PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

GEN-PAYNE CAPSULES, 10 mg/200 mg/250 mg, capsules
Codeine phosphate, ibuprofen, paracetamol
Each capsule contains 10 mg codeine phosphate, 200 mg ibuprofen and 250 mg paracetamol.
Sugar free

Read all of this leaflet carefully because it contains important information for you.
GEN-PAYNE CAPSULES is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use GEN-PAYNE CAPSULES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GEN-PAYNE CAPSULES with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after three days.

What is in this leaflet

1. What GEN-PAYNE CAPSULES is and what it is used for
2. What you need to know before you take GEN-PAYNE CAPSULES
3. How to take GEN-PAYNE CAPSULES
4. Possible side effects
5. How to store GEN-PAYNE CAPSULES
6. Contents of the pack and other information

1. What GEN-PAYNE CAPSULES is and what it is used for

This medicine contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.
This medicine also contains ibuprofen. Ibuprofen, a non-steroidal anti-inflammatory medicine (NSAID), also acts to reduce swelling (inflammation).
This medicine also contains paracetamol. Paracetamol, an analgesic, acts to relieve pain.
This medicine can be used for the short-term treatment of mild to moderate pain (with or without fever).

2. What you need to know before you take GEN-PAYNE CAPSULES

Do not take GEN-PAYNE CAPSULES

- If you are hypersensitive (allergic) to codeine, ibuprofen or paracetamol or any of the other ingredients of GEN-PAYNE CAPSULES (listed in section 6).
- If you have liver or kidney problems.
- If you have heart failure.
- If you have had a bleeding stomach ulcer after taking a non-steroidal anti-inflammatory medicine (NSAID) (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools).
- If you have a stomach ulcer, perforation or bleeding from the ulcer, or have had an ulcer in the past.
- If you have had a condition called cardiovascular disease (you may have had chest pain, or tightness, or discomfort, shortness of breath; or pain, numbness, weakness or coldness in your legs or arms if the blood vessels in those parts of your body are narrowed; or you might have had a blood clot).
- If you have difficulty breathing or breathing problems.
- If you have had an operation on the biliary tract.
- If you regularly drink large quantities of alcohol.
- If you have seizures or have had head injuries.
- If you are taking medicines to treat depression or bipolar disorder called monoamine oxidase inhibitors or have stopped taking these medicines within the last 14 days.
- If you have asthma, urticaria (itchy, raised, red or skin-coloured swellings) or allergic-type reactions after taking aspirin, or other NSAIDs.
- If you are in the third trimester of pregnancy
- If you are breastfeeding your baby
- If your child is under 12 years old
- For pain relief in children and adolescents (0 – 18 years of age) after removal of tonsils or adenoids due to obstructive sleep apnoea syndrome.
- If you suffer from chronic constipation
- If you have glucose-6-phosphate dehydrogenase deficiency

Warnings and precautions

Do not use GEN-PAYNE CAPSULES continuously for more than 5 days without consulting a doctor.

Note that the safety of continuous use of GEN-PAYNE CAPSULES for more than four weeks has not been proven and is therefore seen as unsafe to use it for longer than four weeks.

Take special care with GEN-PAYNE CAPSULES:

Codeine

- If you use more than what you should or for longer periods, it can cause dependence and addiction to GEN-PAYNE CAPSULES.
- If you have any of the following conditions, as GEN-PAYNE CAPSULES can make the symptoms of these conditions worse:
  - hypothyroidism (you may have experienced tiredness, being sensitive to cold, weight gain, constipation, depression, muscle aches and weakness, muscle cramps),
  - adrenocortical insufficiency (you may have experienced upper body obesity, round face and neck, and thinning arms and legs, skin problems, such as acne or reddish-blue streaks on the abdomen or underarm area, high blood pressure, muscle and bone weakness, moodiness, irritability, or depression, high blood sugars),
  - asthma,
  - an enlargement of your prostate gland,
  - low blood pressure,
  - bowel problems including blockage of your bowel,
  - myasthenia gravis (a disorder that causes weakness in the skeletal muscles, which are the muscles your body uses for movement).
- If you are elderly or weak and feeble. You should take a lower dose as it is more likely that you might have side effects.

Tolerance, dependence, and addiction:

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

GEN-PAYNE CAPSULES contains codeine, which is an opioid medicine.

Repeated use of GEN-PAYNE CAPSULES may result in you becoming accustomed to it (needing to take higher doses). Repeated use of GEN-PAYNE CAPSULES may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

If you are taking GEN-PAYNE CAPSULES for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include

serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4 'Possible side effects').

If you experience any of the following signs whilst taking GEN-PAYNE CAPSULES, 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).

Ibuprofen

- If you have high blood pressure or heart failure as GEN-PAYNE CAPSULES may cause water retention, which can result in heart failure.
- If you are elderly, as you have an increased frequency of adverse reactions to NSAIDs including GEN-PAYNE CAPSULES, especially sores on the inside lining of your stomach and intestine and bleeding that can be fatal.
- If you have had a bleeding ulcer as the risk of this to start again is high with increasing doses of GEN-PAYNE CAPSULES. When gastrointestinal bleeding or ulceration occurs in patients receiving
  GEN-PAYNE CAPSULES, stop taking GEN-PAYNE CAPSULES and go to your doctor, pharmacist or other health care provider.
- If you have had gastrointestinal disease (e.g. ulcerative colitis, (inflammation and sores in your digestive tract), Crohn's disease (inflammation of your digestive track), hiatus hernia (stomach pushing through an opening in the diaphragm), gastroesophageal reflux disease (stomach acid flows back into the tube connecting your mouth and stomach)), as GEN-PAYNE CAPSULES can cause these conditions to worsen.

- If you have a serious skin reaction, including peeling and blistering of the skin. The peeling may progress quickly, resulting in large raw areas that may ooze or weep (e.g. Stevens-Johnson syndrome). Stop taking GEN-PAYNE CAPSULES at the first appearance of skin rash, or any other sign of hypersensitivity and go to your doctor or nearest hospital.
- If you are in the last three months of pregnancy. GEN-PAYNE CAPSULES may delay the onset of labour and may increase the duration thereof.
- If you have an infection, as GEN-PAYNE CAPSULES can hide symptoms such as fever and inflammation, which can result in not treating the inflammation effectively.
- If you have a bleeding disorder, as GEN-PAYNE CAPSULES can worsen this condition (see 'Other medicines and GEN-PAYNE CAPSULES').
- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs when you are between 20 weeks of pregnancy or later, your healthcare provider may need to monitor the amount of fluid in your womb around your baby.
- If you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Stop taking GEN-PAYNE CAPSULES and go to your doctor or nearest hospital, as this can be life threatening.

Paracetamol

GEN-PAYNE CAPSULES contains paracetamol which may be fatal if you take a higher dose than you should. In the event of overdosage or if you suspect that you have taken more than you should, even if you do not have any symptoms of an overdose, go to your nearest doctor, hospital or Poison Centre must immediately.

- If you take more paracetamol as in GEN-PAYNE CAPSULES, you may cause your liver to be severely damaged.
- Serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), Drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using GEN-PAYNE CAPSULES immediately and contact your doctor (see section 4 'Possible side effects').

Children and adolescents

Do not give GEN-PAYNE CAPSULES to children under the age of 12 years (see section 2 'Warnings and precautions').

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and GEN-PAYNE CAPSULES

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

Codeine

Tell your doctor if you are taking any of the following medicines:

- Medicines for anxiety and sleeping pills, e.g. temazepam, pentobarbital and phenothiazines and alcohol as GEN-PAYNE CAPSULES may make the effect of these medicines stronger.

Ibuprofen

Tell your doctor if you are taking any of the following medicines:

- Lithium (to treat mood disorder), methotrexate (to treat certain types of cancer and arthritis) and cardiac glycosides (for your heart e.g. digoxin and digitoxin), as GEN-PAYNE CAPSULES can increase the concentrations of these medicines.
- ACE inhibitors (to lower blood pressure, e.g. captopril, enalapril, lisinopril to name a few), cyclosporin and tacrolimus (usually used after an organ transplant), or diuretics (water pills, e.g. furosemide, hydrochlorothiazide and spironolactone to name a few) as GEN-PAYNE CAPSULES together with these medicines can increase your risk to damage your kidneys.
- Medicines for high blood pressure (e.g. ACE inhibitors, beta blockers (e.g. atenolol, metoprolol, propranolol to name a few) and diuretics. GEN-PAYNE CAPSULES has may increase the concentrations of these medicines.
- Quinolones (a type of antibiotic used to treat infections) as you might have convulsions.
- Moclobemide (used to treat depression and anxiety) as you might experience more side effects from ibuprofen as in GEN-PAYNE CAPSULES.
- Phenytoin (used to treat epilepsy) and sulphonylurea (to treat diabetes) as the effects of these medicines may become stronger.
- Mifepristone (a medicine used in abortions): GEN-PAYNE CAPSULES should not be used for 8 to 12 days after you have used mifepristone as ibuprofen can reduce the effect of mifepristone.

- Zidovudine (to treat HIV/AIDS) as using it with GEN-PAYNE CAPSULES may increase your risk to damage your red blood cells.
- NSAIDs and the use of two or more NSAIDs together with GEN-PAYNE CAPSULES could result in you having more side effects.
- Alcohol, bisphosphonates (used to prevent or treat bone loss, e.g. alendronate, etidronate, risedronate and zoledronic acid) or oxpentifylline (to treat muscle pain) as GEN-PAYNE CAPSULES together with these medicines can increase your risk to have peptic ulcers.
- Corticosteroids (medicines that lower inflammation in your body) as GEN-PAYNE CAPSULES together with these medicines can increase your risk to have peptic ulcers and bleeding.
- Anticoagulants (medicines that help to prevent blood clots, e.g. apixaban, dabigatran, edoxaban, rivaroxaban, warfarin). GEN-PAYNE CAPSULES may make the effects of these medicines stronger.
- Antiplatelet medicines (e.g., clopidogrel, ticagrelor, prasugrel dipyridamole or aspirin to name a few) and selective serotonin reuptake inhibitors (SSRIs) (used to treat depression, e.g., escitalopram, fluoxetine, paroxetine to name a few) as it might increase your risk of gastrointestinal bleeding.

Paracetamol

Tell your doctor if you are taking any of the following medicines:

- Medicines that may be damaging or destructive to liver cells.
- Medicines that increase liver enzymes and may therefore result in a further risk for liver damage and a possible decrease in therapeutic effect of paracetamol as contained in GEN-PAYNE CAPSULES.
- Certain medicines for nausea and vomiting like metoclopramide which may accelerate the absorption of paracetamol as contained in GEN-PAYNE CAPSULES.
- Medicines used to treat gout and high blood levels of uric acid, such as probenecid, can decrease the elimination of paracetamol as contained in GEN-PAYNE CAPSULES from the body.
- Certain medicines, such as cholestyramine, that are used to lower high cholesterol levels, may reduce the absorption of paracetamol as contained in GEN-PAYNE CAPSULES if given within one hour after taking of paracetamol as contained in GEN-PAYNE CAPSULES.
- Prolonged concurrent use of paracetamol as contained in GEN-PAYNE CAPSULES 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 of

paracetamol as contained in GEN-PAYNE CAPSULES, even at recommended doses.

- Warfarin or other blood thinning medicines (anticoagulants) together with paracetamol as contained in GEN-PAYNE CAPSULES 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 paracetamol as contained in GEN-PAYNE CAPSULES.
- Zidovudine used to treat viral infections and co-trimoxazole used to treat bacterial infections. These medicines together with paracetamol as contained in GEN-PAYNE CAPSULES 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 paracetamol as contained in GEN-PAYNE CAPSULES and your doctor might change the dose.
- Medications such as anticonvulsants and birth control pills can increase the elimination of paracetamol as contained in GEN-PAYNE CAPSULES from the body.
- In high-risk patients, use of paracetamol as contained in GEN-PAYNE CAPSULES with an antibiotic called flucloxacillin can lead to an increase in acid in the body. This is known as high anion gap metabolic acidosis

GEN-PAYNE CAPSULES with food, drink and alcohol

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine. Alcohol may make you feel drowsier, increase your risk of having a peptic ulcer and bleeding, and increase your risk of liver damage.

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 GEN-PAYNE CAPSULES.

Pregnancy

You should not use GEN-PAYNE CAPSULES during pregnancy, as it may be harmful to your unborn child. Please consult your doctor or pharmacist for advice.

Breastfeeding

You should not take GEN-PAYNE CAPSULES when you are breastfeeding your baby (see section 2 ‘Do not take GEN-PAYNE CAPSULES’).

Fertility

No data on male and female fertility are available.

Driving and using machines

It is not always possible to predict to what extent GEN-PAYNE CAPSULES may interfere with your daily activities. GEN-PAYNE CAPSULES may make you feel dizzy or sleepy. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which GEN-PAYNE CAPSULES affects you.

GEN-PAYNE CAPSULES contain colourant Sunset Yellow (E110)

This may cause allergic reactions see section 6 ‘What GEN-PAYNE CAPSULES contains’.

3. How to take GEN-PAYNE CAPSULES

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

Always take GEN-PAYNE CAPSULES exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose for adults and children over the age of 12 years is:

One to two capsules four to six hourly and not more than six capsules per twenty-four hours.

Start with the lowest effective dose for the shortest possible time. Swallow each capsule with water.

Talk to your doctor if you do not feel better with the recommended dosage after three days.

If you take more GEN-PAYNE CAPSULES than you should

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

Prompt medical attention is critical. Even if you do not show symptoms of an overdose, go immediately to your nearest hospital or Poison Centre.

GEN-PAYNE CAPSULES contains paracetamol and an overdose, can be fatal.

The symptoms of an overdose can include nausea, stomach pain, loss of appetite, vomiting (may be blood streaked), ringing in the ears, excitement, convulsions (mainly in children), and breathing problems.

If you forget to take GEN-PAYNE CAPSULES

It is important to take GEN-PAYNE CAPSULES as your doctor has prescribed. If you miss a dose, resume your usual schedule the following day. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

GEN-PAYNE CAPSULES can have side effects.

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

If any of the following happens, stop taking GEN-PAYNE CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Mouth ulcers, cold sores and ulcers or soreness of your tongue.
- Skin lumps or hives (raised, red or white, itchy patches of skin).
- Blisters on your skin or inside your mouth, nose, vagina, or bottom.
- Rashes or sunburn when you have been outside (even on a cloudy day), including peeling and blistering of the skin. The peeling may progress quickly, resulting in large raw areas that may ooze or weep (e.g. Stevens-Johnson syndrome).
- Swelling of the hands, feet, ankles, face, eyelids, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Bronchospasm (difficult to breath and cause wheezing).
- Liver damage (dark coloured urine, light coloured bowel movements, yellow skin and eyes and loss of appetite).
- Aseptic meningitis (serous inflammation of the linings of the brain with headache and fever).
- Fever, skin rash, swelling of the lymph nodes and/or swelling of the face (also known as DRESS) (see section 2, ‘Warnings and precautions’),

These are all very serious side effects. If you have them, you may have had a serious reaction to GEN-PAYNE CAPSULES. You may need urgent medical attention or hospitalisation.

Codeine

Less frequent side effects

- Abdominal pain including risk of inflammation of pancreas, which causes severe pain in the abdomen and back.

Side effects of unknown frequency

- Mood changes, hallucinations,
- Drowsiness, dizziness, headache, confusion, feeling restless, feeling dizzy (vertigo),
- Small pupils (miosis),
- Irregular heartbeat,
- A sudden drop in blood pressure when you stand up (orthostatic hypotension),
- Nausea, vomiting, constipation, dry mouth,
- Sweating, facial flushing, hives (urticaria), itching,
- Difficult or painful urinating,
- Low sex drive,
- Low body temperature.

Ibuprofen

Frequent side effects

- Hypersensitivity (e.g. fever, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing),
- Dizziness,
- Nausea and pain in the abdomen.

Less frequent side effects

- Low blood cells, may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections,
- Nervousness, depression, drowsiness, sleeplessness (insomnia),
- Change in your vision,
- Ringing in your ears (tinnitus),
- Oedema, hypertension, heart failure,
- Vomiting, diarrhoea, wind (flatulence), constipation, indigestion, peptic ulcers, bleeding from the ulcers, dark sticky stools, vomiting of blood, pain in the abdomen,
- Blistering of the skin, severe skin reaction can occur including Stevens-Johnson syndrome and toxic epidermal necrolysis. Symptoms includes skin rash, blistering and peeling of the skin,
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (for details on this condition, please refer to serious side effects above and section 2, ‘Warnings and precautions’),
- Kidney failure.

Side effects of unknown frequency

- Changes in the way your blood clots,
- Fever,
- Headache and vertigo,
- Worsening of colitis and Crohn's disease, and gastrointestinal discomfort,
- Kidney disorders (blood in the urine, fever, changed in urinating, nausea and vomiting, swelling).
- GEN-PAYNE CAPSULES, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2 'Warnings and precautions'). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Paracetamol

Less frequent side effects

- Low blood cells, may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections,
- Hypersensitivity reactions,
- Skin rashes. The rash is usually reds or itchy but sometimes more serious and accompanied by fever and, swelling and ulcers in the mouth.

Side effects of unknown frequency

Pancreatitis (you may experience abdominal pain that radiates to your back, or abdominal pain that feels worse after eating, fever, tenderness when touching the abdomen)

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 or nurse. This includes any possible side effects not listed in this leaflet. 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's website. By reporting side effects, you can help provide more information on the safety of GEN-PAYNE CAPSULES.

5. How to store GEN-PAYNE CAPSULES

Store all medicines out of reach of children.

- Store at or below 25 °C in well-closed containers.
- Do not use after the expiry date stated on the label/carton/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 GEN-PAYNE CAPSULES contains

The active substances are codeine phosphate 10 mg, ibuprofen 200 mg and paracetamol 250 mg.

The other ingredients are colloidal silica, magnesium stearate, maize starch, potassium sorbate, hard gelatin capsule (capsule shell: opaque green cap, opaque red body), printing ink.

Capsule shell colourants are brilliant blue FCF (E133, C.I. 42090), erythrosine (E127, C.I. 45430), quinoline yellow (E104, C.I. 47005), sunset yellow (E110, C.I. 15985) and titanium dioxide (E171, C.I. 77891).

What GEN-PAYNE CAPSULES looks like and contents of the pack

The cap is opaque green, and the body is opaque red. “ADCO” is printed on both the cap and body. Contents of the capsule are fine white granular powder.

Content of the packaging

- A white high-density polypropylene (HDPP) securitainer with a low-density polyethylene (LDPE) snap on lid or a white high density polyethylene container with a high density polyethylene (HDPE) screw cap containing 30 capsules.
- Push through clear PVC and aluminium blister packs of 10 capsules in unit cartons of 10, 30, 60 or 100 capsules.

Holder of Certificate of Registration

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