

SCHEDULING STATUS: **S5**

ADCO SALTERPYN TABLETS

**Meprobamate 150 mg / Codeine phosphate 8 mg /
Paracetamol 320 mg / Caffeine anhydrous 32 mg
Sugar free.**

Read all of this leaflet carefully before you start taking ADCO SALTERPYN TABLETS.

- 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.
- ADCO SALTERPYN TABLETS have 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 SALTERPYN TABLETS is and what it is used for
2. What you need to know before you take ADCO SALTERPYN TABLETS
3. How to take ADCO SALTERPYN TABLETS
4. Possible side effects
5. How to store ADCO SALTERPYN TABLETS
6. Contents of the pack and other information

1. What ADCO SALTERPYN TABLETS is and what it is used for

ADCO SALTERPYN TABLETS contain four active ingredients namely, paracetamol, codeine phosphate, caffeine and meprobamate.

It is used to treat pain and pain associated with tension.

2. What you need to know before you take ADCO SALTERPYN TABLETS

Do not take ADCO SALTERPYN TABLETS:

- if you are hypersensitive (allergic) to, or ever had an allergic reaction to, paracetamol, codeine phosphate, caffeine, meprobamate or any of the other ingredients of ADCO SALTERPYN TABLETS (listed in section 6).
- if you have porphyria (a rare inherited blood disorder).
- if you have liver or kidney problems.
- if you have asthma or any lung (breathing) problems.
- if you have a head injury or any condition in which your intracranial pressure is raised (increased pressure around your brain).
- if you have heart failure due to a chronic lung disease.
- if you have heart problems.

- if you have epilepsy (seizure disorder/fits).
- if you are taking an antidepressant medicine known as a monoamine oxidase inhibitor or if you have stopped taking such medicine less than 14 days ago.
- if you have had an operation to the biliary tract (liver, gall bladder and bile ducts).
- if you currently have alcohol poisoning because of drinking too much alcohol in a short amount of time.
- if you are under 12 years old.
- if you are breastfeeding.
- if you are in the third trimester of pregnancy
- for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Warnings and precautions

ADCO SALTERPYN TABLETS contains paracetamol which can cause serious liver problems and can even be fatal (cause death) in overdose (taking too many tablets). If you (or anyone else) have taken too many ADCO SALTERPYN TABLETS, or if think you, or someone else, might have taken too much ADCO SALTERPYN TABLETS, contact the nearest doctor, hospital or poison control centre immediately. Do this even if you (or the other person) are not showing or experiencing any symptoms. Prompt specialised treatment is essential as soon as possible.

Take special care and talk to your doctor before taking ADCO SALTERPYN TABLETS:

- if your doctor has told you that you have any of the following conditions: hypothyroidism (underactive thyroid gland), adrenocortical insufficiency (adrenal glands do not produce enough steroid hormones) or prostatic hypertrophy (enlarged prostate gland); or if your body is in shock.
- if you are elderly or frail (weak).
- if you have (or ever had) inflammatory or obstructive bowel disorders, such as ulcers (peptic ulceration) or small bowel obstruction (blockage of the bowel).
- if you are taking or being given any other medicine (or medicines) known as “central nervous depressants”. If taken together with ADCO SALTERPYN TABLETS, such medicines can increase the drowsiness and impairment of concentration caused by ADCO SALTERPYN TABLETS (see “Other medicines and ADCO SALTERPYN TABLETS” below).
- if you have moderate kidney failure or are on dialysis.
- if you have kidney disease, chronic malnutrition or dehydration.
- if you experience any serious skin reactions after you start taking ADCO SALTERPYN TABLETS. Stop taking ADCO SALTERPYN TABLETS and seek urgent advice from your doctor. The skin reactions such as swelling, itching, red severe rash especially those covering the whole body can be a serious reaction to ADCO SALTERPYN TABLETS, serious skin reactions such as toxic epidermal

necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients receiving paracetamol as contained in ADCO SALTERPYN TABLETS (see section 4).

Do not take more tablets than the recommended dose or use ADCO SALTERPYN TABLETS continuously for more than 10 days without talking to your doctor (see section 3: “How to take ADCO SALTERPYN TABLETS” for the dosing instructions):

- Taking too many tablets may cause serious liver problems, and even death, due to the paracetamol component of ADCO SALTERPYN TABLETS (section 3: “If you take more ADCO SALTERPYN TABLETS than you should”).
- Taking too many tablets over a long period of time can lead to dependency and addiction (due to the codeine and meprobamate components of ADCO SALTERPYN TABLETS).

Tolerance, dependence and addiction

Increased risk of addiction in patients with personal or family history of substance abuse or mental health disorders

ADCO SALTERPYN TABLETS contains codeine, which is an opioid medicine. Repeated use of ADCO SALTERPYN TABLETS may result in you becoming accustomed to it (needing to take higher doses). Repeated use of ADCO SALTERPYN TABLETS may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

If you experience any of the following signs whilst taking ADCO SALTERPYN TABLETS, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- You need to take this medicine for longer than advised
- You need to take more than the recommended dose
- You are using this medicine for reasons other than medical reasons, for instance, ‘to stay calm’ or to ‘help you sleep’
- You have made repeated, unsuccessful attempts to quit or control the use of this medicine
- When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again (‘withdrawal effects’)

Opioid Induced Hyperalgesia

Taking opioid medications for too long can paradoxically induce or sensitise patients to acute pain this condition is called opioid-induced hyperalgesia. The type of pain experienced might be the same as or different from the original underlying pain, and in some cases, patients may experience pain from ordinarily non-painful stimuli (allodynia).

Children

ADCO SALTERPYN TABLETS is contraindicated in children under 12 years of age. Codeine as contained in ADCO SALTERPYN TABLETS is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and ADCO SALTERPYN TABLETS

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

Do not take ADCO SALTERPYN TABLETS if you are taking an antidepressant medicine known as a monoamine oxidase inhibitor or if you have stopped taking such medicine less than 14 days ago (see section 2: “Do not take ADCO SALTERPYN TABLETS” above). Examples include tranylcypromine, moclobemide, selegiline and rasagiline.

Some medicines may increase or decrease the effects of ADCO SALTERPYN TABLETS. Talk to your doctor or pharmacist before taking ADCO SALTERPYN TABLETS if you are taking, using or being given any of the following:

- medicines that contain alcohol as this can increase drowsiness when taken with ADCO SALTERPYN TABLETS (see “ADCO SALTERPYN TABLETS with alcohol” below).
- medicines known as anaesthetics, can increase drowsiness when taken with ADCO SALTERPYN TABLETS. Anaesthetics are used during surgical procedures to numb sensation in certain areas of the body or to induce sleep.
- sleeping tablets, also known as hypnotic or sedatives, used to treat insomnia (difficulty in sleeping). When used with ADCO SALTERPYN TABLETS can increase drowsiness.
- medicines known as tranquillisers or sedatives used to make you feel more relaxed. When used with ADCO SALTERPYN TABLETS can increase drowsiness.
- phenothiazines, such as chlorpromazine or prochlorperazine, used to treat mental disorders such as schizophrenia or bipolar disorder. When used with ADCO SALTERPYN TABLETS can increase drowsiness.
- medicines that may be damaging or destructive to liver cells (e.g. carbamazepine)
- medicines that increase liver enzymes (e.g. carbamazepine) and may therefore result in a further risk for liver damage and a possible decrease in therapeutic effect of ADCO SALTERPYN TABLETS.
- certain medicines for nausea and vomiting like metoclopramide and domperidone which may accelerate the absorption of ADCO SALTERPYN TABLETS.
- medicines used to treat gout and high blood levels of uric acid, such as probenecid, can decrease the elimination of ADCO SALTERPYN TABLETS from the body.

- certain medicines, such as cholestyramine, that are used to lower high cholesterol levels, may reduce the absorption of ADCO SALTERPYN TABLETS if given within one hour after taking ADCO SALTERPYN TABLETS.
- prolonged concurrent use of ADCO SALTERPYN TABLETS with salicylates, such as aspirin, increases the risk of adverse kidney effects.
- chronic use of isoniazid and/or rifampicin, antibiotic medicines often prescribed for tuberculosis. It may increase the risk of liver damage when combined with ADCO SALTERPYN TABLETS, even at recommended doses.
- warfarin or other blood thinning medicines (anticoagulants) together with ADCO SALTERPYN TABLETS may increase the risk of bleeding. Your doctor might monitor your blood clotting factors more regularly.
- medicines used for epilepsy, such as carbamazepine, phenobarbital, phenytoin, or primidone. Your doctor might lower the dosage of ADCO SALTERPYN TABLETS.
- zidovudine used to treat viral infections and co-trimoxazole used to treat bacterial infections. These medicines together with ADCO SALTERPYN TABLETS can cause damage to the liver.
- the effect of interferon alfa used to treat cancers and viral infections, can be increased when used together with ADCO SALTERPYN TABLETS and your doctor might change the dose.

ADCO SALTERPYN TABLETS can cause drowsiness with a decrease in your ability to concentrate. This may be worsened if taken with medicines known as “central nervous depressants” (see above examples), causing loss of judgement and co-ordination.

ADCO SALTERPYN TABLETS with alcohol

ADCO SALTERPYN TABLETS can cause drowsiness with a decrease in your ability to concentrate. This may be worsened if taken with other medicines that contain alcohol or with alcohol containing beverages, causing loss of judgement and co-ordination.

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 health care provider for advice before taking this medicine.

Do not take ADCO SALTERPYN TABLETS if you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent ADCO SALTERPYN TABLETS may interfere with your daily activities. Do not engage in any activities until you are aware of the measure to which ADCO SALTERPYN TABLETS affects you.

Do not drive or operate machinery while you are taking ADCO SALTERPYN TABLETS. ADCO SALTERPYN TABLETS can cause drowsiness, and it can be dangerous to drive or operate machinery while taking this medicine.

ADCO SALTERPYN TABLETS contain tartrazine

ADCO SALTERPYN TABLETS contain tartrazine which may cause allergic reactions, including asthma (a chronic lung condition causing breathing problems). This is more likely to occur if you have an aspirin sensitivity (allergic reaction to the anti-inflammatory medicine known as aspirin).

ADCO SALTERPYN TABLETS contains a Paraben blend

ADCO SALTERPYN TABLETS contain a paraben blend. This is a combination of paraben preservatives, which may cause allergic reactions (possibly delayed).

3. How to take ADCO SALTERPYN TABLETS

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

Always take ADCO SALTERPYN TABLETS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adult dose: take 2 (two) tablets every 6 to 8 hours.

DO NOT TAKE MORE TABLETS THAN THE RECOMMENDED DOSE.

Do not take ADCO SALTERPYN TABLETS continuously for more than 10 days without talking to your doctor.

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

If you take more ADCO SALTERPYN TABLETS than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Do this even if you feel well and take the medicine box with you.

ADCO SALTERPYN TABLETS contains paracetamol which can cause serious liver problems and can even be fatal (cause death) in overdose (taking too many tablets). If you (or anyone else) have taken too many ADCO SALTERPYN TABLETS, or if think you, or someone else, might have taken too much ADCO SALTERPYN TABLETS, contact the nearest doctor, hospital or poison control centre immediately. Do this even if you (or the other person) are not showing or experiencing any symptoms. Prompt specialised treatment is essential as soon as possible.

The initial symptoms of paracetamol overdose (taking too much paracetamol), within

the first 24 hours, may include:

- pale appearance.
- nausea (feeling sick).
- vomiting (being sick).
- loss of appetite.
- abdominal pain.

Even though these initial symptoms may appear mild, paracetamol overdose is a serious condition, and liver damage may only become apparent 12 to 48 hours, or even later, after the paracetamol overdose.

Liver damage, due to paracetamol overdose, can lead to brain dysfunction causing confusion and other mental problems (known as encephalopathy), coma and death.

Other serious adverse effects of paracetamol overdose may include:

- kidney problems (and failure).
- abnormal heart rhythm.
- abnormal glucose metabolism.
- metabolic acidosis (abnormal increase in the acidity of the body's fluids).

Due to the seriousness of paracetamol overdose, and the risk for serious side effects (including death), you (or the patient) may be treated even if your (their) symptoms appear mild.

Other symptoms of taking too much ADCO SALTERPYN TABLETS include:

- restlessness and/or exhilaration.
- muscle tremor (uncontrolled shaking).
- increased or excessive urine production.
- palpitations (pounding heartbeat or heart beating faster than usual).
- stupor (state of being speechlessness, motionlessness and unresponsive, but completely conscious).
- convulsions (fits).
- drowsiness.
- breathing problems.
- blueish discolouration of skin.
- low blood pressure with circulation problems (problems with your blood vessels).
- shock and coma.

If you forget to take ADCO SALTERPYN TABLETS

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ADCO SALTERPYN TABLETS

ADCO SALTERPYN TABLETS contain codeine and meprobamate which can cause addiction if you take it continuously for long periods of time, and consequently, when you stop taking it you can get withdrawal symptoms. You should talk to your doctor or

pharmacist if you think you are suffering from withdrawal symptoms.

4. Possible side effects

ADCO SALTERPYN TABLETS can have side effects.

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

If any of the following happens, stop taking ADCO SALTERPYN TABLETS 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 itchy skin.
- fainting.
- bronchospasm causing breathing problems, feeling tight chested, wheezing (a whistling sound when you breathe), chest pain and/or coughing.
- severe skin rash with or without fever.
- skin blisters and large areas of peeling skin.
- serious skin reactions called severe cutaneous adverse reactions (SCARS).

SCARS are a group of potentially very serious adverse drug reactions that can be fatal and involve the skin and mucous membranes (the moist, inner lining of some organs and body openings, such as the nose, mouth, lungs, and stomach).

Examples of SCARS includes toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)/ drug induced hypersensitivity syndrome (DIHS) and fixed drug eruption (FDE) (see section 2).

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO SALTERPYN TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Abdominal pain including risk of inflammation of pancreas, which causes severe pain in the abdomen and back.
- feeling tired, pale skin, shortness of breath, light-headedness, dizziness or a fast heartbeat, increase in nose bleeds or unusual bleeding (blood test shows changes in the blood cell counts).
- inflammation of the liver (you may feel nauseous, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine).
- pain caused by kidney stones.

Side effects of unknown frequency:

- Mood changes
- drowsiness, weakness and confusion.
- headache.
- restlessness, excitement and insomnia (trouble falling and/or staying asleep).
- tingling or pricking feeling (also known as “pins and needles”) and ataxia (slurred speech, stumbling, falling and incoordination).
- dizziness and vertigo (feeling off balance).
- orthostatic hypotension (a sudden drop in blood pressure when you stand from a seated or lying down position).
- raised intracranial pressure (rise in pressure around the brain).
- miosis (constriction of the pupils/small pupils), scintillating scotoma (visual aura or blind spot that affects a part of your vision) and problems with vision (eyesight).
- ringing or buzzing noise in one or both ears (tinnitus).
- loss of hearing
- slow or fast heartbeat, palpitations (pounding heartbeat or heart beating faster than usual) or changes in heart rhythm.
- hypotension (low blood pressure) making you feel tired or weak.
- constipation, nausea (feeling sick), vomiting (being sick), diarrhoea and dry mouth.
- increased gastric secretions (such as stomach acid) and stomach ulcers.
- mild skin rash and itchy skin, sweating, facial flushing (blushing).
- difficulty in urination.
- spasms in urinary tract causing lower abdominal pain or spasm in the bile duct causing upper abdominal pain.
- kidney problems (you may have blood in your urine, cloudy urine, change in how frequent you want to urinate).
- drop in body temperature (hypothermia).
- muscle tremor (unintentional trembling or shaking movements in one or more parts of the body).

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, 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 SALTERPYN TABLETS.

5. How to store ADCO SALTERPYN TABLETS

Store all medicines out of reach of children.

Store at or below 25 °C, in a dry place.

Protect from light.

Store in the original container.

Keep the blisters in the outer carton until required for use.

Do not use after the expiry date stated on the label or blister.

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 SALTERPYN TABLETS contains

- The active substances are meprobamate, codeine phosphate, paracetamol and caffeine anhydrous.

Each tablet contains 150 mg meprobamate, 8 mg codeine phosphate, 320 mg paracetamol and 32 mg caffeine anhydrous.

- The other ingredients are colloidal silicon dioxide, colour apple green deep/lake blend (LB510007), magnesium stearate, povidone, maize starch/pre-gelatinised starch, purified talc, powdered acacia and a paraben blend.

Each tablet contains 0,025 % *m/m* paraben blend as a preservative.

What ADCO SALTERPYN TABLETS looks like and contents of the pack

ADCO SALTERPYN TABLETS are packed in:

- PVC film and aluminium foil blisters of 20 and 100 tablets.
- Amber PVC jars with white HDPE screw on caps, or amber HDPE bottles/jars with screw on closures and cotton wool in pack sizes of 500 and 1000 tablets.

Not all pack sizes or types are necessarily marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

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