance) and not resume until two weeks after complete remobilisation. Another method of contraception should be used to avoid unintentional pregnancy. Your doctor may prescribe other treatment (e.g. treatment for blood clots) if Oralcon 30 ED has not been discontinued in advance.

Other risk factors for blood clotting include temporary immobilisation including air travel of greater than 4 hours, particularly in women with other risk factors. Consult your doctor if you plan to air travel for greater than 4 hours.

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

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.

Keep all of your doctor's appointments so that your progress can be checked. When you are taking the Pill, your doctor will tell you to return for regular check-ups, including getting a Cervical Screening Test. Your doctor will advise how often you need a Cervical Screening Test. A Cervical Screening Test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer. Also, your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

### Stop taking Oralcon 30 ED and see your doctor immediately if you notice possible signs of thrombosis. These include:

- one-sided swelling of the leg and/or foot or along a vein in the leg
- pain or tenderness in the leg which may be felt only when stand or walking
- increased warmth in the affected leg; red or discoloured skin on the leg
- sudden onset of unexplained shortness of breath or rapid breathing
- sudden coughing or coughing up of blood
- sharp chest pain or sudden severe pain in the chest which may increase with deep breathing

- severe light headedness or dizziness
- rapid or irregular heartbeat
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- sudden confusion, slurred speech or aphasia; sudden partial or complete loss of vision, double vision, painless blurring of vision which can progress to loss of vision
- sudden, severe or prolonged headache with no known cause
- loss of consciousness or fainting with or without seizure
- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest arm, or below the breastbone
- discomfort radiating to the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting extreme weakness and anxiety

Consult your doctor if you develop high blood pressure while taking Oralcon 30 ED – you may be told to stop taking it.

If you vomit within 3 to 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 this Pill 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 unlikely that you are pregnant, as long as:

- you have taken the white active tablets at the right time
- you have not been taking a medicine(s) that may interfere with your Pill
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take Oralcon 30 ED 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 Oralcon 30 ED and seek advice from your doctor. You must use a nonhormonal method of contraception, (such as condoms or a diaphragm) until your doctor rules out pregnancy.

Oralcon 30 ED 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 papillomavirus 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 Oralcon 30 ED to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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 Oralcon 30 ED, or do not take a tablet every day.

### In case of overdose

## *If you take too much (overdose)*

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Oralcon 30 ED. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea
- vomiting
- withdrawal bleeding

### Side effects

#### Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Oralcon 30 ED.

This medicine helps most people to prevent pregnancy 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 treatment if you get some of the side effects.

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

#### Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea
- stomach pain
- changes in weight
- headache, including migraines
- mood changes, including depression
- breast tenderness or pain

The above list includes the more common side effects of our

medicine. They are usually mild and short-lived.

#### If any of the following happen, tell your doctor immediately or go to Accident and Emergency 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
- 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).

- jaundice (yellowing skin or yellowing eyes)
- you cough up blood
- breast lumps
- unexplained vaginal bleeding.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

### 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 Oralcon 30 ED and consult your doctor immediately.

To prevent pregnancy, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm).

If you are concerned about an increased risk of blood clots while on Oralcon 30 ED, speak to your doctor.

### 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 Oralcon 30 ED

### Storage

Keep your tablets in the pack until it is time to take them. If you use 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 Oralcon 30 ED or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

### Keep it where children cannot reach it.

A locked cupboard at least one-anda 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.

### **Product description**

### What it looks like

Active tablets: white tablets.

Non-hormonal (placebo) tablets: yellow tablets.

Each blister pack contains 21 white active tablets and 7 yellow placebo tablets.

### Ingredients

White active tablet active ingredients: Oralcon 30 ED white active tablet contains 30 micrograms of ethinylestradiol and 150 micrograms of levonorgestrel as the active ingredients.

White active tablet inactive

#### ingredients:

Oralcon 30 ED white active tablet also contains:

- lactose
- polacrilin potassium
- magnesium stearate
- ethyl cellulose
- talc
- gum acacia
- disodium edetate
- sucrose
- microcrystalline cellulose
- titanium dioxide
- macrogol 6000
- maize starch
- methyl hydroxybenzoate

Contains sulfites and lactose.

Yellow placebo tablet ingredients: Oralcon 30 ED yellow placebo tablet contains:

- lactose
- glycerol
- macrogol 6000
- calcium carbonate
- talc
- povidone K-90
- povidone K-25
- sucrose
- titanium dioxide
- magnesium stearate
- carnuaba wax
- maize starch
- yellow oxide of iron

Contains sulfites and lactose.

# If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

## Who supplies this medicine

Oralcon 30 ED is supplied in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie AUCKLAND <u>www.viatris.co.nz</u> Telephone 0800 168 169

### **Date of Preparation**

7 December 2023 (Based on datasheet dated 7 December 2023)

# Summary of advice if you missed a white active tablet more than 12 hours ago

				No
Before missing your tablet, did you take white active tablets for the previous 7 days?	Νο	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 white active tablets left in the pack, finish the white active tablets and go straight to the white active tablets of the next pack. This means you skip the yellow inactive tablets. Yes See your Doctor or Pharmacist for advice.
	Yes	Does your pack still have 7 white active tablets in a row to follow?		No Take the tablet you missed AND complete taking the white active tablets. Skip the yellow inactive tablets. Start your next pack with white active tablets. Yes Take the tablet you missed AND complete the pack as normal.