SCHEDULING STATUS

S5

1. NAME OF THE MEDICINE

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

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

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.
ADCO-MIRTERON 15: Yellow, scored on both sides, 10 x 5.2 mm oval, biconvex film-coated tablets. Marked I.
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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults
Treatment of major depressive illness.

4.2 Posology and method of administration

Posology:
Adults
ADCO-MIRTERON should be given in an initial daily dose of 15 mg, which may be increased gradually according to clinical response. The usual effective dose lies within the range of 15 to 45 mg. Daily doses may be given as a single dose, preferably at bedtime, or in 2 equally divided doses. Changes in dose should be made at intervals of at least 1 to 2 weeks because of the long half-life.

For treatment of acute, depressive episodes, treatment should be continued for at least 6 months.
ADCO-MIRTERON should be withdrawn gradually to reduce the risk of withdrawal symptoms.

Special populations:
The clearance of mirtazapine may be decreased in elderly patients and in patients with renal or hepatic impairment. This should be taken into account when prescribing ADCO-MIRTERON to this category of patients.

Paediatric population
No information available.

Method of administration:
Tablets should be taken orally.

4.3 Contraindications
- Hypersensitivity to mirtazapine or to any of the excipients listed in section 6.1.
- Pregnancy and lactation, as there is insufficient clinical data available.
- Children and adolescents under the age of 18 years (see section 4.4).
- Concomitant monoamine oxidase inhibitors or within 14 days of discontinuation thereof (see section 4.5).

4.4 Special warnings and precautions for use
ADCO-MIRTERON should be used with caution in patients with epilepsy, hepatic or renal insufficiency.
ADCO-MIRTERON should not be used in the treatment of children and adolescents under the age of 18 years (see section 4.3). Suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants, such as mirtazapine as contained in ADCO MIRTERON, compared to those treated with placebo.

Bone marrow depression
Bone marrow depression, usually presenting as granulocytopenia or agranulocytosis, has been reported during treatment with ADCO-MIRTERON.
Patients should be advised to report any of the following symptoms during treatment: fever, sore throat, stomatitis, or other signs of infection. These may be signs of bone marrow depression (neutropenia, agranulocytosis).
Treatment should be stopped and a blood count performed.

Jaundice
Treatment should be stopped if jaundice develops.

Psychiatric disorders

Patients should be closely monitored during early therapy until improvement in depression is observed because suicide is an inherent risk in depressed patients.

Patients with major depressive disorder, both adults and children, may experience worsening of their depression and / or the emergence of suicidal ideation and behaviour, whether or not they are taking antidepressant medicines. The risk may persist until significant remission occurs. A causal role, however, for antidepressant medicine in inducing such behaviour has not been established. Patients being treated with ADCO-MIRTERON should, nevertheless, be observed closely for clinical worsening and suicidality, especially at the beginning of a course of therapy or at any time of dose changes, either increases or decreases.

Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions observed when treating patients with major depressive disorders should be observed when treating patients with other psychiatric and non-psychiatric disorders.

The following symptoms have been reported in patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric: anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness, impulsivity, akathisia, hypomania, and mania). Although a causal link between the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing ADCO-MIRTERON, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Suicide/suicidal thoughts or clinical worsening

Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). This risk may persist until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.

Patients with a history of suicide-related events or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts and should receive careful monitoring during treatment with ADCO-MIRTERON.

Clinical trials of antidepressants, such as mirtazapine as contained in ADCO MIRTERON, in adult patients with psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants, such as ADCO-MIRTERON, compared to placebo in patients less than 25 years old.

Close supervision of patients and in particular those at high risk should accompany therapy with antidepressants, such as ADCO-MIRTERON, especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behaviour or thoughts and unusual changes in behaviour and to seek medical advice immediately if these symptoms present.

With regards to the change of suicide, in particular at the beginning of treatment, only a limited number of ADCO-MIRTERON tablets should be given to a patient.

Severe cutaneous adverse reactions
Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), bullous dermatitis and erythema multiforme, which can be life-threatening or fatal, have been reported in association with ADCO-MIRTERON treatment.
If signs and symptoms suggestive of these reactions appear, ADCO-MIRTERON should be withdrawn immediately.
If the patient has developed one of these reactions with the use of ADCO-MIRTERON, treatment with ADCO-MIRTERON must be stopped and not restarted in this patient at any time.

Careful dosage as well as regular and careful monitoring is necessary in these patients
Caution should also be exercised in patients with diabetes mellitus, psychoses and those with a history of bipolar disorder.

Renal and urinary disorders
ADCO-MIRTERON has weak antimuscarinic activity, therefore caution should be exercised in patients with micturition disturbances.

Eye disorders
*C*losed angle glaucoma, and raised intraocular pressure.

Patients should be advised to report any of the following symptoms during treatment
Fever, sore throat, stomatitis, or other signs of infection. These may be signs of bone marrow depression (neutropenia, agranulocytosis). Treatment should be stopped and a blood count performed.

Epilepsy and organic brain symptoms
ADCO-MIRTERON should be introduced cautiously in patients who have a history of seizures. Treatment should be discontinued in any patient who develops seizures, or where there is an increase in seizure frequency.

Hepatic impairment
Following a single 15 mg oral dose of mirtazapine as contained in ADCO-MIRTERON 15, the clearance of mirtazapine was approximately 35 % decreased in mild to moderate hepatically impaired patients, compared to subjects with normal hepatic function. The average plasma concentration of mirtazapine as contained in ADCO-MIRTERON was about 55 % increased.

Renal impairment
Following a 15 mg oral dose of mirtazapine as contained in ADCO-MIRTERON, in patients with moderate (10 ml/min ≤ creatinine clearance < 40 ml/min) and severe (creatinine clearance < 10 ml/min) renal impairment the clearance of mirtazapine was about 30 % and 50 % decreased respectively, compared to normal subjects. The average plasma concentration of mirtazapine was about 55 % and 115 % increased, respectively. No significant differences were found in

patients with mild renal impairment (40 ml/min ≤ creatinine clearance < 80 ml/min) as compared to the control group.

Cardiac disorders such as conduction disturbances, angina pectoris, and recent myocardial infarction, as well as in patients with hypotension**,** where normal precautions should be taken, and concomitant medicines carefully administered.

Diabetes mellitus
In patients with diabetes, antidepressants such as ADCO-MIRTERON may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted and close monitoring is recommended.

The following should be taken into account:
Worsening psychotic symptoms can occur when ADCO-MIRTERON is administered to patients with schizophrenia or other psychotic disturbances; paranoid thoughts can be intensified.
When the depressive phase of bipolar disorder is being treated, it can transform into the manic phase. Patients with a history of mania/hypomania should be closely monitored. ADCO-MIRTERON should be discontinued in any patient entering a manic phase.
Post-marketing experience with mirtazapine as contained in ADCO-MIRTERON shows that abrupt termination of treatment after long term administration of ADCO-MIRTERON may result in withdrawal symptoms. The majority of withdrawal reactions are mild and self-limiting. Among the various reported withdrawal symptoms, dizziness, agitation, anxiety, headache and nausea were the most frequently reported. As advised in section 4.2 it is recommended to discontinue treatment with ADCO-MIRTERON gradually.

Akathisia/psychomotor restlessness
The use of ADCO-MIRTERON has been associated with the development of akathisia, characterized by a subjectively unpleasant or distressing restlessness and a need to move often, accompanied by an inability to sit or stand still. This is most likely to occur within the first few weeks of treatment. In patients who develop these symptoms, increasing the dose may be detrimental.
The effect of mirtazapine, such as contained in ADCO-MIRTERON, on QTc interval was assessed in a randomized, placebo and moxifloxacin controlled clinical trial involving 54 healthy volunteers using exposure response analysis. This trial revealed that both 45 mg (therapeutic) and 75 mg (supratherapeutic) doses of mirtazapine did not affect the QTc interval to a clinically meaningful extent. During the post-marketing use of mirtazapine, cases of QT prolongation, Torsades de Pointes, ventricular tachycardia and sudden death, have been reported. The majority of reports occurred in association with overdose or in patients with other risk factors for QT prolongation, including concomitant use of QTc prolonging medicines (see section 4.5). Caution should be exercised when ADCO-MIRTERON is prescribed in patients with known cardiovascular disease or family history of QT prolongation, and in concomitant use with other medicines thought to prolong the QTc interval.

Hyponatraemia
Hyponatraemia, probably due to inappropriate antidiuretic hormone secretion (SIADH), has been reported with the use of ADCO-MIRTERON. Caution should be exercised in patients at risk, such as elderly patients or patients concomitantly treated with medications known to cause hyponatraemia.

Serotonin syndrome
Interaction with serotonergic active substances:
Serotonin syndrome may occur when ADCO-MIRTERON is used concomitantly with other serotonergic active substances (see section 4.5). Symptoms of serotonin syndrome may be hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, mental status changes that include confusion, irritability and extreme agitation progressing to delirium and coma.

Elderly patients
Elderly patients are often more sensitive, especially with regards to the undesirable effects of antidepressants, including ADCO-MIRTERON. During clinical research with mirtazapine as contained in ADCO-MIRTERON, undesirable effects have not been reported more often in elderly patients than in other age groups.

MAO-Inhibitors
In patients receiving ADCO-MIRTERON in combination with a monoamine oxidase inhibitor (MAOI) and in patients who have recently discontinued ADCO-MIRTERON and then are started on an MAOI, there have been reports of serious and sometimes fatal reactions e.g. including nausea, vomiting, flushing, dizziness, tremor, myoclonus, rigidity, diaphoresis, hyperthermia, autonomic instability with rapid fluctuations of vital signs, seizures and mental status changes ranging from agitation to coma. ADCO-MIRTERON should not be used in combination with an MAOI, or within 14 days of initiating or discontinuing therapy with an MAOI including linezolid (see sections 4.3 and 4.5).

If the decision is made to discontinue treatment, ADCO-MIRTERON should be tapered (See section 4.2).

ADCO-MIRTERON may decrease alertness, judgment, thinking and concentration. Therefore, operating machinery or driving a vehicle should be avoided during treatment.

Contains lactose
Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, total lactase deficiency or glucose-galactose malabsorption
should not take ADCO-MIRTERON.

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

4.5 Interactions with other medicines and other forms of interaction

Pharmacodynamic interactions
MAOI: ADCO-MIRTERON should not be used concomitantly with MAO inhibitors, including linezolid or within two weeks of discontinuing a MAOI (see section 4.3).
Alcohol: ADCO-MIRTERON may potentiate the central nervous depressant action of alcohol and patients should therefore be advised to avoid alcohol.
Anxiolytics and Hypnotics: Use of ADCO-MIRTERON may potentiate the sedative effects of benzodiazepines and other sedatives (including antipsychotics, antihistamine H1 antagonists, opioids. Caution should be taken when these medicines are prescribed together with ADCO-MIRTERON.
Co-administration with other serotonergic active substances (L-tryptophan, triptans, tramadol, linezolid, methylene blue, SSRI's, venlafaxine, lithium and St. John's Wort - *Hypericum perforatum* - preparations) may lead to an incidence of serotonin associated effects (serotonin syndrome: see section 4.4). Caution should be advised, and a closer clinical monitoring is required when these active substances are combined with ADCO-MIRTERON.
Mirtazapine such as contained in ADCO-MIRTERON dosed at 30 mg once daily caused a small, but statistically significant increase in the international normalised ratio (INR) in subjects treated with warfarin. As at a higher dose of ADCO-MIRTERON a more pronounced effect cannot be excluded. It is advisable to monitor the INR in case of concomitant treatment of warfarin with ADCO-MIRTERON.
The risk of QT prolongation and/or ventricular dysrhythmias (e.g. Torsades de Pointes) may be increased with concomitant use of medicines which prolong the QTc interval (e.g. some antipsychotics and antibiotics) and in case of ADCO-MIRTERON overdose.

Pharmacokinetic interactions
Carbamazepine and phenytoin, CYP3A4 inducers, increased mirtazapine, as contained in ADCO-MIRTERON, clearance about two-fold, resulting in a decrease in average plasma mirtazapine concentration of 60 % and 45 %, respectively. When carbamazepine or any other inducer of hepatic metabolism (such as rifampicin) is added to ADCO-MIRTERON therapy, the ADCO-MIRTERON dose may have to be increased. If treatment with such medicinal product is discontinued, it may be necessary to reduce the ADCO-MIRTERON dose.
Co-administration of the potent CYP3A4 inhibitor ketoconazole increased the peak plasma levels and the AUC of mirtazapine, as contained in ADCO-MIRTERON, by approximately 40 % and 50 % respectively.
When cimetidine (weak inhibitor of CYP1A2, CYP2D6 and CYP3A4) is administered with ADCO-MIRTERON, the mean plasma concentration of mirtazapine may increase more than 50 %. Caution should be exercised, and the dose may have to be decreased when co-administering ADCO-MIRTERON with potent CYP3A4 inhibitors, HIV protease inhibitors, azole antifungals, erythromycin, cimetidine or nefazodone.

Interaction studies did not indicate any relevant pharmacokinetic effects on concurrent treatment of ADCO-MIRTERON with paroxetine, amitriptyline, risperidone or lithium.

ADCO-MIRTERON should be used cautiously when co-administered with:
Buprenorphine/opioids as the risk of serotonin syndrome, a potentially lifethreatening condition, is increased (see section 4.4).

4.6 Fertility, pregnancy and lactation

ADCO-MIRTERON is contraindicated in pregnancy and lactation (see section 4.3).

Pregnancy

Epidemiological data have suggested that the use of SSRIs in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). Although no studies have investigated the association of PPHN to mirtazapine treatment, this potential risk cannot be ruled out taking into account the related mechanism of action (increase in serotonin concentrations).

Breastfeeding

Although animal experiments show that mirtazapine is excreted only in very small amounts in the milk, the use of mirtazapine in breast-feeding mothers is not recommended. No human data is available.

Fertility

Non-clinical reproductive toxicity studies in animals did not show any effect on fertility.

4.7 Effects on ability to drive and use machines

ADCO-MIRTERON may decrease alertness, judgment, thinking and concentration. Therefore, operating machinery or driving a vehicle should be avoided during treatment.

4.8 Undesirable effects

Tabulated summary of adverse reactions

MedDRA System Organ Class	**Frequent**	**Less Frequent**	**Frequency unknown**
Blood and lymphatic system disorders		Reversible agranulocytosis	Leucopenia, granulocytopaenia
Metabolism and nutritional disorders	An increase in appetite and weight gain, dry mouth, constipation	Thirst, nausea, vomiting	Bitter taste (in the mouth)
Nervous system disorders	Drowsiness or sedation,-dizziness, headache, tremor, lethargy, amnesia	Epileptic seizure, vertigo, nightmares, agitation, mania, paraesthesia,	

		hallucinations, convulsions, myoclonus and restless legs syndrome	
Psychiatric disorders	Abnormal dreams, confusion, anxiety, insomnia	Nightmares, psychomotor restlessness (incl. akathisia, hyperkinesia), aggression	
Vascular disorders	Postural hypotension, orthostatic hypotension	Oedema, peripheral oedema	
Gastrointestinal disorders	Dry mouth, constipation, nausea, vomiting, diarrhoea	Thirst, oral hypoaesthesia, pancreatitis	Bitter taste in mouth, mouth oedema, increased salivation
Hepatobiliary disorders		Increases in liver enzyme levels have been reported	Jaundice may occur
Skin and subcutaneous tissue disorders	Exanthema	Oedema	
Musculoskeletal and connective tissue disorders	Arthralgia and myalgia, back pain		
General disorders and administration site conditions	Flu-like syndrome, asthenia, increased sweating		

Post-marketing side effects

The reported post-marketing adverse reactions of which the *frequency is not known*:

MedDRA System Organ Class	**Description**
Blood and the lymphatic system disorders	Bone marrow depression (granulocytopenia, agranulocytosis, aplastic anaemia and thrombocytopenia), eosinophilia
Metabolism and nutrition disorders	Hyponatraemia
Psychiatric disorders	Suicidal ideation, suicidal behaviour, somnambulism
Nervous system disorders	Convulsions (insults), serotonin syndrome, oral paraesthesia, dysarthria

Gastrointestinal disorders	Mouth oedema, increased salivation
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome, dermatitis bullous, erythema multiforme, toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS).
General disorders and administration site conditions	Generalised oedema, localised oedema.
Renal and urinary disorders	Urinary retention
Investigations	Increased creatinine kinase
Musculoskeletal and connective tissue disorders	Rhabdomyolysis
Endocrine disorders	Inappropriate antidiuretic hormone secretion, hyperprolactinemia (and related symptoms galactorrhoea and gynaecomastia)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose
There is no specific antidote for ADCO-MIRTERON.
Treatment is symptomatic and supportive.
Present experience concerning overdose with ADCO-MIRTERON alone indicates that symptoms are usually mild. Depression of the central nervous system with disorientation and prolonged sedation have been reported, together with tachycardia and mild hyper- or hypotension.
However, there is a possibility of more serious outcomes (including fatalities) at dosages much higher than the therapeutic dose, especially with mixed overdoses. In these cases, QT prolongation and Torsade de Pointes have also been reported.
ECG monitoring should be undertaken.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: A 1.2. Psychoanaleptics (antidepressants)
ATC code: N06AX11
Mirtazapine is a tetracyclic antidepressant, belonging to the piperazino-azepine group of compounds.

Mechanism of action:
Mirtazapine is centrally acting as a pre-synaptic α_2-antagonist, which increases the central

noradrenergic and serotonergic neurotransmission. It limits the effectiveness of inhibitory α_2-adrenergic heteroreceptors on serotonergic neurons as well as inhibitory α_2-autoreceptors and 5-HT_{2A} heteroreceptors on noradrenergic neurons, which enhances the release of both amines. It has antagonistic effects at several post-synaptic serotonin receptor types (including 5-HT_{2A}, 5-HT_{2C}, and 5-HT_3 receptors) and can produce gradual down regulation of 5-HT_{2A} receptors. These several actions probably contribute to the antidepressant effect. Mirtazapine also is a histamine H_1-receptor antagonist, and correspondingly, relatively sedating.

5.2 Pharmacokinetic properties

Absorption

Mirtazapine is well absorbed (bioavailability = 50 %) from the gastrointestinal tract with peak plasma levels occurring after about 2 hours. Food intake has no influence on the pharmacokinetics of mirtazapine.

Distribution

Plasma protein binding is about 85 %. Steady state concentrations are reached after 3-4 days, after which there is no further accumulation. Mirtazapine displays linear pharmacokinetics within the recommended dose range.

Metabolism and elimination

Mirtazapine is extensively metabolized in the liver and the major biotransformation pathways are demethylation and oxidation followed by glucuronide conjugation; *In vitro* studies of human liver microsomes show that cytochrome P450 isoenzymes involved are CYP2D6, CYP1A2, and CYP3A4. The N-desmethyl metabolite is pharmacologically active. The mean plasma elimination half-life is 20 to 40 hours. Elimination is via urine (75 %) and faeces (15 %).

Special patient populations

The clearance of mirtazapine may be decreased in patients with renal or hepatic insufficiency.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Croscarmellose sodium,
Lactose monohydrate,
Magnesium stearate,
Pregelatinised maize starch (Starch 1500),
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).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Store at or below 25 °C in a cool, dry place.
Protect from light and moisture.
Keep well closed. Keep blister in carton until required for use.

6.5 Nature and contents of container:
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.

6.6 Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with local requirements.

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

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Registration date: 07 July 2006

10. DATE OF REVISION OF THE TEXT

12 January 2026

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