1.3.2 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

METHADONE ADCO 10 mg, (oral solution)

Each ml contains 10 mg methadone hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking METHADONE ADCO 10 mg

- 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.
- METHADONE ADCO 10 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 this leaflet

Dharmisha Bhaga

1. What METHADONE ADCO 10 mg is and what it is used for

METHADONE ADCO 10 mg is a medicine which contains methadone hydrochloride. This belongs to a group of medicines called narcotic analgesics.

METHADONE ADCO 10 mg is used in the treatment of opioid drug addiction.

2. What you need to know before you use METHADONE ADCO 10 mg

Do not take METHADONE ADCO 10 mg if:

- you are hypersensitive (allergic) to methadone or any of the other ingredients of METHADONE ADCO 10 mg (listed in section 6);
- you have any breathing difficulties or during an asthma attack;
- you are dependent on alcohol or any other medicines;
- you have or have recently had a head injury;
- you are taking monoamine oxidase inhibitors (MAOIs) which are medicines used to treat depression or if you have taken a MAOI medicine in the past two weeks (see Other medicines and Methadone Adco 10 mg);
- you are in labour;
- you have ulcerative colitis (inflammatory bowel disease);
- you have liver failure
- you have biliary and renal tract spasm.

You must not use METHADONE ADCO 10 mg during an asthma attack. Wait until the asthma attack has passed and you are fully recovered before taking METHADONE ADCO 10 mg. METHADONE ADCO 10 mg should not be given to children.

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Warnings and precautions

Special care should be taken with METHADONE ADCO 10 mg:

- If you have any breathing problems or lung conditions;
- If you have problems with your adrenal glands. These are linked to your kidneys;
- If you have liver or kidney problems;
- If you have low thyroid function (hypothyroidism);
- If you have convulsive disorders (seizures);
- If you have a head injury;
- If you are an elderly or very ill person. You may be sensitive to the medicine and it may cause low blood pressure and fainting;
- Myasthenia gravis (weakness and rapid fatigue of the muscles);
- If you have any heart condition as this can be aggravated with the use of METHADONE ADCO 10 mg.
- If you have bowel problems;
- If you have problems with your gallbladder and bile duct.

Addiction/Tolerance/Dependence

Taking this medicine regularly, particularly for a long time, can lead to addiction. Taking higher doses or more frequent doses of METHADONE ADCO 10 mg, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

You may notice that some of the side effects become less severe with time as you get used to METHADONE ADCO 10 mg.

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Withdrawal

This medicine should not be stopped suddenly, but gradually, as sudden stoppage could lead to withdrawal symptoms. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Children

You should not take this medicine if you are under 16 years of age. If your child is under is under 16 years of age, you should not give your child this medicine as it may cause breathing difficulty.

Other medicines and METHADONE ADCO 10 mg

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

Tell your doctor if you are taking the following medicines:

- Medicines used to treat depression (e.g. monoamine oxidase inhibitors, fluvoxamine, fluoxetine). Caution must be exercised in concomitant administration of MAO inhibitors and for two weeks after treatment;
- CNS depressants (e.g. medicines such as sedatives, tranquilizers, hypnotics, anaesthetics);
- H_2 antagonists (e.g. cimetidine, used to reduce stomach acid production);
- Antibacterial medicines such as rifampicin (used to treat tuberculosis), ciprofloxacin, and macrolide antibiotics (e.g. erythromycin);

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- Medicines used to treat epilepsy (e.g. phenytoin, carbamazepine);
- Medicines that make the urine acidic (e.g. ascorbic acid –vitamin C);
- Opioid agonist analgesics (e.g. strong painkillers such as codeine, pentazocine);
- Medicines used to block or reverse the effects of opioids (e.g. naloxone, naltrexone, buprenorphine);
- Antiretroviral medicines (e.g. nelfinavir, nevirapine, efavirenz) - may affect blood concentrations of methadone and therefore, your doctor may consider METHADONE ADCO 10 mg dosage adjustments if you are taking these medicines;
- Azole antifungal medicines (e.g. ketoconazole, fluconazole);
- St John's Wort (herbal preparation used for depression);
- Sedative medicines (medicines that make you sleepy e.g. benzodiazepines including alprazolam or diazepam);
- Medicines for heart problems (e.g. verapamil, enalapril);
- Medicines which affect the electrolyte balance such as diuretics (water tablets) or lithium.

Please consult your doctor, pharmacist, nurse or other health care provider for advice.

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.

Withdrawal symptoms, difficulty breathing and a low birth weight may occur in babies after METHADONE ADCO 10 mg treatment during pregnancy.

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METHADONE ADCO 10 mg should not be administered during pregnancy.

METHADONE ADCO 10 mg is distributed into breast milk. You should therefore not use METHADONE ADCO 10 mg while breastfeeding your baby.

Driving and using machines

Your ability to drive or use machinery may be severely affected during and after treatment with METHADONE ADCO 10 mg. You must not drive or use machinery until you are told that you can do so by your doctor.

This medicine can affect your ability to drive as it may make you sleepy or dizzy. Do not drive while taking this medicine until you know how it affects you.

METHADONE ADCO 10 mg contains amaranth

METHADONE ADCO 10 mg contains amaranth and may cause allergic reactions.

3. How to take METHADONE ADCO 10 mg

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

METHADONE ADCO 10 mg is to be taken by mouth.

METHADONE ADCO 10 mg is normally administered once daily.

Always take METHADONE ADCO 10 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Treatment with METHADONE ADCO 10 mg assumes that you are taking part in a programme including drug-assisted rehabilitation for narcotics abuse, approved by a relevant authority.

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The dose will be determined by your doctor and is tailored for each individual patient.

The correct dosage should be extracted from the bottle by using a dispenser, measuring cylinder or syringe.

Adults: The usual dose for addiction is initially 20 mg once daily. Your doctor will increase the dose over three weeks until you feel well and do not have withdrawal symptoms. The final dose is usually between 60 mg and 120 mg in 24 hours.

Children: METHADONE ADCO 10 mg must not be used in children.

If you are elderly or very ill, you should be careful when taking repeated doses.

If you suffer from impaired liver function, hypothyroidism or prostatic hypertrophy, your doctor may prescribe a lower initial dose.

Your doctor will tell you how long your treatment with METHADONE ADCO 10 mg will last.

If you have the impression that the effect of METHADONE ADCO 10 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more METHADONE ADCO 10 mg than you should

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take METHADONE ADCO 10 mg

Do not take a double dose to make up for the forgotten individual doses.

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If you stop taking METHADONE ADCO 10 mg

Do not stop taking METHADONE ADCO 10 mg unless your doctor tells you to. If you stop this medicine abruptly, you will experience withdrawal effects. Your doctor will reduce your dose gradually.

4. Possible side effects

METHADONE ADCO 10 mg can have side effects.

Not all side effects reported for METHADONE ADCO 10 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking METHADONE ADCO 10 mg, please consult your health care provider for advice.

If any of the following happens, stop taking METHADONE ADCO 10 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe itching of your skin with raised lumps.

These are all very serious side effects. If you have them, you may have had a serious reaction to METHADONE ADCO 10 mg. 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:

- Changes in the way your heart beats, for example if you notice it beating faster;
- Breathing difficulties and worsening of existing asthma;
- If your breathing becomes slow and shallow.
- Confusion;

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- Sleep disturbances;
- Feeling elated (very happy); feeling down (dysphoria);
- Agitation (annoyance);
- Blurred vision, small pupils, dry eyes, visual disturbances
- Seeing or hearing things that are not there (hallucinations).
- Breast growth and production of breast milk;

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:

- Nausea (feeling sick);
- Vomiting;
- Constipation;
- Sweating;
- Dizziness;
- Drowsiness;
- Feeling weak, tired;
- Weight gain;

Less frequent side effects:

- Dry mouth;
- Low blood pressure;
- Itching skin;
- Problems passing urine;
- Reduced sexual urge;

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- Inflammation of the tongue;
- Facial flushing;
- Low body heat (hypothermia);
- Painful periods or lack of periods.

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

When taken for a long period of time, it is possible that you may become dependent on the medication.

You may develop tolerance to the effects of METHADONE ADCO 10 mg; this means you may notice that your medicine is less effective at relieving your symptoms

Reporting of 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 METHADONE ADCO 10 mg.

For reporting of side effects directly to the HCR, contact +27 635 0134 or email adcock.aereports@adcock.com .

5. How to store METHADONE ADCO 10 mg

Store at or below 30 ºC.

Keep the bottle in the outer carton to protect from light.

Do not use the medicine after the expiry date printed on the carton and bottle.

Return all unused medicine to your pharmacist.

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Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What METHADONE ADCO 10 mg contains

The active substance is methadone hydrochloride.

The other ingredients are FD & C Red Dye E123 (Amaranth/Permicol Red), sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and purified water.

What METHADONE ADCO 10 mg looks like and contents of the pack

METHADONE ADCO 10 mg is a clear pink coloured oral solution.

METHADONE ADCO 10 mg is packed in:

- A 1 litre amber or white coloured round high-density polyethylene (HDPE) bottle with a white HDPE screw cap which is then packed in a printed E fluted carton, or
- A 1 litre white coloured round high-density polyethylene (HDPE) bottle with a white polypropylene (PP) screw cap which is then packed in a printed E fluted carton, or
- A 100 ml white coloured round high-density polyethylene (HDPE) bottle with a white HDPE child resistant (CR) cap which is then packed in a printed E fluted carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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