PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

ADCO-MIRTERON 15, 15 mg film-coated tablets
ADCO-MIRTERON 30, 30 mg film-coated tablets
ADCO-MIRTERON 45, 45 mg film-coated tablets

ADCO-MIRTERON 15: Each tablet contains mirtazapine 15 mg
Sugar (lactose monohydrate) 101,80 mg

ADCO-MIRTERON 30: Each tablet contains mirtazapine 30 mg
Sugar (lactose monohydrate) 203,60 mg

ADCO-MIRTERON 45: Each tablet contains mirtazapine 45 mg
Sugar (lactose monohydrate) 305,40 mg

Mirtazapine

Read all of this leaflet carefully before you start taking ADCO-MIRTERON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- ADCO-MIRTERON 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 ADCO-MIRTERON is and what it is used for

ADCO-MIRTERON contains active substance called mirtazapine, which belongs to group of medicines called antidepressants.
ADCO-MIRTERON is used to treat major depressive illness in adults (persistently depressed mood or loss of interest in activities, causing significant impairment in daily life).

2. What you need to know before you take ADCO-MIRTERON

Do not take ADCO-MIRTERON:

- If you are hypersensitive (allergic) to mirtazapine or any of the other ingredients of ADCO-MIRTERON (as listed in section 6).

- If you are pregnant or breastfeeding.
- If you are a child and under 18 years old.
- If you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).

Warnings and precautions
Take special care with ADCO-MIRTERON:

Children and adolescents
ADCO-MIRTERON should not be used for children and adolescents under 18 years. You should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take antidepressants such as with mirtazapine as contained in ADCO MIRTERON.

Thoughts of suicide and worsening of your depression
If you are depressed, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants such as with mirtazapine as contained in ADCO MIRTERON, since these medicines all take time to work, usually about two weeks but sometimes longer.
You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself.
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Also take special care with ADCO-MIRTERON.
If you have, or have ever had one of the following conditions:

- seizures (epilepsy). If you develop seizures or your seizures become more frequent, stop taking ADCO-MIRTERON and contact your doctor immediately;
- serious skin reactions like severe cutaneous adverse reactions (SCARs) including stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of ADCO-MIRTERON . Stop taking ADCO-MIRTERON and seek medical attention immediately if you notice any of the symptoms described in section 4 in relation to these skin reactions. If you ever developed any severe skin reactions, treatment with ADCO-MIRTERON must be stopped and should not be restarted;

- liver disease, including jaundice. If jaundice occurs, stop taking ADCO-MIRTERON and contact your doctor immediately;
- kidney disease;
- heart disease, or low blood pressure;
- certain kinds of heart conditions that may change your heart rhythm, a recent heart attack, heart failure, or take certain medicines that may affect the heart's rhythm;
- diabetes (you may need to adjust your dose of insulin or other antidiabetic medicines);
- schizophrenia. If psychotic symptoms, such as paranoid thoughts become more frequent or severe, contact your doctor straight away;
- manic depression (alternating periods of feeling elated/overactivity and depressed mood). If you start feeling elated or over-excited, stop taking ADCO-MIRTERON and contact your doctor immediately;
- eye disease, such as increased pressure in the eye (glaucoma);
- difficulty in passing water (urinating), which might be caused by an enlarged prostate;
- if you develop signs of infection such as inexplicable high fever, sore throat and mouth ulcers. Stop taking ADCO-MIRTERON and consult your doctor immediately for a blood test. In rare cases these symptoms can be signs of disturbances in blood cell production in the bone marrow.
- if you are an elderly person. You could be more sensitive to the side-effects of antidepressants such as ADCO-MIRTERON.

Other medicines and ADCO-MIRTERON
Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.

Do not take ADCO-MIRTERON in combination with:

- monoamine oxidase inhibitors (MAO inhibitors). Also, do not take ADCO-MIRTERON during the two weeks after you have stopped taking MAO inhibitors. If you stop taking ADCO-MIRTERON, do not take MAO inhibitors during the next two weeks either. Examples of MAO inhibitors are moclobemide, tranylcypromine (both antidepressants) and selegiline (used for Parkinson's disease).

Take care when taking ADCO-MIRTERON in combination with:

- antidepressants such as SSRIs, venlafaxine and L-tryptophan, or triptans (used to treat migraine), tramadol (a pain-killer), linezolid (an antibiotic), venlafaxine (used to treat depression), lithium (used to treat some psychiatric conditions), methylene blue (used to treat high levels of methaemoglobin in the blood and St. John's Wort - *Hypericum perforatum* preparations (a herbal remedy for depression). In very rare cases ADCO-MIRTERON alone or the combination of ADCO-MIRTERON with these medicines, can lead to a so-called serotonin syndrome. Some of the symptoms of this syndrome are: inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes, and unconsciousness. If you get a combination of these symptoms, talk to your doctor immediately.

- warfarin - medicines to prevent blood clotting. ADCO-MIRTERON can increase the effects of warfarin on the blood. In case of combination it is advised that your doctor monitors your blood carefully.
- medicines for anxiety or insomnia such as benzodiazepines; medicines for schizophrenia such as olanzapine; medicines for allergies such as cetirizine; medicines for severe pain such as morphine; alcohol.

In combination with these medicines ADCO-MIRTERON can increase the drowsiness caused by these medicines.

- medicines for infections; medicines for bacterial infections (such as erythromycin); medicines for fungal infections (such as ketoconazole); medicines for HIV/AIDS (such as HIV protease inhibitors) and medicines for stomach ulcers (such as cimetidine).

In combination with ADCO-MIRTERON, these medicines can increase the amount of ADCO-MIRTERON in your blood. Inform your doctor if you are using these medicines. It might be needed to lower the dose of ADCO-MIRTERON, or when these medicines are stopped, to increase the dose of ADCO-MIRTERON again.

- medicines for epilepsy such as carbamazepine and phenytoin; medicines for tuberculosis such as rifampicin.

In combination with ADCO-MIRTERON, these medicines can reduce the amount of ADCO-MIRTERON in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of ADCO-MIRTERON, or when these medicines are stopped, to lower the dose of ADCO-MIRTERON again.

- medicines that may affect the heart’s rhythm such as certain antibiotics and some anti-psychotics.to your doctor immediately.

ADCO-MIRTERON with food, drink and alcohol

You may get drowsy if you drink alcohol while you are taking ADCO-MIRTERON. You are advised not to drink any alcohol when taking ADCO-MIRTERON.

Pregnancy, breastfeeding and fertility

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.

You should not take ADCO-MIRTERON if you are pregnant or breastfeeding your baby (Refer to Do not take ADCO-MIRTERON, section 2).

If you use ADCO-MIRTERON tablets until, or shortly before birth, your baby should be supervised for adverse effects. When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your healthcare provider or doctor immediately.

Driving and using machines
ADCO-MIRTERON may decrease your concentration, alertness, judgment and thinking.
It is not always possible to predict to what extent ADCO-MIRTERON may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machinery until you are aware of the measure to which ADCO-MIRTERON affects you.

ADCO-MIRTERON contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

ADCO-MIRTERON contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take ADCO-MIRTERON

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

Always use ADCO-MIRTERON exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual starting dose is 15 mg every day. Your doctor may advise you to increase your dose after a few days to the amount that is best for you (between 15 and 45 mg per day).

Take ADCO-MIRTERON at the same time each day. It is best to take ADCO-MIRTERON as a single dose before you go to bed. However, your doctor may suggest you split your dose of ADCO-MIRTERON, once in the morning and once at night time, before you go to bed. The higher dose should be taken before you go to bed.

However, if you are an elderly person or if you have renal or liver disease, your doctor may adapt the dose.

If you take more ADCO-MIRTERON than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.
The most likely signs of an overdose of ADCO-MIRTERON alone are drowsiness, disorientation and increased heart rate. The symptoms of a possible overdose may include changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes.

If you forget to take ADCO-MIRTERON
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

If you stop taking ADCO-MIRTERON
Your doctor will tell you how long to take the treatment. Do not stop earlier than you are told, even if you feel better.
Do not suddenly stop taking ADCO-MIRTERON, even when your depression has lifted. If you suddenly stop taking ADCO-MIRTERON you may feel sick, dizzy, agitated or anxious, and have headaches. These symptoms can be avoided by stopping gradually. Your doctor will tell you how to decrease the dose gradually.

4. Possible side effects

ADCO-MIRTERON can have side effects.
Not all side effects reported for ADCO-MIRTERON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO-MIRTERON, please consult your healthcare provider for advice.
If any of the following happens, stop taking ADCO-MIRTERON and tell your doctor immediately or go to the casualty department of your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat (angioedema), 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 allergic reaction to ADCO-MIRTERON. 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:
Frequent

- Skin rash with fever
- Abnormal physical weakness or lack of energy

Less frequent

- Signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis);
- Feeling elated or emotionally ‘high’ (mania), false perceptions (hallucinations)
- Convulsions (fits)
- Inability to sit or keep still
- Inflammation of the pancreas which may cause abdominal pain and nausea
- Aggression

Frequency unknown

- Thoughts of harming or killing yourself;
- A skin reaction known as ‘erythema multiforme (itchy reddish purple patches on the skin, especially on the palms of the hands or soles of the feet, ‘hive-like’ raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and genitals, which may be accompanied by fever and tiredness);

- Reddish patches on the torso which are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis);
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome);
- Jaundice (yellowing of skin and/or eyes)
- ADCO-MIRTERON can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because ADCO-MIRTERON can cause shortage of white blood cells (granulocytopenia). ADCO-MIRTERON can also cause a shortage of red and white blood cells, as well as blood platelets (aplastic anaemia),a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia).

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

- Abnormal dreams
- Confusion
- Anxiety
- Trouble falling or staying asleep (insomnia)
- Drowsiness, sleepiness
- Dizziness
- Headache
- Involuntary shaking (tremor)
- Lack of energy and enthusiasm
- Memory loss
- Increase in appetite and weight gain
- Dry mouth
- Constipation
- Nausea, vomiting
- Diarrhoea
- Low blood pressure when you stand up from sitting or lying position
- Joint pain, muscle pain, back pain
- Abrupt onset of fever, headache, and fatigue (flu-like syndrome)
- Increased sweating

Less frequent side effects

- Thirst
- Moving or spinning sensation (vertigo)
- Abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paraesthesia)
- Sensations of numbness in the mouth (oral hypoaesthesia)
- Increase in liver enzymes

- Muscle twitching or contractions (myoclonus)
- Restless legs

Unknown frequency
- A bitter or bad taste in the mouth
- Condition that occurs when the level of sodium in the blood is too low (hyponatraemia)
- Sleepwalking
- A combination of symptoms such as inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes, unconsciousness and increased salivation. These can be signs of serotonin syndrome
- Slowed or slurred speech
- Your salivary glands produce more saliva than usual
- General swelling throughout the body
- Difficulty urinating and completely emptying the bladder
- A breakdown of muscle tissue that releases a damaging protein into the blood (rhabdomyolysis)
- Increased prolactin hormone levels in blood (hyperprolactinemia,including symptoms of enlarged breasts and/or milky nipple discharge).
- Increased enzyme level in blood (creatinine kinase).

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 or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO-MIRTERON.

5. How to store ADCO-MIRTERON
Store all medicines out of the reach of children.
Protect from light and moisture.
Store at or below 25 °C in a cool, dry place.
Store blisters in the original carton until required for use.
Do not use after the expiry date stated on the label and carton.
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 ADCO-MIRTERON contains
Each film-coated tablet contains either 15 mg, 30 mg and 45 mg of the active ingredient mirtazapine
The other ingredients are:

Tablet core: Croscarmellose sodium, lactose monohydrate, magnesium stearate, pregelatinised maize starch, silica colloidal anhydrous, talc.

Film-coating ingredients:
ADCO-MIRTERON 15: Opadry 03F22322 Yellow containing
hypromellose 6 cP (E464), iron oxide red (E172), iron oxide yellow (E172), macrogol/PEG 8000, titanium dioxide (E171), talc (used on film coat).
ADCO-MIRTERON 30: Opadry 03F23252 Orange containing hypromellose 6 cP (E464), iron oxide red (E172), iron oxide yellow (E172), macrogol/PEG 8000, titanium dioxide (E171), talc (used on film coat).
ADCO-MIRTERON 45: Opadry 03F28635 White containing hypromellose 6 Cp (E464), macrogol/PEG 8000, titanium dioxide (E171), talc (used on film coat).

What ADCO-MIRTERON looks like and contents of the pack
ADCO-MIRTERON 15: Yellow, scored on both sides, 10 x 5,2 mm oval, biconvex film-coated tablets. Marked 1.
ADCO-MIRTERON 30: Brownish, scored on both sides, 12.7 x 6.5 mm oval, biconvex film-coated tablets. Marked I.
ADCO-MIRTERON 45: White, 14.5 x 7.5 mm oval, biconvex film-coated tablets. Marked I.

Blister packs: Each carton contains 3 transparent PVC/silver aluminium blister strips of 10 tablets each to give a final pack size of 30 tablets.
Securitainers: White HDPE container with white LDPE cap containing 30 tablets.
Not all pack sizes may be marketed.

HOLDER OF THE CERTIFICATE OF REGISTRATION
Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685,
Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in
12 January 2026

REGISTRATION NUMBER (S):
ADCO-MIRTERON 15: A39/1.2/0217
ADCO-MIRTERON 30: A39/1.2/0218
ADCO-MIRTERON 45: A39/1.2/0219

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Product names	**Registration numbers**
ADCO-MIRTERON 15	12/1.2/0125
ADCO-MIRTERON 30	12/1.2/0124