Ava 20 ED
Levonorgestrel 0.1 mg and Ethinylestradiol 0.02 mg tablets
Contraceptive tablets for women.

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Ava 20 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 Ava 20 ED 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 AVA 20 ED IS USED FOR

Ava 20 ED is a combined oral contraceptive (often called "the Pill") consisting of 21 hormonal tablets and 7 non-hormonal tablets. Each pink hormonal tablet contains a small amount of two different female hormones. These are levonorgestrel (a progestogen) and ethinylestradiol (an estrogen). Because of the small amount of hormones, Ava 20 ED is considered to be a low-dose combined oral contraceptive preparation. Ava 20 ED also contains 7 yellow non-hormonal tablets that do not contain any active ingredients.

Ava 20 ED is used to prevent pregnancy. You may also experience the following benefits:

- more regular and shorter periods and a decrease in the amount of blood you lose each month
- a decrease in anaemia (iron deficiency)
- a decrease in period pain.

Some medical conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy and disorders of the uterus (womb), ovaries and breast are less common in women using oral contraceptives.

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

- inhibiting the egg release by stopping it maturing
- 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.

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 AVA 20 ED

When you must not take it

Do not take Ava 20 ED if you have an allergy to:

- ethinylestradiol and/or levonorgestrel, the active ingredients in Ava 20 ED
- 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 Ava 20 ED if you have or have had a blood clot in:

- the blood vessels of the legs (deep vein thrombosis)
- the lungs (pulmonary embolism)
- the heart (heart attack)
- the brain (stroke)
- other parts of the body.

Do not take Ava 20 ED 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 when taking the Pill is less than the risk during pregnancy.

Do not take Ava 20 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 Ava 20 ED if you are taking any antiviral medicines which contain 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 Ava 20 ED if you have, or have had:

- angina (chest pain)
- severe kidney insufficiency or an acute failure of your kidney
- 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
- jaundice (yellowing of the skin)
- 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.

Do not take this medicine if you are pregnant or think you might be pregnant. It may affect your developing baby if you take it during pregnancy.
Do not give this medicine to a child.

Do not take this medicine after the expiry date printed on the carton and on each blister. If it has expired, return it to your pharmacist for disposal.

Do not take this medicine 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 are overweight
- you or anyone in your immediate family has had blood clots in the legs (thrombosis), 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
- epilepsy.

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 too much exposure to the sun or ultraviolet radiation
- have hereditary angioedema – you should see your doctor immediately if you experience symptoms of angio-oedema, 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 Ava 20 ED, you should contact your doctor.

If you have not told your doctor about any of the above, tell him/her before you start taking Ava 20 ED.
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.

Some medicines and Ava 20 ED 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 HCV, such as boceprevir, telaprevir, ombitasvir, paritaprevir, dasabuvir
- antibiotics (penicillin, ampicillin, erythromycin, tetracycline)
- medicines used to treat fungal infections, such as itraconazole, voriconazole, fluconazole, griseofulvin
- 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 Ava 20 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 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 AVA 20 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 printed on the pharmacist label, ask your doctor or pharmacist for help.

How to take it

Take one tablet daily at about the same time everyday. You must take Ava 20 ED every day even if you do not have sex very often. It will also help you remember when to take it. It does not matter if you take this medicine before or after food.

Swallow the tablets whole with a full glass of water.

Take your first pink hormonal tablet from the blue 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. Each blister pack is marked with the day of the week next to each tablet.
If you do not understand the instructions on the blister pack, ask your doctor or pharmacist for help.

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

**When to take it**

If you are starting Ava 20 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. on the first day of your menstrual bleeding. Take a tablet marked with that day of the week. For example, if your period starts on a Monday, take the tablet marked Monday from the blue area on the blister pack. Then follow the days in order of the directional arrows. Ava 20 ED will work immediately, it is not necessary to use an additional contraceptive method.

You may also start taking Ava 20 ED on days 2-3 of your cycle, but in this case make sure that you use an additional barrier contraceptive method (such as condoms or a diaphragm) for the first 7 days of tablet taking.

**Your doctor will advise you when to start if you**

- are taking Ava 20 ED after having a baby
- are breast-feeding - Ava 20 ED is not recommended
- have had a miscarriage or an abortion.

**Changing from a combined oral contraceptive:**

If you are switching from a 28 day pack combined oral contraceptive, start taking Ava 20 ED on the day after taking the last hormonal tablet in your previous Pill pack. You will be protected from pregnancy immediately if you start this way (a withdrawal bleed/period may not occur until the end of the first pack of Ava 20 ED).

**Ask your doctor or pharmacist if you are not sure which the hormonal tablets were in your previous Pill pack.** Your previous Pill pack may have different colour tablets to those of Ava 20 ED.

**Changing from a progestogen-only pill:**

If you are switching from a progestogen-only Pill (minipill), stop taking the minipill on any day and start taking Ava 20 ED at the same time the next day. But make sure you 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 an injectable, implant or progestogen-releasing intrauterine system (IUS):**

If you are switching from an injectable, implant or IUS, start taking Ava 20 ED when your next injection is due, or on the day that your implant or IUS is removed. Make sure you also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.

**If you forget to take it**

If you miss a tablet and take the missing tablet within 12 hours of missing it, you will be protected against pregnancy. If you are more than 12 hours late follow these detailed instructions:

**For Ava 20 ED to be most effective, pink hormonal tablets need to be taken uninterrupted for 7 days.**

If you have been taking the pink hormonal tablets for 7 uninterrupted days and miss a pink hormonal 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 be protected against pregnancy.

The chance of pregnancy after missing a pink hormonal 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 pink hormonal tablets left in a row, you should finish the pink hormonal tablets in your pack but skip the yellow non-hormonal tablets. Start taking the pink hormonal 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 pink hormonal tablets in the second pack. You may have spotting or breakthrough bleeding on tablet taking days.

If you have been taking the pink hormonal tablets for less than 7 days and miss a pink hormonal 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. In addition, you should 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 pink hormonal 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 non-hormonal tablet, take it as soon as you remember and take the next tablet at the usual time. You are still protected against pregnancy because the yellow non-hormonal tablets do not contain any active ingredients.

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

(Please refer to diagram on last page of this leaflet for a summary of advice if you missed a tablet more than 12 hours ago).

If you take too much (overdose)

If you think that you or anyone else may have taken too much Ava 20 ED, immediately telephone your doctor or the Poisons Information Centre (0800 poison or 0800 764 766) for advice, or go to the Emergency Department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

WHILE YOU ARE TAKING AVA 20 ED

What 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 Ava 20 ED.

Stop taking Ava 20 ED and see your doctor immediately if you notice possible signs of thrombosis.

These include:
- an unusual cough
- severe pain in the chest which may reach the left arm
- 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 or swelling in either of your legs.

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

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. The excess risk of thrombosis is highest during the first year a woman takes a combined oral contraceptive. 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 thrombosis, stop taking the Pill and consult your doctor immediately.

Consult your doctor if you develop high blood pressure while taking Ava 20 ED – you may be told to stop taking it.

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

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

If you want to delay a period

You can delay your period if you miss out the yellow non-hormonal tablets and go straight to the pink hormonal tablets in the blue section of your next pack.

Continue with this pack until this pack is empty. Your period will start while you are taking the yellow non-hormonal tablets in the next pack. You may have some breakthrough bleeding or spotting while you are taking the pink hormonal tablets.
If you want to change the starting day of your period

If you take your tablets as directed, you will have your period on about the same day every 4 weeks. If you want to change this, just shorten, (never lengthen) the duration of taking the yellow non-hormonal tablets. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) you should start your next pack 3 days sooner than you usually do, discard the 3 remaining yellow tablets of your previous pack and then continue with the next pack without having a break between the packs. If you make the duration of taking the yellow non-hormonal tablets very short (e.g. 3 days or less), you may not have bleeding during the break. You may have some breakthrough bleeding or spotting during the use of the next pack.

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

- you have taken the pink hormonal 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 Ava 20 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 and you should seek advice from your doctor. Do not start the next pack of Ava 20 ED until your doctor has checked that you are not pregnant.

Ava 20 ED will not protect you from HIV-AIDS or any other sexually transmitted diseases (STDs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.

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

What you must not do

Do not take Ava 20 ED 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 Ava 20 ED, 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 Ava 20 ED.

This medicine helps most women, although a few may have unwanted side effects.

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. Tell your doctor or pharmacist if you feel unwell.

Other side effects not listed on the following pages may also occur in some people.

The following list includes the more common side effects of your medicine. These are usually mild and lessen with time.

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

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

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:

- chest pain
- breathlessness and/or difficulty breathing
- painful swelling in your leg(s)
- weakness, numbness or bad ‘pins and needles’ of an arm or leg
- severe, sudden stomach pains
- a bad fainting attack or you collapse
- unusual headaches or migraines that are worse than usual
- sudden problems with your speech or eyesight

The side effects listed above are possible signs of a thrombosis.

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

**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 (deep venous thrombosis (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 are a rare occurrence and can develop whether or not you are taking an oral contraceptive. They can also happen during pregnancy. The risk of having blood clots is higher in oral contraceptive users than in non users, but not as high as during pregnancy.

Therefore, one should keep the possibility of an increased thromboembolic risk in mind, particularly where there is a history of thromboembolic diseases.

If you notice possible signs of a thrombosis, stop taking Ava 20 ED 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.

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 using 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.

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**AFTER TAKING AVA 20 ED**

**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 25°C. Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car. Heat and damp can destroy some medicines.

Keep it 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.

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**PRODUCT DESCRIPTION**

**What it looks like**

Ava 20 ED comes in a carton containing 3 blister packs, each sealed in a foil sleeve. Each blister pack contains 21 pink hormonal tablets and 7 yellow non-hormonal tablets. The blister pack is marked with days of the week next to each tablet.

**Ingredients**

Active ingredients:
- Ava 20 ED (pink hormonal tablet) – 0.10 mg levonorgestrel and 0.02 mg ethinylestradiol per tablet.

Inactive ingredients (pink hormonal tablet):
- Lactose
- Microcrystalline Cellulose
- Croscarmellose Sodium
- Polyvinylpyrrolidone
Each yellow non-hormonal 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

Supplier
Ava 20 ED is distributed in New Zealand by:
Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

Date of Preparation
5 May 2017
(based on the data sheet dated 10 February 2017)

Summary of advice if you missed a tablet more than 12 hours ago.

<table>
<thead>
<tr>
<th>Before missing your tablet, did you take pink hormonal tablets for the previous 7 days?</th>
<th>No</th>
<th>Did you have sex in the 7 days before missing the tablet?</th>
<th>→</th>
<th>No</th>
<th>Take the tablet missed AND use extra barrier precaution for 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Does your pack still have 7 pink hormonal tablets in a row to follow?</td>
<td>→</td>
<td>No</td>
<td>Take the tablet you missed AND complete taking the pink hormonal tablets. Skip the yellow non-hormonal tablets. Start your next pack with pink hormonal tablets.</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Take the tablet you missed AND complete the pack as normal</td>
<td>→</td>
<td>Yes</td>
<td>See your Doctor or Pharmacist for advice</td>
<td></td>
</tr>
</tbody>
</table>

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This table provides an overview of what to do if you missed a tablet more than 12 hours ago. It considers whether you took pink hormonal tablets in the previous 7 days and whether you had sex in the 7 days before missing the tablet. Based on these factors, specific actions are recommended, including taking the missed tablet and possibly using extra barrier precautions or seeking medical advice.