

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S2**Colstat hard capsules**

300 mg paracetamol, 75 mg ascorbic acid, 30 mg caffeine, 5 mg phenylephrine hydrochloride and 2 mg chlorphenamine maleate per capsule.

Sugar free.

Read all of this leaflet carefully because it contains important information for you.

Colstat is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take **Colstat** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Colstat** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What Colstat is and what it is used for

Colstat capsules contain the active ingredients paracetamol, ascorbic acid, caffeine, phenylephrine hydrochloride and chlorphenamine maleate.

Colstat is used for the symptomatic treatment and relief of colds and influenza.

2. What you need to know before you take Colstat

Do not take Colstat:

- If you are hypersensitive (allergic) to paracetamol, ascorbic acid, caffeine, phenylephrine hydrochloride, chlorphenamine maleate or any of the other ingredients of **Colstat** (listed in section 6).
- If you have severe liver problems.
- If you have an enlarged prostatic gland or obstruction in your bowel.
- If you have abnormally high pressure in your eye (glaucoma).
- If you suffer from epilepsy.
- If you suffer from severe heart disease or severe high blood pressure.
- If you have an overactive thyroid gland.
- If you are pregnant.
- If you are taking or have been taking within the last 10 days medicines from the class called monoamine oxidases.
- Do not give **Colstat** capsules to children under the age of 6 years.

Warnings and precautions

Take special care with **Colstat**:

- If you have kidney or liver disorders.
- Do not use in combination with any other medicines containing paracetamol. Paracetamol overdose may cause liver failure, which may require liver transplant and may be fatal.
- If you are malnourished (underfed), anorexic, have a low body mass index, are drinking large amounts of alcohol or have sepsis (your body's response to an infection).
- If you have low levels of glutathione, you may have an increased risk of developing metabolic acidosis (a condition in which there is too much acid in your body fluids) when taking **Colstat** capsules.

- If you have a history of peptic ulceration (a small sore on the lining of your stomach, small intestine or oesophagus).
- If you have problems with your thyroid gland, heart problems or had any heart operation.
- If you have bronchitis or bronchiectasis (coughing up thickened mucus and shortness of breath) and asthma (difficulty breathing, chest pain, cough and wheezing).
- If you are an elderly patient and may sometimes be confused.
- If you have a condition called porphyria.
- 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 **Colstat** 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.

Other medicines and Colstat

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

The following medicines may cause an interaction when used with **Colstat**:

- metoclopramide or domperidone (used to treat nausea)
- colestyramine (used to lower high cholesterol levels in the blood)
- warfarin (used to prevent blood clots from forming)
- probenecid (used in the treatment of chronic gout or gouty arthritis)
- omeprazole (used to treat stomach ulcers)
- guanethidine (used to treat high blood pressure)
- barbiturates, hypnotics (used to treat insomnia, seizures and headaches)
- narcotic analgesics (used to treat severe pain)
- sedatives (used to treat anxiety and sleep disorders)

- tranquillisers (used to treat anxiety, sleep disorders and mood disorders).

Colstat with food, drink and alcohol

Colstat capsules may be taken with or without food.

Do not drink alcohol while you are taking **Colstat** capsules.

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 **Colstat**.

Driving and using machines

The ability to drive a motor vehicle or operate machinery may be impaired by **Colstat**. This applies particularly in combination with alcohol.

3. How to take Colstat

Adults: Two capsules three times daily.

Children 6 – 12 years: One capsule three times daily.

Not recommended for children under the age of 6 years.

Do not take **Colstat** capsules continuously for more than 10 days without consulting your doctor.

DO NOT EXCEED THE RECOMMENDED DOSE.

If you take more Colstat than you should:

Colstat contains paracetamol which may be fatal in overdose.

In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison centre must be contacted immediately. Take this leaflet and any remaining Colstat capsules with you, so that the doctor knows what you have taken.

4. Possible side effects

Colstat can have side effects.

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

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

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

These are all very serious side effects. If you have them, you may have had a serious reaction to **Colstat** capsules. 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:

- fast and slow heartbeats or irregular heartbeats
- kidney failure (less urine than is normal for you), renal colic (acute, intense pain in your back or lower stomach area, spreading to your back or groin, nausea)
- inflammation in your liver, including jaundice (yellowing of the skin and eyes, dark urine and tiredness)
- 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 (see Take special care with **Colstat**).

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

Tell your doctor if you notice any of the following:

Frequent:

- headache
- dryness of the mouth with difficulty in swallowing, flushing, thirst
- blurred vision
- sleepiness, attention disorders, abnormal coordination, dizziness, sleeplessness, tremors (shaking movements), convulsions (seizures)
- nausea (feeling sick)
- unusual weakness or tiredness.

Less frequent:

- bleeding disorders, characterised by bleeding gums, blood in your stools or urine, fever, chills, easy bruising, abnormal bleeding, purple or red spots on the skin, fatigue, weakness, pale or yellowish skin, irregular heartbeats
- severe skin rash, hives, fever, peeling of skin without blistering, Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis
- bronchospasm (wheezing, chest pain or tightness, coughing)
- liver problems (yellow eyes and skin, nausea, stomach pain).

Frequency unknown:

- vomiting, diarrhoea, constipation
- tingling, heaviness and weakness of the hands, muscle contractions
- pancreatitis (inflammation of your pancreas, characterised by stomach pain, nausea and vomiting)
- high or low blood pressure
- anorexia

- feeling confused, excited, irritable or depressed, nightmares
- tinnitus (ringing sound in your ears)
- thickening of bronchial secretions (chronic daily cough, wheezing, shortness of breath)
- stomach pain, heart burn
- sensitivity of your skin to sunlight
- difficulty urinating and completely emptying the bladder
- chest tightness.

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 via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of **Colstat**.

5. How to store Colstat

Store at or below 25 °C.

Protect from light and moisture.

Do not remove capsules from blister strips until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused or expired medicines to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Colstat contains

The active substances per capsule are 300 mg paracetamol, 75 mg ascorbic acid, 30 mg caffeine, 5 mg phenylephrine hydrochloride and 2 mg chlorphenamine maleate.

Other ingredients are dibasic calcium phosphate, magnesium stearate, liquid paraffin, gelatine, titanium dioxide (E171), Brilliant Blue FCF (E133) and Quinoline Yellow (E104).

What Colstat looks like and contents of the pack

Size 0 hard gelatine capsule with white body and light green cap.

Clear PVC/silver aluminium blister strips of 12 capsules in packs of 24 capsules in a unit carton.

Holder of Certificate of Registration

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Access to corresponding Professional Information

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