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 of 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 overdosage, 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.

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SKEDULERINGSTATUS: S5

ADCO SALTERPYN TABLETS
Meprobamaat 150 mg / Kodeïenfosfaat 8 mg /
Parasetamol 320 mg / Kafeïen, watervry 32 mg
Suikervry.

Lees hierdie hele biljet noukeurig deur voordat u begin om ADCO SALTERPYN TABLETS te neem.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- ADCO SALTERPYN TABLETS is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat in hierdie biljet is

1. Wat ADCO SALTERPYN TABLETS is en waarvoor dit gebruik word
2. Wat u moet weet voordat u ADCO SALTERPYN TABLETS neem
3. Hoe om ADCO SALTERPYN TABLETS te neem
4. Moontlike newe-effekte
5. Hoe om ADCO SALTERPYN TABLETS te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat ADCO SALTERPYN TABLETS is en waarvoor dit gebruik word

ADCO SALTERPYN TABLETS bevat vier aktiewe bestanddele, naamlik parasetamol, kodeïenfosfaat, kafeïen en meprobamaat.

Dit word gebruik om pyn, en pyn wat verband hou met spanning, te behandel.

2. Wat u moet weet voordat u ADCO SALTERPYN TABLETS neem

Moenie ADCO SALTERPYN TABLETS neem nie:

- indien u hipersensitief (allergies) is vir, of ooit 'n allergiese reaksie gehad het vir parasetamol, kodeïenfosfaat, kafeïen, meprobamaat of enige van die ander bestanddele van ADCO SALTERPYN TABLETS (gelys in afdeling 6).
- indien u porfirie het ('n seldsame oorerflike bloedafwyking).
- indien u lewer- of nierprobleme het.
- indien u asma of enige long (asemhaling) probleme het.
- indien u 'n kopbesering het of enige toestand waarin u intrakraniale druk verhoog word (verhoogde druk rondom u brein).
- indien u hartversaking het indien gevolg van 'n chroniese longsiekte.
- indien u hartprobleme het.
- indien u epilepsie het (stuipe-versteuring/stuipaanvalle).

- indien u 'n antidepressante medisyne gebruik wat bekend staan as 'n monoamienoksidase-remmer, of indien u minder as 14 dae gelede opgehou het om sulke medisyne te neem.
- indien u 'n operasie aan die galweg (lewer, galblaas en galbuise) ondergaan het.
- Indien u tans alkoholvergiftiging het as gevolg van die drink van te veel alkohol in 'n kort tydjie.
- indien u jonger as 12 jaar oud is.
- indien u borsvoed.
- Indien u in die derde trimester van swangerskap is
- vir pynverligting by kinders en adolessente (0-18 jaar oud) na verwydering van hul mangels of adenoïede, as gevolg van obstruktiewe slaapapnee-sindroom.

Waarskuwings en voorsorgmaatreëls

ADCO SALTERPYN TABLETS bevat parasetamol wat ernstige lewerprobleme kan veroorsaak en selfs fataal kan wees (dood veroorsaak) in oordosis (neem van te veel tablette). Indien u (of enigiemand anders) te veel ADCO SALTERPYN TABLETS geneem het, of indien u dink dat u, of iemand anders, dalk te veel ADCO SALTERPYN TABLETS geneem het, kontak dadelik die naaste dokter, hospitaal of gifhulpsentrum. Doen dit selfs indien u (of die ander persoon) geen simptome toon of ervaar nie. Vinnige gespesialiseerde behandeling is so gou moontlik noodsaaklik.

Wees veral versigtig en raadpleeg u dokter voordat u ADCO SALTERPYN TABLETS neem:
- indien u dokter u vertel het dat u enige van die volgende toestande het: hipotireose (onderaktiewe tiroïedklier), adrenokortikale ontoereikendheid (byniere produseer nie genoeg steroïedhormone nie) of prostaat-hipertrofie (vergrote prostaatklier); of indien u liggaam in skok is.
- indien u bejaard of broos (swak) is.
- indien u inflammatoriese of obstruktiewe dermafwykings het (of ooit gehad het), soos maagulkusse (maagsere) of dunderm obstruksie (verstopping van die derm).
- indien u enige ander medisyne (of verskeie middels) wat bekend staan as "sentrale senuweestelsel depressante" neem of gegee word. Indien dit saam met ADCO SALTERPYN TABLETS geneem word, kan sulke medisyne die lomerigheid en verswakking van konsentrasie, wat veroorsaak word deur ADCO SALTERPYN TABLETS, verhoog (sien "Ander medisyne en ADCO SALTERPYN TABLETS" hieronder).
- indien u matige nierversaking het of op dialise is.
- indien u niersiekte, aan chroniese wanvoeding of dehidrasie ly.
- indien u enige ernstige velreaksies ervaar nadat u begin om ADCO SALTERPYN TABLETS te neem. Staak ADCO SALTERPYN TABLETS en soek dringende advies van u dokter. Die velreaksies soos swelling, jeukerigheid, ernstige rooi uitslag, veral dié wat die hele liggaam bedek, kan 'n ernstige reaksie wees op ADCO SALTERPYN TABLETS, ernstige velreaksies soos toksiese epidermale nekrolise (TEN), Stevens-Johnson se sindroom (SJS), akute algemene eksantematiese pustulose (AAEP), eosinofilie en

sistemiese (GRESS) / Geneesmiddel-geïnduseerde hipersensitiwiteitsindroom (GIHS) en gelokaliseerde geneesmiddel veluitslag (FDE) is aangemeld by pasiënte wat parasetamol ontvang, soos vervat in ADCO SALTERPYN TABLETS (sien afdeling 4).

Moenie meer tablette as die aanbevole dosis ADCO SALTERPYN TABLETS neem of aaneenlopend vir meer as 10 dae gebruik sonder om u dokter te raadpleeg nie (sien afdeling 3: "Hoe om ADCO SALTERPYN TABLETS te neem" vir die doseringsinstruksies):

- Die neem van te veel tablette kan ernstige lewerprobleme veroorsaak, en selfs die dood, as gevolg van die parasetamol-komponent van ADCO SALTERPYN TABLETS (afdeling 3: "Indien u meer ADCO SALTERPYN TABLETS neem as wat u moes").
- Die neem van te veel tablette oor 'n lang tydperk kan lei tot afhanklikheid en verslawing (as gevolg van die kodeïen- en meprobamaat-komponente van ADCO SALTERPYN TABLETS).

Verdraagsaamheid, afhanklikheid en verslawing
Verhoogde risiko vir verslawing by pasiënte met persoonlike of familiegeskiedenis van dwelmmisbruik of geestesgesondheidsversteurings

ADCO SALTERPYN TABLETS bevat kodeïen, wat 'n opioïed-medisyne is.
Herhaalde gebruik van ADCO SALTERPYN TABLETS kan daartoe lei dat u gewoond raak daaraan (moet hoër dosisse neem). Herhaalde gebruik van ADCO SALTERPYN TABLETS kan ook lei tot afhanklikheid, misbruik en verslawing, wat kan lei tot lewensgevaarlike oordosis.
Indien u enige van die volgende tekens ervaar terwyl u ADCO SALTERPYN TABLETS neem, raadpleeg u dokter of apteker aangesien dit 'n aanduiding kan wees dat u afhanklik of verslaaf is.

- U moet hierdie medisyne langer neem as wat aanbeveel word
- U moet meer as die aanbevole dosis neem
- U gebruik hierdie medisyne om ander redes as mediese redes, byvoorbeeld 'om kalm te bly' of om 'u te help slaap'
- U het herhaalde, onsuksesvolle pogings aangewend om op te hou, of die gebruik van hierdie medisyne te beheer
- Wanneer u ophou om hierdie medisyne te neem, voel u sleg, en u voel beter sodra u hierdie medisyne weer neem ('onttrekkingseffekte')

Opioïed-geïnduseerde Hiperalgesie
Om opioïed-medikasie te lank te neem, kan in pasiënte teenstrydig akute pyn veroorsaak, of hulle sensitief maak vir pyn, hierdie toestand word opioïed-geïnduseerde hiperalgesie genoem. Die tipe pyn wat ervaar word, kan dieselfde wees as, of verskil van, die oorspronklike onderliggende pyn, en in sommige gevalle kan pasiënte pyn ervaar as gevolg van gewoonlik nie-pynlike stimuli (allodenie).

Kinders
ADCO SALTERPYN TABLETS is teenaangedui by kinders jonger as 12 jaar.
Kodeïen, soos vervat in ADCO SALTERPYN TABLETS, word nie aanbeveel by kinders met asemhalingsprobleme nie, aangesien die simptome van morfientoksisiteit erger kan wees by hierdie kinders.

Ander medisyne en ADCO SALTERPYN TABLETS
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem (dit sluit alle komplementêre of tradisionele medisyne in).

Moenie ADCO SALTERPYN TABLETS neem indien u 'n antidepressant gebruik wat bekend staan as 'n monoamienoksidase-remmer of indien u minder as 14 dae gelede opgehou het om sodanige medisyne te neem nie (sien afdeling 2: "Moenie ADCO SALTERPYN TABLETS neem nie" hierbo). Voorbeelde sluit in tranielsipromien, moklobemied, selegilien en rasagilien.

Sommige medisyne kan die effekte van ADCO SALTERPYN TABLETS verhoog of verminder. Raadpleeg u dokter of apteker voordat u ADCO SALTERPYN TABLETS neem, indien u enige van die volgende neem, gebruik of gegee word:

- medisyne wat alkohol bevat, aangesien dit slaperigheid kan verhoog wanneer dit saam met ADCO SALTERPYN TABLETS geneem word (sien "ADCO SALTERPYN TABLETS met alkohol" hieronder).
- medisyne bekend as verdowingsmiddels, kan slaperigheid verhoog wanneer dit saam met ADCO SALTERPYN TABLETS geneem word. verdowingsmiddels word tydens chirurgiese prosedures gebruik om sensasie in sekere dele van die liggaam te verdoof of om slaap te veroorsaak.
- slaaptablette, ook bekend as hipnotiese of kalmeermiddels, wat gebruik word om slapeloosheid (probleme om te slaap) te behandel. Wanneer dit saam met ADCO SALTERPYN TABLETS gebruik word, kan lomerigheid verhoog.
- medisyne bekend as kalmeermiddels of slaapmiddels word gebruik om u meer ontspanne te laat voel. Wanneer dit saam met ADCO SALTERPYN TABLETS gebruik word, kan lomerigheid verhoog.
- fenotiasiene, soos chloorpromasien of prochlorperasien, word gebruik om geestesversteurings soos skisofrenie of bipolêre versteuring te behandel. Wanneer dit saam met ADCO SALTERPYN TABLETS gebruik word, kan lomerigheid verhoog.
- medisyne wat skadelik of vernietigend vir lewerselle kan wees (bv. karbamasepien)
- medisyne wat lewerensieme verhoog (bv. karbamasepien) en dus 'n verdere risiko vir lewerskade en 'n moontlike afname in terapeutiese effek van ADCO SALTERPYN TABLETS tot gevolg kan hê.
- sekere medisyne vir naarheid en braking soos metoklopramied en domperidoon wat die absorpsie van ADCO SALTERPYN TABLETS kan versnel.
- medisyne wat gebruik word om jig en hoë bloedvlakke van uriensuur te behandel, soos

probenesied, kan die eliminasie van ADCO SALTERPYN TABLETS uit die liggaam verminder.
- sekere medisyne, soos cholestiramien, wat gebruik word om hoë cholesterolvlakke te verlaag, kan die absorpsie van ADCO SALTERPYN TABLETS verminder indien dit binne een uur na die neem van ADCO SALTERPYN TABLETS gegee word.
- langdurige gelyktydige gebruik van ADCO SALTERPYN TABLETS met salisilate, soos aspirien, verhoog die risiko van nadelige niereffekte.
- chroniese gebruik van isoniasied en/of rifampisien, antibiotiese medisyne wat dikwels vir tuberkulose voorgeskryf word. Dit kan die risiko van lewerskade verhoog wanneer dit gekombineer word met ADCO SALTERPYN TABLETS, selfs teen aanbevole dosisse.
- warfarien of ander bloedverdunnende medisyne (antikoagulante) saam met ADCO SALTERPYN TABLETS kan die risiko van bloeding verhoog. U dokter kan u bloedstollingsfaktore meer gereeld monitor.
- medisyne wat vir epilepsie gebruik word, soos karbamasepien, fenobarbitaal, fenitoïen of primidoon. U dokter kan die dosis van ADCO SALTERPYN TABLETS verlaag.
- Sidovudien, wat gebruik word om virusinfeksies te behandel en kotrimoksasool wat gebruik word om bakteriële infeksies te behandel. Hierdie medisyne saam met ADCO SALTERPYN TABLETS kan skade aan die lewer veroorsaak.
- die effek van interferon alfa, wat gebruik word om kankers en virusinfeksies te behandel, kan verhoog word wanneer dit saam met ADCO SALTERPYN TABLETS gebruik word, en u dokter kan die dosis verander.

ADCO SALTERPYN TABLETS kan lomerigheid veroorsaak met 'n afname in u vermoë om te konsentreer. Dit kan vererger word indien dit geneem word saam met medisyne wat bekend staan as "sentrale senuweestelsel depressante" (sien voorbeelde hierbo), wat verlies aan oordeel en koördinasie veroorsaak.

ADCO SALTERPYN TABLETS met alkohol
ADCO SALTERPYN TABLETS kan lomerigheid veroorsaak met 'n afname in u vermoë om te konsentreer. Dit kan vererger word indien dit saam met ander medisyne geneem word wat alkohol bevat of met alkoholbevattende drankies, wat verlies aan oordeel en koördinasie veroorsaak.

Swangerskap en borsvoeding
Indien u swanger is of borsvoed, dink u kan swanger wees of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.
Moenie ADCO SALTERPYN TABLETS neem indien u swanger is of u baba borsvoed nie.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel in watter mate ADCO SALTERPYN TABLETS met u daaglikse aktiwiteite kan inmeng nie. Moenie aan enige aktiwiteite deelneem totdat u bewus is van die mate waartoe ADCO SALTERPYN TABLETS u beïnvloed nie.

Moenie bestuur of masjinerie hanteer terwyl u ADCO SALTERPYN TABLETS neem nie. ADCO SALTERPYN TABLETS kan lomerigheid veroorsaak, en dit kan gevaarlik wees om te bestuur of masjinerie te hanteer terwyl u hierdie medisyne neem.

ADCO SALTERPYN TABLETS bevat tartrasien
ADCO SALTERPYN TABLETS bevat tartrasien wat allergiese reaksies kan veroorsaak, insluitend asma ('n chroniese longtoestand wat asemhalingsprobleme veroorsaak). Dit is meer geneig om te voorkom indien u 'n aspiriensensitiwiteit het (allergiese reaksie op die anti-inflammatoriese medisyne bekend as aspirien).

ADCO SALTERPYN TABLETS bevat 'n Parabeen-mengsel
ADCO SALTERPYN TABLETS bevat 'n parabeen-mengsel. Dit is 'n kombinasie van parabeen-preserveermiddels, wat allergiese reaksies kan veroorsaak (kan moontlik vertraag voorkom).

3. Hoe om ADCO SALTERPYN TABLETS te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Neem altyd ADCO SALTERPYN TABLETS presies soos u dokter of apteker u vertel het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Volwasse dosis: neem 2 (twee) tablette elke 6 tot 8 uur.
MOENIE MEER TABLETTE AS DIE AANBEVOLE DOSIS NEEM NIE.

Moenie ADCO SALTERPYN TABLETS aaneenlopend vir meer as 10 dae neem sonder om u dokter te raadpleeg nie.

Indien u die indruk het dat die effek van ADCO SALTERPYN TABLETS te sterk of te swak is, raadpleeg u dokter of apteker.

Indien u meer ADCO SALTERPYN TABLETS neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum. Doen dit selfs indien u goed voel en neem die medisyneboksie saam.

ADCO SALTERPYN TABLETS bevat parasetamol wat ernstige lewerprobleme kan veroorsaak en selfs fataal kan wees (dood veroorsaak) in oordosis (neem te veel tablette). Indien u (of enigiemand anders) te veel ADCO SALTERPYN TABLETS geneem het, of indien u dink u, of iemand anders, het dalk te veel ADCO SALTERPYN TABLETS geneem, kontak dadelik die naaste dokter, hospitaal of gifhulpsentrum. Doen dit selfs indien u (of die ander persoon) geen simptome toon of ervaar nie. Vinnige gespesialiseerde behandeling is so gou moontlik noodsaaklik.

Die aanvanklike simptome van parasetamol-oordosis (neem van te veel parasetamol), binne die eerste 24 uur, kan die volgende insluit:

- bleek voorkoms.
- naarheid (naar voel).
- braking (opgooi).
- verlies aan eetlus.
- buikpyn.

Alhoewel hierdie aanvanklike simptome minder ernstig mag voorkom, is parasetamol-oordosis 'n ernstige toestand, en lewerskade kan eers 12 tot 48 uur, of selfs later, ná die parasetamol-oordosis sigbaar word.
Lewerskade, as gevolg van parasetamol-oordosis, kan lei tot breindisfunksie wat verwarring en ander verstandelike probleme (bekend as enkefalopatie), koma en dood veroorsaak.
Ander ernstige nadelige gevolge van parasetamol-oordosis kan die volgende insluit:

- nierprobleme (en versaking).
- abnormale hartritme.
- abnormale glukosemetabolisme.
- metaboliese asidose (abnormale toename in die suurheid van die liggaam se vloeistowwe).

As gevolg van die erns van parasetamol-oordosis, en die risiko vir ernstige newe-effekte (insluitend die dood), mag u (of die pasiënt) behandel word, selfs al lyk u (hulle) simptome minder ernstig.

Ander simptome van die neem van te veel ADCO SALTERPYN TABLETS sluit in:

- rusteloosheid en/of opgewondenheid.
- spierbewing (onbeheerde skudding).
- verhoogde of oormatige urienproduksie.
- hartkloppings (kloppende hartslag of hart klop vinniger as gewoonlik).
- stupor (toestand van sprakeloosheid, roerloosheid en kan nie reageer nie, maar is heeltemal by bewussyn).
- stuiptrekkings (stuipaanvalle).
- lomerigheid.
- asemhalingsprobleme.
- blouerige verkleuring van die vel.
- lae bloeddruk met sirkulasieprobleme (probleme met u bloedvate).
- skok en koma.

Indien u vergeet om ADCO SALTERPYN TABLETS te neem
Indien u 'n dosis mis, neem dit so gou as moontlik. Indien dit egter amper tyd is vir die volgende dosis, slaan die vergete dosis oor en gaan terug na u gereelde doseringskedule. Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Indien u ophou om ADCO SALTERPYN TABLETS te neem
ADCO SALTERPYN TABLETS bevat kodeïen en meprobamaat wat verslawing kan

veroorsaak indien u dit aanhoudend vir lang tydperke neem, en gevolglik, wanneer u ophou om dit te neem, kan u onttrekkingsimptome kry. U moet u dokter of apteker raadpleeg indien u dink u ly aan onttrekkingsimptome.

4. Moontlike newe-effekte

ADCO SALTERPYN TABLETS kan newe-effekte hê.

Nie alle newe-effekte wat vir ADCO SALTERPYN TABLETS aangemeld is, word ingesluit in hierdie biljet nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u ADCO SALTERPYN TABLETS neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak ADCO SALTERPYN TABLETS en lig u dokter onmiddellik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak.
- veluitslag of jeukerige vel.
- floute.
- bronchospasma wat asemhalingsprobleme veroorsaak, benoude bors, hygende asemhaling ('n fluitgeluid wanneer u asemhaal), borspyn en/of hoes.
- erge veluitslag met of sonder koors.
- velblase en groot dele met afskilferende vel.
- ernstige velreaksies wat ernstige kutane newe-reaksies (SCARS) genoem word. SCARS is 'n groep geneesmiddelreaksies wat potensieel baie ernstig nadelig kan wees, en dodelik kan wees, en die vel en slymvliese (die klam, binneste voering van sommige organe en liggaamsopeninge, soos die neus, mond, longe en maag) aantas. Voorbeelde van SCAR's sluit in toksiese epidermale nekrolise (TEN), Stevens-Johnson se sindroom (SJS), akute algemene eksantematiese pustulose (AGEP), geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS) / geneesmiddel-geïnduseerde hipersensitiwiteitsindroom (GIHS) en gelokaliseerde geneesmiddel veluitslag (FDE) (sien afdeling 2).

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op ADCO SALTERPYN TABLETS gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Minder gereelde newe-effekte:

- Buikpyn, insluitend die risiko van inflammasie van die pankreas, wat erge pyn in die buik en rug veroorsaak.
- voel moeg, bleek vel, kortasem, lighoofdigheid, duiseligheid of 'n vinnige hartklop, toename in neusbloeding of ongewone bloeding (bloedtoets toon veranderinge in die bloedseltellings).
- inflammasie van die lewer (u kan naarheid, braking, verlies aan eetlus, algemene ongesteldheid, koors, jeukerigheid, vergeling van die vel en oë, en donkerkleurige urien

ervaar).
- pyn veroorsaak deur nierstene.

Newe-effekte van onbekende frekwensie:
- Gemoedsverandering
- lomerigheid, swakheid en verwarring.
- hoofpyn.
- rusteloosheid, opgewondenheid en slapeloosheid (probleme om aan die slaap te raak en/of aan die slaap te bly).
- tintelende of prikkelende gevoel (ook bekend as "naalde en spelde") en ataksie (onduidelike spraak, struikel, val en ongekoördineerd wees).
- duiseligheid en vertigo (voel van balans af).
- ortostatiese hipotensie ('n skielike daling in bloeddruk wanneer u uit 'n sittende of lêende posisie opstaan).
- verhoogde intrakraniale druk (styging in druk rondom die brein).
- miose (vernouing van die pupille/klein pupille), skitterende skotoom (visuele aura of blindekol wat 'n deel van u visie beïnvloed) en probleme met visie (sig).
- lui of gonsende geluid in een of albei ore (tinnitus).
- verlies van gehoor
- stadige of vinnige hartklop, hartkloppings (kloppende hartslag of hartklop vinniger as gewoonlik), of veranderinge in hartritme.
- hipotensie (lae bloeddruk) wat u moeg of swak laat voel.
- hardlywigheid, naarheid (naar voel), braking (opgooi), diarree en droë mond.
- verhoogde maagafskeidings (soos maagsuur) en maagsere.
- ligte veluitslag en jeukerige vel, sweet, gesigblosing (bloos).
- probleme met urinering.
- spasmas in urienweg wat pyn in die onderbuik veroorsaak of spasma in die galbuis wat pyn in die boonste buik veroorsaak.
- nierprobleme (u kan bloed in u urien hê, troebel urien, verandering in hoe gereeld u wil urineer).
- daling in liggaamstemperatuur (hipotermie).
- spierbewing (onwillkeurige bewing of skudbewegings in een of meer dele van die liggaam).

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van ADCO SALTERPYN TABLETS te verskaf.

5. Hoe om ADCO SALTERPYN TABLETS te bêre

Bêre alle medisyne buite bereik van kinders.
Bêre teen of benede 25 °C, op 'n droë plek.
Beskerm teen lig.
Bêre in die oorspronklike houer.
Hou die stulpstroke in die buitenste kartonhouer totdat dit benodig word vir gebruik.
Moenie gebruik ná die vervaldatum wat op die etiket of stulpstrook vermeld word nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat ADCO SALTERPYN TABLETS bevat

- Die aktiewe bestanddele is meprobamaat, kodeïenfosfaat, parasetamol en watervrye kafeïen.
  Elke tablet bevat 150 mg meprobamaat, 8 mg kodeïenfosfaat, 320 mg parasetamol en 32 mg watervrye kafeïen.
- Die ander bestanddele is kolloïdale silikondioksied, kleur appelgroen diep/lak-mengsel (LB510007), magnesiumstearaat, povidoon, mieliestysel/voorafgegelatiniseerde stysel, gesuiwerde talk, gepoeierde akasia en 'n parabeen-mengsel.
  Elke tablet bevat 0,025% *m/m* parabeen-mengsel as 'n preserveermiddel.

Hoe ADCO SALTERPYN TABLETS lyk en die inhoud van die verpakking

ADCO SALTERPYN TABLETS is verpak in:

- PVC-film en aluminiumfoelie stulpstroke van 20 en 100 tablette.
- Amber PVC-flesse met wit HDPE-opskroef proppe, of amberkleurige HDPE-bottels/flesse met opskroef proppe en watte in verpakkingsgroottes van 500 en 1000 tablette.

Nie alle verpakkingsgroottes of -tipes word noodwendig bemark nie.

Houer van Sertifikaat van Registrasie

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Hierdie biljet is mees onlangs hersien op

03 Februarie 2025

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