

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S2**VARIPAN CO 500 mg/8 mg tablets****Paracetamol / Codeine phosphate****Sugar free.****Read all of this leaflet carefully because it contains important information for you**

VARIPAN CO is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to take VARIPAN CO carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VARIPAN CO with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

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

1. What VARIPAN CO is and what it is used for

Paracetamol and codeine phosphate are the active substances in VARIPAN CO. Paracetamol acts as an analgesic (painkiller) and an antipyretic (lowers body temperature) and codeine phosphate is

also a painkiller. VARIPAN CO is used for the relief of mild to moderate pain and fever.

2. What you need to know before you take VARIPAN CO

Do not take VARIPAN CO

- If you are hypersensitive (allergic) to paracetamol or codeine phosphate, or to any of the other ingredients of VARIPAN CO (listed in section 6).
- If you have problems to breathe, especially if you have a bluish discolouration of your skin (due to decreased oxygen) or have excessive mucus.
- If you suffer from asthma or any other lung disease.
- If you are an alcoholic or addicted to any substance.
- If you have a gallbladder disease, gallstones or recently had an operation on your gallbladder or bile duct.
- If you have any liver problems.
- If you have any kidney problems or recently had an operation on your kidneys, bladder or urethra.
- If you have an infection in your pancreas.
- If you don't have enough fluid (blood) volume circulating in your body, caused by vomiting, diarrhoea or excessive bleeding, which may lead to shock (symptoms include weakness, fatigue, dizziness and fainting).
- If you have an irregular heartbeat.
- If you suffer from Addison's disease (a disorder in which your adrenal glands don't produce enough hormones).
- If you have a history of convulsions (fits).
- If you suffer from any stomach conditions, including diarrhoea, or recently had surgery on your stomach or intestines.
- If you are emotionally unstable.
- If you have an enlarged prostate gland (difficulty passing urine).
- If you suffer from a spinal condition which causes an abnormal curve of your spine.

- If you have an underactive thyroid.
- If you have growing pressure inside your skull (headache, blurred vision, weakness), e.g. following a head injury.
- If you have heart failure secondary to a lung disease (shortness of breath, swollen legs, irregular heartbeat, fatigue).
- If you have been told that you are a CYP2D6 ultra-rapid metabolisers.
- In children that are having their tonsils and/or adenoids removed due to difficult/disturbed breathing during sleep.
- If you have been using antidepressants called monoamine oxidase inhibitors or have just stopped using these medicines in the last 2 weeks.

Warnings and precautions

VARIPAN CO contains paracetamol which may be fatal in overdose.
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Take special care with VARIPAN CO:

- If you or a family member previously had mental health problems, characterised by a persistently low or depressed mood (major depression), feeling of fear or worry (anxiety), or misused alcohol or drugs, as it may increase the risk of addiction.
- VARIPAN CO may cause severe liver damage if taken in excess.
- Consult your doctor if no relief is obtained with the recommended dosage.
- Do not use continuously for longer than 10 days without consulting your doctor.
- If you suffer from a condition known as myasthenia gravis which weakens the muscles.
- If you are elderly or weak. You may need to reduce your dose.
- If you are in a state of shock (cold sweat may be a sign).
- Exceeding the prescribed dose, together with prolonged and continuous use of VARIPAN CO, may lead to dependency and addiction.
- If you develop any skin adverse reaction, such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with

eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE), treatment with VARIPAN CO must immediately be discontinued. These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain. Should you experience any of these symptoms, contact your health care provider immediately.

- If you are taking sedating medicines, also known as central nervous system (CNS) depressants, such as benzodiazepines (used to treat anxiety, panic attacks and insomnia or trouble sleeping) (see **Other medicines and VARIPAN CO**).
- Codeine, as in VARIPAN CO, is metabolised in your liver by an enzyme. Some people have a variation of this enzyme, and this can affect people in different ways. In some people, they may not get enough pain relief but other people, known as ultra-rapid metabolisers, are more likely to get serious side effects (such as breathing difficulties, with slow or shallow breathing, confusion, sleepiness, feeling or being sick, constipation and lack of appetite). If you experience any of these side effects, stop taking VARIPAN CO and consult with your doctor immediately. You should not take VARIPAN CO if you are known to be a CYP2D6 ultra-rapid metaboliser (see **Do not take VARIPAN CO**).
- Do not take VARIPAN CO for longer than directed by your doctor. Taking codeine regularly for a long time can lead to addiction, which might cause you feel restless and irritable when you stop taking the tablets. Taking a painkiller for headaches too often or for too long can make them worse.

Children and adolescents

- VARIPAN CO should not be given to children below 6 years of age.
- VARIPAN CO should not be given to children below 18 years of age after an operation to remove their tonsils or adenoids for airflow blockage during sleep (obstructive sleep apnoea) (see **Do not take VARIPAN CO**).
- VARIPAN CO is not recommended for use in children with breathing problems, including neuromuscular disorders (conditions that impair the functioning of the muscles, either directly

or indirectly, through the nervous system), severe heart or lung conditions, lung infections, several serious injuries or major surgery.

Other medicines and VARIPAN CO

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

Do not take VARIPAN CO if you are taking monoamine oxidase inhibitors (used to treat depression) or have taken them in the last 14 days before treatment with VARIPAN CO.

Tell your doctor or pharmacist if you are currently taking:

- Sedatives or tranquillisers, also known as central nervous system (CNS) depressants, such as benzodiazepines (used to treat anxiety, panic attacks, insomnia or trouble sleeping).
- Anticoagulants such as warfarin (used to thin your blood).
- Medicines that may be harmful to your liver such as carbamazepine, phenobarbital (phenobarbital) and phenytoin (used to treat epilepsy).
- Probenecid (used to treat gout).
- Isoniazid (used to treat tuberculosis).
- Antidiarrhoeal and antiperistaltic medicines such as loperamide and kaolin (used to treat diarrhoea).
- Antimuscarinic medicines (used to treat an overactive bladder).
- Neuromuscular blocking medicines (potent muscle relaxants typically only used during surgery).
- Antihypertensive medicines such as diuretics (used to treat high blood pressure).
- Hydroxyzine (used to treat anxiety disorders and allergic conditions).
- Cimetidine (used to treat stomach ulcers or heartburn).
- Naloxone (used to treat a narcotic overdose).
- Naltrexone (used as part of a treatment program for medicine or alcohol dependence).

- Nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin or other salicylates (used to treat pain, inflammation and fever).
- Medicines which may increase the CYP3A4 enzyme in your body, such as rifampicin (used to prevent and treat tuberculosis) and phenytoin (used to treat and prevent seizures/fits).
- Zidovudine (anti-retroviral therapy, used in the treatment of HIV infection).
- Metoclopramide or domperidone (used to treat nausea and vomiting).
- Colestyramine (used to lower high cholesterol levels in the blood).
- Mexiletine (used to treat irregular heartbeat).
- Cisapride (used to treat heartburn or gastro-oesophageal reflux disease).
- Other opioid painkillers (used to treat pain).
- Antitussive medicines (used to treat a cough).
- Antihistamines (used to treat allergies).
- Antipsychotics (used to treat depression or a psychotic disorder).
- Tell your doctor or pharmacist if you need to go for any laboratory tests.

VARIPAN CO with alcohol

Do not drink alcohol during treatment with VARIPAN CO as it may have additive sedative effects.

Pregnancy and breastfeeding

Safe use in pregnancy and breastfeeding has not been established.

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 VARIPAN CO.

Driving and using machines

VARIPAN CO may cause drowsiness and dizziness and affect your ability to drive a vehicle or use machinery. This is particularly in conjunction with other medicines that may affect your mental state, behaviour or mood, including alcohol.

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

3. How to take VARIPAN CO

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

Always take VARIPAN CO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.

The usual dose is:

Adults:

One or two tablets every four to six hours.

Children over 12 years:

One tablet every four to six hours.

Children 6 to 12 years:

Half to one tablet every six hours.

Do not exceed 8 tablets per day.

Do not use continuously for longer than ten (10) days without consulting your doctor.

VARIPAN CO tablets may be taken with or without food.

If you have the impression that the effect of VARIPAN CO is too strong or too weak, tell your doctor or pharmacist.

If you take more VARIPAN CO than you should

Possible signs and symptoms of overdosage may include cold, clammy skin, confusion, severe

dizziness or drowsiness, low blood pressure, severe nervousness or restlessness, narrowing of the pupil of your eye, slow heartbeat, slow or troubled breathing, severe weakness, unconsciousness, unusually pale skin, nausea (feeling sick), vomiting (being sick), weight loss or stomach pain.

Even if you feel well after having taken more VARIPAN CO than you should have, you should still seek medical assistance as there is a risk of delayed, serious liver damage.

Immediate treatment is essential. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining VARIPAN CO tablets with you, so that the doctor knows what you have taken.

If you forget to take VARIPAN CO

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next dose at the usual time.

4. Possible side effects

VARIPAN CO can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- A rash or itching.
- Shock.
- Fainting.

- Coma.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Anaemia (a condition in which your body does not have enough healthy red blood cells, with symptoms such as extreme tiredness, pale skin, shortness of breath, dizziness).
- Medicine dependence, withdrawal reactions.
- Convulsions/fits.
- Slow/ineffective breathing, shortness of breath, collapse of your lung (trouble breathing, cough, low-grade fever).
- Changes in the way your heart beats, such as pounding of your heart, beating faster or slower than normal, irregular heartbeat.
- Growing pressure inside your skull (headache, blurred vision, weakness).
- Lack of fluid (blood) circulating in your body, which may lead to shock (symptoms include weakness, fatigue, dizziness and fainting).
- Stomach pain including inflammation of your pancreas (pain of the upper stomach area that radiates to your back, tenderness, nausea, vomiting, fever).
- Functional bowel obstruction (paralytic ileus) causing symptoms such as bloating, gas, nausea and vomiting.
- Passing less urine than is normal for you, difficulty in emptying your bladder completely (urinary retention), ureteral or biliary spasms (burning or cramping pain in your stomach), kidney damage/failure (swelling of your hands, feet and face, nausea, weakness).
- Skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE). These reactions can be life-threatening and are characterised by

redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain.

- Yellowing of your skin and eyes, dark urine, fever and tiredness, which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Drowsiness.
- Constipation.

Less frequent side effects:

- Dizziness, headache, uncontrolled shaking (tremors).
- Restlessness, confusion.
- Decline in mental ability (memory/thinking), abnormal thinking, hallucinations (seeing or hearing things that are not real).
- Insomnia (difficulty falling/staying asleep).
- Loss of appetite.
- Blurred or double vision.
- Low blood pressure (dizziness).
- Dry mouth, stomach pain, nausea, vomiting.
- Muscle stiffness.
- Unusual tiredness or weakness, general feeling of discomfort.
- Allergic skin rash.

Frequency unknown side effects:

- Raised, itchy rash (urticaria).
- Skin redness.
- Changes in your white/red blood cells or platelet count when tests are done.

- Changes in your mood (feeling happy or irritated/unhappy).
- Light-headedness.
- Increased blood pressure (dizziness, headache).
- Reddening of your face, neck or upper chest (flushing).
- Postural hypotension (a form of low blood pressure that happens when standing up from sitting or lying down, which may cause dizziness or light-headedness).
- Spinning sensation (vertigo).
- Narrowing of your pupils.
- Drop in your body temperature.
- Ringing or buzzing in your ears.

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 doctor or pharmacist. 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 VARIPAN CO.

5. How to store VARIPAN CO

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in airtight containers.
- Protect from light.
- Keep the blister strips in the outer carton until required for use.
- Do not use after the expiry date printed on the label or carton.
- 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 VARIPAN CO contains

- The active substances are paracetamol and codeine phosphate.
Each tablet contains 500 mg paracetamol and 8 mg codeine phosphate.
- The other ingredients are maize starch, potassium sorbate 0,1 % *m/m* (preservative), povidone K30, pregelatinised starch, purified talc and stearic acid.

What VARIPAN CO looks like and contents of the pack

White to off-white capsule-shaped tablet with a half score on both sides and embossed 'P' and 'C' on one side.

Ten (10) tablets packed in Aluminium/PVC blister strips. Each outer carton contains 3 blisters strips.

Pack size: 30 tablets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Request via the email address: info@lebasi.co.za