



123® Complete

Cold, Cough & Flu Tablets

Day tablet: Paracetamol 500 mg, Dextromethorphan Hydrobromide 15 mg, Phenylephrine Hydrochloride 5 mg;
Night tablet: Paracetamol 500 mg, Dextromethorphan Hydrobromide 15 mg, Phenylephrine Hydrochloride 5 mg and Carbinoxamine Maleate 3 mg

Read all of this leaflet carefully before you start taking this medicine.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor or pharmacist.
• This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
• If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What 123® Complete is and what it is used for

123® Complete is used for the temporary relief of the following symptoms of cold and flu: headache, runny or blocked nose, sore throat, dry cough, body aches and pains. Reduces fever. The NIGHT tablet also relieves runny nose, sneezing, itchy and watery eyes and allows rest by providing fast, effective temporary relief from these symptoms.

123® Complete DAY tablets contain the active ingredients paracetamol, dextromethorphan hydrobromide and phenylephrine hydrochloride.

123® Complete NIGHT tablets contain the active ingredients paracetamol, dextromethorphan hydrobromide, phenylephrine hydrochloride and carbinoxamine maleate.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.
Dextromethorphan hydrobromide is a cough suppressant that is used to suppress a dry cough.
Phenylephrine HCl works to reduce nasal stuffiness.
Carbinoxamine maleate belongs to a group of medicines called ‘antihistamines’. Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances that the body is allergic to.

Ask your pharmacist or doctor if you have any questions about this medicine. Your pharmacist or doctor may have given it for another reason. This medicine is not addictive. It is only available in the pharmacy.

2. Before you take 123® Complete

Do not take 123® Complete

- If you have an allergy to:
 - any medicine containing paracetamol, dextromethorphan, phenylephrine, carbinoxamine or other antihistamines.
 - any of the ingredients listed at the end of the leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat, or other parts of the body
- rash, itching or hives on the skin or mouth ulcers.
- if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep
- if you have very high blood pressure, heart problems or are taking antidepressant medicines unless your doctor has told you to
- if you are taking or have taken in the last 14 days, drugs called monoamine oxidase inhibitors, medicines used to treat depression
- if you are taking other medicines for the relief of colds and flu, congestion or blocked nose, appetite suppressants or stimulants, or other medicines containing antihistamines (sometimes used to treat allergy)
- if you are underweight or malnourished
- if you regularly drink alcohol, you may need to avoid using this product altogether or limit the amount of paracetamol that you take.
- if you have a chest infection, worsening asthma or severe respiratory problems
- if you are having an asthma attack
- if you are pregnant or breastfeeding
- if you have:
 - glaucoma (high pressure in the eyes)
 - stomach or duodenal ulcer, or other stomach problems
 - prostate problems
 - bladder problems
- a severe infection as this may increase the risk of metabolic acidosis, sign of metabolic acidosis include:
 - deep, rapid, difficult breathing
 - feeling sick (nausea), being sick (vomiting)
 - loss of appetite

Contact a doctor immediately if you get a combination of these symptoms.

Warnings and precautions

Tell your pharmacist or doctor:

- if you have allergies to any other medicines, foods, preservatives or dyes
- if you have or had any of the following medical conditions:
 - liver or kidney disease
 - overactive thyroid gland
 - heart disease, blood vessel disease such as Raynaud’s phenomenon (which may appear as pain in the fingers or toes in response to cold or stress)
 - irregular heartbeat
 - epilepsy (fits)
 - diabetes
 - glaucoma (high pressure in the eyes)
 - phaeochromocytoma (a tumour near the kidney)
 - prostate gland enlargements
 - long term or persistent cough
 - asthma, bronchitis or a chronic lung disorder or a cough with excessive phlegm
 - signs of metabolic acidosis

Contact a doctor immediately if you get a combination of these symptoms.

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines,

including any that you get without a prescription from your pharmacy. Some medicines and 123® Complete may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots or similar medicines used to thin the blood
- medicines to treat anxiety, or help you sleep or relax (sedatives and hypnotics)
- phenytoin, a medicine used to treat epilepsy (fits)
- medicines to treat depression e.g. a selective serotonin reuptake inhibitor (SSRI) such as fluoxetine, or tricyclic antidepressant (such as amitriptyline, clomipramine or imipramine)
- metoclopramide, a medicine used to control nausea and vomiting
- chloramphenicol, an antibiotic used to treat ear and eye infections
- alcohol
- monoamine oxidase inhibitors, a medicine used to treat depression, especially if taken within the last 14 days
- quinidine and amiodarone, medicines used to treat abnormal or irregular heartbeat
- medicines used to treat:
 - heart conditions
 - high blood pressure
 - urinary tract infections and bladder problems
 - behavioral disorders
 - congestion
- appetite suppressants
- opioid analgesics, medicines used to treat pain.

These medicines may be affected by 123® Complete or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your pharmacist and doctor will have more information on these and other medicines to be careful with or avoid while taking this medicine.

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or plan to become pregnant. It may affect your developing baby if you take it during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy or if you are breastfeeding. Ask your pharmacist or doctor before taking 123® Complete or any other medicine.

Driving and using machines

This medicine may cause drowsiness, dizziness or blurred vision in some people. You should not drive or operate machinery until you are sure you are not affected.

3. How to take 123® Complete

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the box/bottle, ask your pharmacist or doctor for help.
Always use the lowest effective dose to relieve your symptoms.

Dosage:

Adults and children 12 years and over:

DAY: Take 2 DAY tablets by mouth every 6 hours with water as necessary.

Maximum 4 DAY tablets in 24 hours.

NIGHT: At bedtime, take 2 NIGHT tablets by mouth with water as necessary.

Maximum 2 NIGHT tablets in 24 hours.

Do not take the NIGHT tablets within 6 hours of the DAY tablets. Do not take more than the recommended dose.

Adults and children 12 years and over:

Only take 123® Complete for a few days at a time except on medical advice.

Children aged 12 to 17 years:

Do not take for more than 48 hours except on medical advice.

Do not use in children below 12 years old

Do not take 123® Complete to treat any other complaints unless your pharmacist or doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you.

Do not drink alcohol (wine, beer, spirits) while taking 123® Complete. The sedation effects of alcohol may be increased.

If you take 123® Complete more than you should

Immediately call your doctor. Seek medical advice immediately even if you feel well because of the risk of delayed, serious liver damage. You may need urgent medical attention.

Taking too much paracetamol can lead to delayed, serious liver damage

While you are using 123® Complete:

Talk to your pharmacist or doctor if your symptoms do not improve or if your cough is accompanied by high temperature, skin rash or persistent headache.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

4. Possible side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking 123® Complete. This medicine helps most people with the relief of sinus congestion and pain, nasal congestion, runny nose or dry cough but there may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Children and the elderly are more likely to develop side effects with this medicine.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- nausea, dyspepsia or vomiting
- drowsiness or sleepiness
- difficulty sleeping
- nervousness
- fatigue
- headache
- blurred vision
- excitability
- restlessness
- dizziness
- difficulty concentrating
- lack of co-ordination
- rapid heartbeat
- increased blood pressure
- dry mouth, nose and throat

- nervousness and irritability

If any of the following happens, stop using the product, tell your pharmacist or doctor immediately or go to your nearest hospital:

- allergic reactions such as:
 - skin rash or peeling, or mouth ulcers
 - skin rash or itching, redness sometimes with breathing problems (difficulty breathing)
 - swelling of mouth or eyes, lips, tongue, throat or face
- previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience similar reactions with this product
- difficulty passing water (this is most likely to occur in men with enlarged prostate gland)
- unexplained bruising or bleeding
- severe drowsiness or dizziness
- severe excitability
- unusually fast pulse rate or a sensation of an unusually fast or irregular heartbeat
- tremor
- hallucinations (this is rare but more likely in children)
- twitching or jerking muscles
- severe nausea and vomiting
- experience some or all of the following symptoms:
 - extreme confusion
 - nervousness and anxiety
 - restlessness
 - sweating
 - shaking
 - shivering
 - sudden jerks of the muscles
 - increased blood pressure.

These may be symptoms of a condition called serotonin syndrome, which may be rare.

- loss of vision, which may be due to abnormally high blood pressure in the eye. This is very rare but is more likely to occur in those with glaucoma.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare for low doses of this medicine and when used for a short period of time. Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

5- How to store 123® Complete

Keep your medicine in the original pack until it is time to take.

Keep out of the reach and sight of children.

Do not store 123® Complete above 30°C.

Do not store 123® Complete or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

6. Content of the pack and further information

What 123® Complete tablet contains

123® Complete day tablet contains 500mg paracetamol, 15mg Dextromethorphan Hydrobromide and 5mg Phenylephrine Hydrochloride as the active ingredients.

The DAY tablet also contains:

- Cellulose – microcrystalline
- Potassium sorbate
- Povidone
- Starch - pregelatinised maize
- Stearic acid
- Magnesium Stearate
- Colloidal Silicone Dioxide
- Talc – purified.

123® Complete night tablet contains 500 mg Paracetamol, 15 mg Dextromethorphan Hydrobromide, 5 mg Phenylephrine Hydrochloride, and 3 mg of Carbinoxamine Maleate as the active ingredients.

The NIGHT tablet also contains:

- Cellulose – microcrystalline
- Potassium sorbate
- Povidone
- Starch - pregelatinised maize
- Stearic acid
- Magnesium Stearate
- Colloidal Silicone Dioxide
- Ethyl Cellulose
- Talc - purified
- FD & C blue.

What 123® Complete DAY & NIGHT tablets look like and contents of the pack

123® Complete DAY tablets are white capsule-shaped tablets with flat edges uncoated embossed on one side “ALG D” and “123C” on the other.

123® Complete NIGHT tablets are blue capsule-shaped tablets with flat edges uncoated embossed on one side “ALG N” and “123C” on the other.

A pack contains 24 tablets consisting of 16 DAY (white) tablets and 8 NIGHT (blue) tablets.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab pharmacists

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