Approved Patient Information Leaflet for Medicines for Human Use:

CODEP XR

SCHEDULING STATUS: S6

CODEP XR 5/2,5 mg Prolonged release film-coated tablets

CODEP XR 10/5 mg Prolonged release film-coated tablets

CODEP XR 20/10 mg Prolonged release film-coated tablets

CODEP XR 30/15 mg Prolonged release film-coated tablets

CODEP XR 40/20 mg Prolonged release film-coated tablets

Oxycodone Hydrochloride and Naloxone Hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking CODEP XR

- 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.
- CODEP XR 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 CODEP XR is and what it is used for

CODEP XR is indicated for the treatment of severe pain, which requires the use of a strong opioid analgesic and to reduce the risk of constipation.

2. What you need to know before you take CODEP XR

Do not take CODEP XR:

- if you are hypersensitive (allergic) to oxycodone or naloxone, or any of the other ingredients of CODEP XR.
- if your doctor has told you not to take medicines called “opioids”, usually for treating pain
- if you are having breathing problems, such as breathing more slowly or weakly than expected (respiratory depression)
- if you have a condition called sleep apnoea (a sleep disorder in which your breathing repeatedly stops and starts).
- if you suffer from a severe lung disease which causes narrowing of the airways (chronic obstructive pulmonary disease or COPD)
- if you suffer from a condition known as cor pulmonale (a condition whereby the right side of the heart becomes enlarged, due to increased blood pressure in the lungs)
- if you suffer from severe bronchial asthma
- if you have a type of bowel (lower intestine) obstruction called paralytic ileus, which is not caused by opioid class (strong pain medication) medicines
- if you suffer from moderate to severe liver problems
- if you suffer from moderate to severe kidney problems.

Warnings and precautions

Take special care with CODEP XR:

- if you are elderly or debilitated (weak)
- if you have a type of bowel (lower intestine) obstruction called paralytic ileus, which is caused by opioid class (strong pain medication) medicines
- if you have mild kidney problems
- if you have mild liver problems
- if you have severe lung problems (breathing difficulty)
- if you have a condition called myxoedema (a thyroid disorder which may occur when your thyroid gland is not producing enough hormones, which results in swelling of the skin (puffiness), affecting the face and limbs)
- if your thyroid gland is not producing enough hormones (underactive thyroid or hypothyroidism)
- if your adrenal glands are not producing enough hormones (adrenal insufficiency or Addison's disease)
- if you had been abusing medicines in the past and now suffer from a mental disorder (difficulty in thinking, understanding and judging clearly which causes loss of touch with reality)
- if you suffer from gallstone problems
- if your prostate gland is abnormally enlarged (prostate hypertrophy)
- if you are addicted to alcohol or have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping the use of alcohol or medicines
- if your pancreas is inflamed (pancreatitis)
- if you have low blood pressure (hypotension)
- if you have high blood pressure (hypertension)
- if you have heart problems
- if you have a head injury (due to the risk of increased pressure in the brain)
- if you suffer from epilepsy or are prone to fits (convulsions)

- if you are also taking a type of medicine known as a monoamine oxidase inhibitor (MAOI) (used to treat depression or Parkinson's disease), which includes medicines containing tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid
- if you have been receiving long term opioid treatment with higher doses of opioids and are switched to CODEP XR as you may suffer from withdrawal symptoms
- if you have been receiving long term treatment with CODEP XR, as you may develop a tolerance to the prescribed dose, which may require higher doses to be prescribed to provide the desired pain relief
- if you have been receiving long term treatment with CODEP XR, as this may lead to physical or psychological (addiction) dependence
- if you have been receiving long term treatment with CODEP XR, and stop taking it immediately, as you may suffer from withdrawal symptoms
- if you are a professional athlete, as CODEP XR may produce positive results in doping controls
- if you are about to have an operation or for the first 12-24 hours after an operation.

If any of these warnings apply to you, talk to your doctor before starting to take CODEP XR tablets.

CODEP XR is not recommended for use in patients with advanced digestive (stomach or intestine) or pelvic cancers where bowel (lower intestine) obstruction may be a problem.

Children and adolescents under 18 years:

The safety and efficacy of CODEP XR in patients below the age of 18 years of age has not been established and CODEP XR is not recommended for use in this patient group.

Other medicines and CODEP XR

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

If you take CODEP XR with other medicines, the effect of CODEP XR or the other medicines may be changed.

Medicines or substances, which have effects on the central nervous system (CNS) (CNS depressant effects), e.g. alcohol, other opioid class medicines (strong pain medicines), medicines to help you sleep, antidepressants, mood stabilising medication, anti-histamines (medicines for allergies or travel sickness) and anti-emetics (medicines to stop you from vomiting) may increase the effect of CODEP XR on your breathing ability.

If you are taking CODEP XR with medicines which decrease the blood's clotting ability (warfarin), your blood clotting time may be faster or slower.

If you are taking CODEP XR with medicines known as anticholinergics or medications with anticholinergic activity (examples include tricyclic antidepressants, antihistamines, antipsychotics, muscle relaxants, anti-Parkinson medicines), it may increase the side effects of these medicines.

Tell your doctor or pharmacist:

- if you are taking antibiotics (such as clarithromycin)

- if you are taking antifungal medicines (such as ketoconazole)
- if you are taking medicine to treat HIV (such as ritonavir)
- if you are taking medicine to treat tuberculosis (such as rifampicin)
- if you are taking medicine to treat epilepsy (such as carbamazepine or phenytoin)
- if you are taking medicine to treat depression (such as paroxetine or St.John's Wort)
- if you are taking quinidine (a medicine to treat a fast heart beat).

Grapefruit juice may also increase the blood levels of oxycodone and should not be drunk whilst taking CODEP XR.

CODEP XR with food and drink

You can take CODEP XR with or without food.

Drinking alcohol during your treatment with CODEP XR may make you sleepy or increase the risk of serious side effects, such as shallow breathing with the risk to stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you are taking CODEP XR.

Pregnancy and breastfeeding

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 healthcare professional for advice before taking CODEP XR.

CODEP XR is not recommended for use in pregnancy or during labour. Both oxycodone and naloxone pass into the placenta.

Use of CODEP XR tablets during pregnancy should be avoided. If used over prolonged periods during pregnancy, oxycodone may lead to withdrawal symptoms

in the newborn baby. If oxycodone is given during childbirth, the baby may have breathing problems (respiratory depression).

Breastfeeding should be discontinued during treatment with CODEP XR.

Driving and using machines

CODEP XR may reduce your ability to drive and use machines safely.

It is not always possible to predict to what extent CODEP XR 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 CODEP XR affects them.

3. How to take CODEP XR

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

Always take CODEP XR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

CODEP XR must be taken orally and should be swallowed whole, without being broken or chewed.

Your doctor will determine the correct dose for you to treat your pain. Your doctor will advise you at what times you should take your dose in the mornings and evenings.

You should not exceed the dose recommended by your doctor.

Adults:

The usual starting dose is one CODEP XR 10 mg/5 mg tablet every 12 hours.

Your doctor may adjust your dose during treatment, depending on your level of pain and how you respond to CODEP XR.

The maximum daily dose is 80 mg oxycodone hydrochloride and 40 mg naloxone hydrochloride (e.g. one CODEP XR 40 mg/20 mg tablet twice a day).

If you experience pain between doses, talk to your doctor.

Method of administration

Oral use

Children and adolescents under 18 years

The safety and efficacy of CODEP XR in patients below the age of 18 years of age has not been established and CODEP XR is not recommended for use in this patient group.

Elderly patients

The dosing of elderly patients is the same as that for younger adults.

Impaired kidney or liver function

If you have mild kidney or liver function problems, your doctor may prescribe a lower dose.

You must not take CODEP XR if you have moderate to severe liver or kidney function problems.

Your doctor will tell you how long your treatment with CODEP XR will last.

When you no longer require CODEP XR treatment, your doctor may reduce your dose over time.

If you think that the effect of CODEP XR is too strong or weak, tell your doctor or pharmacist.

If you take more CODEP XR than you should

In the event of overdosage, consult your doctor or pharmacist immediately.

If you forget to take CODEP XR

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

If you forget to take your tablets and your next usual dose is due in 8 hours' time or more: Take the forgotten tablet immediately and continue with your normal dosing routine.

Do not take more than one dose of CODEP XR within any 8-hour period.

If you stop taking CODEP XR

Do not stop taking CODEP XR without first speaking with your doctor. If you do not require any further treatment with CODEP XR, your doctor will advise you how to reduce the daily dose gradually.

If you have any further questions on the use of CODEP XR, ask your doctor or pharmacist.

4. Possible side effects

CODEP XR can have side effects.

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

If any of the following happens, stop taking CODEP XR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice.

These are very serious side effects. If you have them, you may have had a serious reaction to CODEP XR. 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:

- loss of appetite
- finding it difficult to balance when standing up (vertigo)
- hot flushes
- decreased blood pressure
- restlessness
- being unable to sleep (insomnia)
- drowsiness (feeling sleepy)
- abdominal (stomach) pain
- constipation
- diarrhoea
- nausea and vomiting

- increased liver enzymes (observed after taking a liver test)
- itchy skin
- rash
- sweating
- medicine withdrawal symptoms such as agitation, anxiety, shaking or sweating
- feeling hot and cold
- chills
- lack of energy (asthenia)
- tiredness or exhaustion

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:

- dizziness
- headaches
- dry mouth
- heartburn (indigestion)
- flatulence (feeling full of wind)

Less frequent side effects:

- breaking wind (burping)
- erectile dysfunction
- running nose
- cough
- yawning

Side effects with frequency unknown:

- increased sensitivity to pain which cannot be improved by increasing the dose
- tooth decay
- problems with bile flow
- withdrawal symptoms in new-born infants

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 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 CODEP XR.

5. How to store CODEP XR

• Store all medicines out of reach and sight of children.

• Store at or below 25 °C (Blister pack).

• Store at or below 30 °C (HDPE bottle).

• Store in the original package.

• Keep the blisters in the outer carton.

• Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

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

5/2,5 mg tablets are: White, round, biconvex, prolonged release film-coated tablets with a diameter of 4,7 mm and a height of 2,9 – 3,9 mm.

10/5 mg tablets are: Pink, oblong, biconvex, prolonged release film-coated tablets with break scores on both sides with a length of 10,2 mm, a width of 4,7 mm and a height of 3,0 – 4,0 mm.
The tablet can be divided into equal doses.

20/10 mg tablets are: White, oblong, biconvex, prolonged release film-coated tablets with break scores on both sides with a length of 11,2 mm, a width of 5,2 mm and a height of 3,3 – 4,3 mm.
The tablet can be divided into equal doses.

30/15 mg tablets are: Yellow, oblong, biconvex, prolonged release film-coated tablets with break scores on both sides with a length of 12,2 mm, a width of 5,7 mm and a height of 3,3 – 4,3 mm.
The tablet can be divided into equal doses.

40/20 mg tablets are: Pink, oblong, biconvex prolonged release film-coated tablet with break scores on both sides with a length of 14,2 mm, a width of 6,7 mm and a height of 3,6 – 4,6 mm.
The tablet can be divided into equal doses.

What CODEP XR contains

- The active substance are oxycodone hydrochloride equivalent to oxycodone and naloxone hydrochloride equivalent to naloxone.

- The other ingredients are:

Tablet core: povidone*, Kollidon® SR, cellulose, microcrystalline, silica, colloidal anhydrous, magnesium stearate

Kollidon® SR, consisting of: Polyvinyl acetate (80 %)

Povidone (19 %)

Sodium lauryl sulphate (0,8 %)

Silica, colloidal anh. (0,2 %)

Film-coat: Opadry white, Opadry Red (Used in 10 / 5 mg & 40 / 20 mg

Opadry Yellow (used in 30 mg / 15 mg), Purified water

*Povidone is used in 5/2,5 mg & 10/5 mg Tablets

Opadry® II White,

consisting of:

Polyvinyl alcohol (40 %)

Talc (14,8 %)

Titanium dioxide (E171) (25 %)

Macrogol 3350 (20,2 %)

Opadry® II Red,

consisting of:

Polyvinyl alcohol (40 %)

Talc (14,8 %)

Macrogol 3350 (20,2 %)

Iron oxide red (E172) (25 %)

Opadry® II Yellow,

consisting of:

Polyvinyl alcohol (40 %)

Talc (14,8 %)

Iron oxide yellow (E172) (25 %)

Macrogol 3350 (20,2 %)

What CODEP XR looks like and contents of the pack

The tablets are packaged in and blister pack manufactured from PVC-PE-PVDC bottom film and reinforced aluminium lid foil ensuring child-resistance in pack sizes of 10, 14, 20, 28, 30, 50, 56, 60, 90, 98 or 100 tablets in carton boxes.

Not all pack sizes may be marketed.

High density polyethylene (HDPE) bottles with child-resistant polypropylene (PP) twist-off caps pack of 50, 100 and 100 tablets.

Holder of Certificate of Registration

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CODEP XR 40/20 mg: 53/2.9/0754.749

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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