SCHEDULING STATUS

S5

ADCO PAROXETINE 20 mg, (20 mg film-coated tablets)
Paroxetine
Contains sugar (lactose monohydrate): 3,81 mg

Read all of this leaflet carefully before you start taking ADCO PAROXETINE 20 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.
- ADCO PAROXETINE 20 mg 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 the leaflet

1. What ADCO PAROXETINE 20 mg is and what it is used for
2. What you need to know before you take ADCO PAROXETINE 20 mg
3. How to take ADCO PAROXETINE 20 mg
4. Possible side effects
5. How to store ADCO PAROXETINE 20 mg
6. Contents of the pack and other information

1. What ADCO PAROXETINE 20 mg is and what it is used for

The active substance is paroxetine, and belongs to a group of medicines called antidepressants.
ADCO PAROXETINE 20 mg is used for depression (major depressive episodes), panic disorder with and without agoraphobia (fear of leaving the house, entering shops, or fear of public places), obsessive compulsive disorder (compulsive thoughts and compulsive actions) and social phobia (overwhelming fear or avoidance of everyday social situations).

2. What you need to know before you take ADCO PAROXETINE 20 mg

Do not take ADCO PAROXETINE 20 mg:

- If you are hypersensitive (allergic) to paroxetine or any of the other ingredients of ADCO PAROXETINE 20 mg (listed in section 6).
- If you are using monoamine-oxidase (MAO) inhibitors.
- If you are pregnant or lactating.
- If you are younger than the age of 18 years.

Warnings and precautions

Take special care with ADCO PAROXETINE 20 mg:

- If you have major depressive disorder. Both adults and children may experience worsening of their depression and/or the development of suicidal ideation and behaviour, whether or not they are taking antidepressant medicines.
- Your doctor will observe you closely for worsening of your original complaint, as well as increased thoughts or behaviours towards suicide; especially at the start of taking ADCO PAROXETINE 20 mg**,** or at any time when the dose changes, either increases or decreases.
- If you experience any of the following side effects: anxiety, agitation, panic attacks, insomnia (inability to sleep), irritability, hostility (aggressiveness), impulsivity, involuntary movements, depression, and mania (a state of mind characterised by excessive cheerfulness and increased activity); and if these symptoms are severe, quick in onset, or were not part of your original symptoms; contact your doctor. He or she may consider changing your medicine. If you are required to discontinue ADCO PAROXETINE 20 mg your dose will be decreased very slowly.
- If ADCO PAROXETINE 20 mg is discontinued without being decreased slowly you may experience the following side effects: dizziness, confusion, nausea, sleep problems, inability to sleep, problems with your senses (seeing, hearing, touch, taste, smell), shaking and sweating.
- If you have a history of mania.
- If you are using neuroleptic medicine or warfarin. Please consult your doctor, pharmacist or other health care professional for advice.
- If you have serious heart problems.
- If you have epilepsy, patients receiving ADCO PAROXETINE 20 mg may experience seizures.
- If you have narrow angle glaucoma.
- If you have a history of bleeding disorders or if you are pregnant (see Pregnancy, breastfeeding and fertility in section 2).
- If you are undergoing electro-convulsive therapy while taking paroxetine. Limited clinical experience is available.

Children and adolescents

Safety and efficacy in children under 18 years of age have not been established.

Other medicines and ADCO PAROXETINE 20 mg

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

ADCO PAROXETINE 20 mg interacts with cimetidine, phenytoin, debrisoquine, sparteine, monoamine-oxidase (MAO) inhibitors, tryptophan medication, lithium, procyclidine and warfarin.

ADCO PAROXETINE 20 mg with alcohol
It is advisable to avoid alcohol during therapy with ADCO PAROXETINE 20 mg.

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.
The safety of ADCO PAROXETINE 20 mg in human pregnancy has not been established.
Paroxetine is excreted in breast milk, and therefore should not be used during lactation.
If you take ADCO PAROXETINE 20 mg near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor, nurse or other health care professional should be aware that you are taking ADCO PAROXETINE 20 mg so they can advise you.

Driving and using machines
Patients taking ADCO PAROXETINE 20 mg should exercise caution when driving a car or operating machinery.
It is not always possible to predict to what extent ADCO PAROXETINE 20 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ADCO PAROXETINE 20 mg affects them.

ADCO PAROXETINE 20 mg contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take ADCO PAROXETINE 20 mg
Do not share medicines prescribed for you with any other person.
Always take ADCO PAROXETINE 20 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Depression
The recommended initial dose is 20 mg daily. It may be necessary in some patients to increase the dose. This should be done gradually by 10 mg increments (half a tablet) to a maximum of 50 mg daily, according to the patient’s response.

Panic disorder
The recommended dose is 40 mg a day. Patients should start on 10 mg (half a tablet) per day to avoid a possible worsening of the panic symptomatology during early treatment of panic disorders; a low initial starting dose is therefore recommended. The dose may be increased weekly in 10 mg increments (half a tablet), according to the patient’s response, to a maximum of 60 mg per day.

Obsessive compulsive disorder
The recommended dose is 40 mg per day. Patients should start on 20 mg per day and the dose may be increased weekly in 10 mg increments (half a tablet) according to the patient's response to a maximum of 60 mg per day.

Social phobia
The recommended dose is 20 mg per day. The dose may be increased weekly in 10 mg increments (half a tablet) according to the patient's response to a maximum of 40 mg per day.

General Information
ADCO PAROXETINE 20 mg is administered orally.
The tablets must be swallowed and not chewed.
The tablets should preferably be taken once daily in the morning with food, as it has been shown that a morning dose does not affect duration or quality of sleep. Sleep patterns are likely to improve in patients as they respond to ADCO PAROXETINE 20 mg therapy.
It is recommended that a course of antidepressant treatment should continue for a sufficient period, which may be several months for depression and may be even longer for obsessive compulsive disorder and panic disorder to ensure that patients are symptom free.

Elderly
Increased plasma concentrations occur in the elderly. The recommended dose is 20 mg per day. In some patients it may be necessary to increase the dose. This should be done gradually by 10 mg increments to a maximum of 40 mg according to the patient's response.

Renal/hepatic impairment
The dosage given to patients with severe renal (creatinine clearance < 30 ml/min) or severe hepatic impairment should be restricted to the lower end of the dosage range as elevated plasma concentrations of paroxetine have occurred in such patients.

If you have the impression that the effect of ADCO PAROXETINE 20 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more ADCO PAROXETINE 20 mg than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Overdosage may result in nausea, vomiting, tremor, dilated pupils, dry mouth and irritability.

If you forget to take ADCO PAROXETINE 20 mg
Do not take a double dose to make up for forgotten individual doses.

If you stop taking ADCO PAROXETINE 20 mg
Your doctor will tell you how long your treatment with ADCO PAROXETINE 20 mg will last. Following abrupt discontinuation of paroxetine, symptoms including dizziness, confusion, nausea, sleep disturbance, insomnia, sensory disturbances, tremor and sweating have been reported. Your doctor will taper your dose downwards on discontinuation of therapy.

4. Possible side effects

ADCO PAROXETINE 20 mg can have side effects.
A decrease in the intensity and frequency of adverse events may be expected with continued treatment.

Not all side effects reported for ADCO PAROXETINE 20 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO PAROXETINE 20 mg, please consult your health care provider for advice.

The most frequently reported adverse events are: nausea, vomiting, dyspepsia (indigestion), constipation, diarrhoea, sexual dysfunction, somnolence (sleepiness), sweating, tremor, asthenia, dry mouth, insomnia, dizziness, anxiety, decreased appetite and headaches.

Abnormal liver function tests (elevated levels of hepatic enzymes) have occurred, with isolated cases of serious liver function abnormalities. Treatment should be discontinued in these cases.

There have been reports of extrapyramidal symptoms (involuntary or uncontrollable movements, tremors or muscle contractions) associated with the use of paroxetine and of aggravation of Parkinson's disease in patients taking paroxetine. It should therefore be avoided in patients with extrapyramidal disorders or who were using neuroleptic medication.

ADCO PAROXETINE 20 mg should be used with caution in patients already receiving neuroleptics, since symptoms suggestive of neuroleptic malignant syndrome cases have been reported with this combination.

Hyponatraemia possibly due to inappropriate secretion of antidiuretic hormone, has been associated with the use of antidepressants, particularly in the elderly.

The hyponatraemia generally reverses on discontinuation of paroxetine.
Bruising, rash, acute glaucoma, urinary retention, peripheral and facial oedema, neuroleptic malignant syndrome, confusion, abnormal bleeding (mostly ecchymosis and purpura) and symptoms suggestive of hyperprolactinaemia/galactorrhoea have been reported.

"Serotonin Syndrome": which includes symptoms of confusion, hallucinations, agitation, inco-ordination, excessive sweating, hyperreflexia, tachycardia, myoclonus, diarrhoea, shivering, fever and tremor.

Following abrupt discontinuation of paroxetine, symptoms including dizziness, confusion, nausea, sleep disturbance, insomnia, sensory disturbances, tremor and sweating have been reported.

Heavy vaginal bleeding shortly after birth (postpartum haemorrhage) has been reported (frequency unknown). See Pregnancy, breastfeeding and fertility in section 2 for more information.

In children, reports of hostility, suicidal ideation and self-harm.

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

Reporting side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ADCO PAROXETINE 20 mg.

5. How to store ADCO PAROXETINE 20 mg

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Keep blister strips in outer carton until required for use.
ADCO PAROXETINE 20 mg should be stored at or below 25 °C.
Protect from light and moisture.
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 PAROXETINE 20 mg contains
The active substance is paroxetine.
The other ingredients are calcium hydrogen phosphate anhydrous, iron oxide yellow (E172) and iron oxide red (E172), lactose monohydrate, magnesium stearate, methylhydroxypropyl cellulose, polyethylene glycol 4000, sodium starch glycolate and titanium dioxide (E171).

What ADCO PAROXETINE 20 mg looks like and contents of the pack
A yellow to orange, round shaped, film-coated tablet. The tablet is debossed with "POT 20" on one side. The tablet is scored on both sides.

Carton boxes with 1, 2, 3 or 5 PVC/PE/PVDC/Al-blisters or PVC/TE/PVDC/Al-blisters or Alu/Alu blisters with 10 tablets each, resulting in total pack sizes of 10, 20, 30 or 50 tablets or

carton boxes with 1, 2 or 4 PVC/PE/PVDC/Al-blisters or PVC/TE/PVDC/Al-blisters or Alu/Alu blisters with 14 tablets each, resulting in total pack sizes of 14, 28 or 56 tablets
or
300 ml white, opaque HDPE container with child-resistant closure containing 500 tablets.
Not all pack sizes may be marketed.

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