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Package Leaflet: Information for the user**Flamingo Cold and Flu Relief 500mg/ 25mg/ 6.1mg hard capsules**

(paracetamol/ caffeine/ phenylephrine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

The full name of this medicine is Flamingo Cold and Flu Relief 500mg/25mg/ 6.1mg hard capsules. It is referred to as Flamingo cold and flu capsules throughout this leaflet.

This medicine is available without prescription, however, you still need to use this product carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet?

1. What Flamingo cold and flu capsules are and what they are used for
2. What you need to know before you take Flamingo cold and flu capsules
3. How to take Flamingo cold and flu capsules
4. Possible side effects
5. How to store Flamingo cold and flu capsules
6. Contents of the pack and other information

1. What Flamingo cold and flu capsules are and what they are used for**This medicine contains:**

- Paracetamol which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever.
- Phenylephrine which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily
- Caffeine which helps to increase the pain relief from paracetamol and makes you more alert.

These capsules are used for the relief of the symptoms of colds and flu, including aches and pains, sore throat, headache, fatigue (tiredness) and drowsiness, nasal congestion (blocked nose) and feverishness (high temperature).

2. What you need to know before you take Flamingo cold and flu capsules**Do not take this medicine if:**

- are allergic to paracetamol, caffeine, phenylephrine or any of the other ingredients listed in section 6
- are under 16 years of age
- have a serious heart condition or cardiovascular disorder(s)
- have high blood pressure (hypertension)
- have a history of stomach ulcers
- have an overactive thyroid
- have an enlarged prostate
- are taking antidepressant drugs called monoamine oxidase inhibitors (MAOIs), or have taken them within the last 14 days – these are medicines such as phenelzine and isocarboxazid.
- are taking tricyclic antidepressants, such as imipramine, amitriptyline.

Please see your doctor or pharmacist before taking this medicine if you:

- are pregnant or breast-feeding
- have kidney or liver problems, including alcoholic liver disease or have alcohol dependence
- have diabetes
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes.

During treatment with Flamingo cold and flu capsules, tell your doctor straightaway if:

- you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Other medicines and Flamingo cold and flu capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as colestyramine.
- medicines to control feeling sick or being sick such as metoclopramide or domperidone.
- medicines called anti-coagulants, which are used to thin the blood such as warfarin or other coumarins - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis.
- barbiturates (for epilepsy or to help you sleep), such as phenobarbitone.
- medicines to treat migraines such as ergotamine or methysergide.
- medicines to lower blood pressure, treat heart or circulatory problems such as beta blockers (e.g. atenolol) or vasodilators (e.g. hydralazine).
- other decongestant drugs such as ephedrine or xylometazoline.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Flamingo cold and flu capsules contain paracetamol.**Do not take anything else containing paracetamol while taking this medicine.**

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Flamingo cold and flu capsules with food, drink and alcohol.**Do not drink alcohol** (beer, wine, spirits etc.) while taking this product.**Information about some of the ingredients in this medicine.**

This medicine contains less than 1mmol sodium (23 mg) per 2 capsules, that is to say essentially 'sodium-free'.

3. How to take Flamingo cold and flu capsules

Swallow the capsules whole with water.

Do not chew.

Adults, the elderly and children aged 16 years and over: Two capsules every 4 to 6 hours, as required. Do not take more than 8 capsules (4 doses) in any 24 hour period.**Do not give to children under 16 years.**

Do not take for more than 3 days unless advised by your doctor.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Taking this medicine with food and drink:

You should avoid too much caffeine in drinks like coffee and tea. If you are also consuming other medicines or food that contains caffeine (coffee, tea, cola drinks, chocolate) you may have a high caffeine intake and might have difficulty sleeping, start shaking and/or have an uncomfortable feeling in the chest.

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.**4. Possible side effects**

Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Frequency not known (frequency cannot be estimated from the available data):

- bronchospasm
- restlessness, anxiety, nervousness, irritability, agitation
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Rare side effects are:

- allergic reactions such as skin rash
- nausea (feeling sick) or vomiting (being sick) or diarrhoea
- headache, tremor, dizziness
- difficulty sleeping (insomnia)
- fast, slow or irregular heart beat (palpitations)
- high blood pressure
- glaucoma
- problems or pain passing urine
- sudden weight loss, loss of appetite and yellowing of the eyes and skin.

More rarely, the following side effects can happen:

- you may become more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers, due to changes in your blood.

Very rare cases of serious skin reactions have been reported.

Reporting of side effectsIf you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flamingo cold and flu capsules**Keep all medicines out of the sight and reach of children.**

Do not use this medicine after the expiry date (EXP) which is stated on the carton and blister. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions. Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**Flamingo Cold and Flu Relief 500mg/ 25mg/ 6.1mg hard capsules contain:**

- The active substances are: paracetamol 500mg, caffeine 25mg and phenylephrine hydrochloride 6.1mg.
- The other ingredients are: maize starch, sodium laurilsulfate, povidone K-30, croscarmellose sodium, magnesium stearate, purified talc, empty hard gelatin capsules of size "0" red cap/yellow body.

The capsule shell contains gelatin, iron oxide red (E172), iron oxide yellow (E172) and purified water.

What this medicine looks like and contents of the pack: Size "0" hard gelatin capsule with red opaque cap and yellow opaque body, containing white to off-white granular powder or powder plug. The length of capsule is 21.55 mm.

This medicine is available in child-resistant white opaque aluminium- PVC or PVC/PVDC blister packs of 8 and 16 capsules.

Not all pack sizes may be marketed.

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