PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

ORALCON 0,15 mg/0,03 mg tablets

Levonorgestrel, ethinyl oestradiol

Contains sugar:

Active tablets:

Sucrose: 21,20 mg

Lactose monohydrate: 47,44 mg

Inert tablets:

Sucrose: 24,5 mg

Lactose monohydrate: 71,38 mg

Read all of this leaflet carefully before you start taking ORALCON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- ORALCON has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ORALCON is and what it is used for

2. What you need to know before you take ORALCON

3. How to take ORALCON

4. Possible side effects

5. How to store ORALCON

6. Contents of the pack and other information

1. What ORALCON is and what it is used for

ORALCON is used for prevention of pregnancy. When used as instructed you are unlikely to become pregnant.

Oral contraceptives are also used for control of painful menstrual bleeding and/or to control abnormal uterine bleeding.

2. What you need to know before you take ORALCON

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. If you are using oral contraceptives for contraception, you should understand how their benefits and risks compare to those of other birth control methods. This is a decision you, your sexual partner, and your doctor will make. Before you start taking ORALCON your pelvic organs, breasts and blood pressure should be checked by your doctor and these checks should be repeated regularly.

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Do not take ORALCON

- If you have depression, which is not well controlled with treatment
- If you have had depression with previous use of hormonal contraceptives

Before you take ORALCON tell your doctor if you have any of these:

- If you have blood clots in any part of the body or ever had these before.
- If you ever had a heart attack or heart related disease.
- Cancer of the breast or womb or have ever had either of these conditions or have family history for either of these conditions.
- If you have (or history of) tumours in uterus.
- Abnormal bleeding from vagina.
- If you are pregnant or think you are pregnant.
- If you had liver related disease or liver tumours.
- If you suffer from migraine or frequent severe headache.
- If you are allergic to any of the ingredients of ORALCON.

Warnings and precautions

Take special care with ORALCON:

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. WOMEN WHO USE ORAL CONTRACEPTIVES SHOULD BE STRONGLY ADVISED NOT TO SMOKE.

Tell your doctor before using ORALCON:

- If you have (or family history of) high blood pressure.
- If you have (or history of) diabetes.
- If you have (or history of) gall bladder disease.

- Tell your doctor in case that you are taking this medicine before any kind of surgery (including dental surgery) or emergency treatment.
- If you are a porphyria patient.
- If you have (or history of) epilepsy seizures.
- If you have (or history of) asthma.
- If you are mentally depressed.
- That you are on treatment for depression
- That you have had depression with previous use of hormonal contraceptives
- That you have a substance abuse problem
- You have underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder
- That you have a family history of mental disorders
- That you have a history of physical or sexual abuse
- If you have vomiting or diarrhoea you need to take extra protection during and for 7 days after recovery.
- Tell your doctor in case that you are taking this medicine before any laboratory test.
- Tell your doctor if you have recently got evacuation of a hydatidiform mole.

Hormonal contraceptives including ORALCON, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g. 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.

Stop taking ORALCON, immediately consult your doctor if any of following occur:

- Sudden severe chest pain, sudden breathlessness, or severe pain/swelling in calf of one leg.
- Unusual, severe prolonged headache, sudden disturbances of vision or hearing or other perceptual disorders, collapse, marked numbness or weakness affecting one side of the body or other signs or symptoms suggestive of cerebrovascular accident.
- A first unexplained epileptic seizure.
- Severe upper abdominal pain
- Onset of severe depression
- Significant rise in blood pressure

Other medicines and ORALCON

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Oral contraceptive may affect the action of antibacterials, antidepressant, antidiabetics, antifungals, antivirals, retinoid, stimulants, antiepileptics, analgesics, anticonvulsants, anticoagulants, antihypertensives, benzodiazepines, cyclosporins, clofibrate, corticosteroids, lidocaine, selegiline, levothyroxine and xanthines.

If you have diarrhoea, carry on taking ORALCON and use another method of contraception, until 7 days after you have recovered from stomach upset.

If you are taking other medicines on a regular basis, including complementary or traditional medicine, the use of ORALCON with these medicines may cause undesirable interactions. Please consult your doctor, Pharmacist or other health care professional for advice.

ORALCON with food and drink

There are no known interactions between ORALCON and food or drinks.

Pregnancy and breastfeeding

Pregnancy

If you think you might be pregnant or if two or one menstrual cycle have been missed stop taking ORALCON and consult your doctor immediately. Use another method of contraception until you see your doctor.

If you are taking oral contraceptive and wish to start a family, you should discontinue ORALCON and use non-hormonal method (like a condom or a spermicide gel) of contraception for minimum 3 months before attempting to conceive.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Lactation

You can start using ORALCON after six months of breastfeeding or weaning whichever is earlier.

Driving and using machines

ORALCON should not make you sleepy and has no or negligible effect on driving skills and the use of machinery that requires fine motor capabilities.

ORALCON contains sucrose and lactose

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

Patients with the rare hereditary condition of lactose, fructose or galactose intolerance should not take ORALCON.

ORALCON contains sucrose and lactose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take ORALCON

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

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

This memo pack has been specially designed to help you to remember to take your tablets. Each tablet is placed in its own bubble.

If you are new to this tablet treatment or are starting the tablets again after a break, take your first ORALCON Tablet on the first day of bleeding of your next period or as directed by your doctor. Always take ORALCON exactly as told by your doctor. You should check with your doctor or pharmacist if you are unsure of how to use ORALCON. The usual dose is one tablet every day at the same time, preferably after the evening meal or at bedtime. During the first cycle of administration, take one white tablet daily for 21 consecutive days beginning on Day 1 of your menstrual cycle, i.e. the first day of bleeding. Take one red tablet daily for the next 7 consecutive days. You may have withdrawal bleeding within 2 to 4 days after the last white tablet is taken. You should use an additional method of protection until 14 tablets have been taken.

TAKING YOUR FIRST PACK OF ORALCON

- You must start by taking the tablet with the “Start” mark. It is important to realise that all tablets are not the same and that they must therefore be taken in the right order, starting with “Start” mark. The foil over first tablet is marked “Start”.
- After taking your first tablet, take one tablet each day, following the direction of the arrows, until you have finished all white 21 tablets in pack and then take 7 red tablets.
- You should try to take tablet at the same time every day.
- Swallow each tablet whole, with water if necessary
- By starting in this way, you will have contraceptive protection.

TAKING YOUR NEXT PACK OF ORALCON

Start taking your next pack of ORALCON the day after you have finished the current pack.

If you take more ORALCON than you should

If you have taken more than one tablet, you may experience nausea and withdrawal bleeding.

You should consult your doctor who will be able to advise you what action is necessary.

In the event of overdosage, consult your doctor or pharmacist. If neither is available seek help at the nearest hospital or poison centre.

If you forget to take ORALCON

You should take the missed tablet as soon as you remember. If you forgot to take tablets for two consecutive days, then you should take both the tablets as soon as you remember. In either case, you should take the next tablet at its usual time. Each time you miss one or two consecutive white tablets, you or your partner must use another method of contraception until you have taken tablets for next 14 consecutive days. If you miss one or more inert tablets, you will be still protected against pregnancy, provided you start the white tablets on the proper day. If you miss three consecutive white tablets discontinue the remainder of the package and discard it. Start a new package on the eighth day after you have taken the last tablet. You or your partner must use another method of contraception until you have taken tablets for next 14 consecutive days.

If you do not have withdrawal bleeding and you have taken ORALCON as per directions, it is unlikely that you have conceived. You must begin a second course of ORALCON on the usual day.

If you do not get bleeding at the end of your second cycle; you should stop taking ORALCON immediately and consult your doctor.

If you are taking the tablet for the treatment of painful menstrual bleeding or abnormal uterine bleeding, take the tablet in the same way as mentioned prevention of pregnancy.

4. Possible side effects

ORALCON can have side effects.

Not all side-effects reported for ORALCON are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while taking ORALCON, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea and/or vomiting, bloating, abdominal cramps
- Water retention
- Breast tenderness and menstrual irregularities such as spotting, breakthrough bleeding or complete stopping of menstrual bleeding
- Acne

Less frequent side effects:

- High blood pressure
- Intolerance to contact lenses has been reported and vision may deteriorate in some patients
- Headache, weight gain
- Impaired liver function
- Reduced glucose tolerance and changes in lipid metabolism
- Increased risk of cervical cancer, breast cancer, and liver tumours
- Rapid, involuntary movements
- Depression and other mental changes
- Changes in libido, vaginal infections.
- Spots or patches on the skin, and other skin or hair changes, skin rashes, increased facial

hair.

Post marketing reported side effects:

- Suicidal thoughts/behaviour and suicide

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

5. How to store ORALCON

- Store at or below 25 °C. Protect from light.
- In order to protect from light and moisture do not store in a bathroom.
- Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage system (e.g. toilet).

Store all medicines out of reach of children.

6. Contents of the pack and other information

What ORALCON contains

Active white tablets:

- The active substances are levonorgestrel 0,15 mg and ethinyl oestradiol 0,03 mg
- The other ingredients are: Acacia, disodium edetate, ethyl cellulose, lactose monohydrate, magnesium stearate, maize starch, methyl hydroxybenzoate, microcrystalline cellulose, polacrilin potassium, polyethylene glycol, purified talc, sucrose, titanium dioxide (CI no. 77891).

Inert red tablets:

Carnauba wax, disodium edetate, ethyl cellulose, gum acacia, lactose monohydrate, magnesium stearate, maize starch, methyl hydroxybenzoate, polacrilin potassium, ponceau 4R lake (CI no.

16255), purified talc, sodium benzoate, sucrose, titanium dioxide (CI no. 77891).

What ORALCON looks like and contents of the pack

Each white tablet is circular, biconvex and sugar-coated. Each red tablet is circular, biconvex and sugar-coated.

Aluminium/PVdC/PVC foil blister packs of 28 tablets (21 white and 7 red tablets) packed in a cardboard carton together with a leaflet.

Holder of Certificate of Registration

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