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Pharmacode Reading Direction

160 mm

250 mm

Package Leaflet: Information for the user
Flamingo Cold and Chesty Cough All-in-one
250mg/100mg/5mg Film-coated tablets

(paracetamol, guaifenesin and phenylephrine hydrochloride)

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription but you still need to use Flamingo Cold and Chesty Cough All-in-one 250mg/100mg/5mg Film-coated tablets carefully to get the best results from them.

- Keep this leaflet you may need to read it again.
 - If you have any questions or if there is anything you do not understand ask your pharmacist.
- The full name of this medicine is Flamingo Cold and Chesty Cough All-in-one 250mg/100mg/5mg Film-coated tablets. It is referred to as Flamingo All-in-one tablets throughout this leaflet.

What is in this leaflet:

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

1. What Flamingo All-in-one tablets are and what they are used for

Flamingo All-in-one tablets are used for the relief of the symptoms of colds, chills and flu with chesty coughs. These symptoms include headache, shivers, aches and pains, blocked nose and painful sinuses, catarrh, sore throat and a chesty, productive cough. This medicine contains three active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever. Guaifenesin is an expectorant which loosens phlegm and relieves a chesty cough. Phenylephrine hydrochloride is a decongestant which unblocks your nose and sinuses helping you breathe more easily.

2. What you need to know before you take Flamingo All-in-one tablets

Do not take Flamingo All-in-one tablets:

- if you have ever had an allergic reaction to paracetamol, guaifenesin, phenylephrine hydrochloride or to any of the other ingredients (listed in section 6)
- if you have kidney or liver problems (including alcoholic liver disease), overactive thyroid, diabetes, high blood pressure or heart disease
- if you have phaeochromocytoma or glaucoma
- if you are taking tricyclic antidepressants (e.g. imipramine or amitriptyline) or if you are taking or have taken in the last two weeks monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide) prescribed for depression
- if you are taking beta-blockers (e.g. atenolol)
- if you have an enlarged prostate

Contains paracetamol.

Taking too much paracetamol can cause serious harm to your liver.

Do not take anything else containing paracetamol while taking this medicine.

Do not take with any other flu, cold, decongestant products or cough suppressants.

Take special care with this tablets

This product may cause dizziness. If affected do not drive or operate machinery.

Ask your doctor before you take this medicine:

- if you have blood vessel disease such as Raynaud's phenomenon
- if you have asthma or chronic cough
- if you have liver or kidney problems
- if you have a severe infection as this may increase the risk of metabolic acidosis.
- Signs 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.

During treatment with this tablet, tell your doctor straight away if:

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).

If you are taking other medicines

Talk to your doctor or pharmacist before taking Flamingo All-in-one tablets if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]), or ergotamine or methylsergide (for migraine), or colestyramine (to lower blood

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cholesterol) or drugs to lower blood pressure; appetite suppressants or stimulants; drugs to treat depression such as tricyclic antidepressants (e.g. amitriptyline) or heart disease (e.g. digoxin) or if you take blood thinning drugs (anticoagulants e.g. warfarin); flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Pregnancy and breast-feeding

Talk to your doctor before taking this product if you are pregnant or breastfeeding.

Flamingo All-in-one tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How to take Flamingo All-in-one tablets

For oral use. Take tablets with water and swallow whole. Adults and children 12 years and over: Swallow 2 tablets every 4 hours as needed.

- Do not take more frequently than every 4 hours.
- Do not take more than 8 tablets in 24 hours.
- Always use the lowest effective dose to relieve your symptoms.
- Do not take more than the recommended dose.
- Do not take for more than 5 days without asking your doctor.
- Do not give to children under 12 years.

If you take too many tablets

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.

If symptoms persist, **see your doctor.**

4. Possible side effects

Like all medicines, this tablets can have side effects, but not everybody gets them. A small number of people have had side effects. Very rare cases of serious skin reactions have been reported.

Stop taking this medicine and tell your doctor immediately if you experience:

- **Allergic reactions** which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath.
- **Skin rash or peeling, or mouth ulcers.**
- **Breathing problems.** These are more likely if you have experienced them before when taking other painkillers such as ibuprofen or aspirin.
- **Unexplained bruising or bleeding.**
- **Reoccurring fevers or infections.**
- **Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.**
- **Visual disturbances.** This is rare but is more likely in those with glaucoma.
- Unusually **fast pulse rate** or sensation of an unusually **fast or irregular heartbeat.**
- **Difficulty passing water.** This is more likely to occur in men with an enlarged prostate gland.
- **Metabolic acidosis: Frequency not known:** A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

The following side effects may also occur.

Tell your doctor if you get them:

- Raised blood pressure, headache, dizziness, difficulty sleeping, nervousness, anxiety, diarrhoea or sickness.

Reporting of side effects

If 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 All-in-one tablets

Keep out of the sight and reach of children.

Do not use this medicine after the 'EXP' date shown on the pack. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions.

6. Contents of the pack and other information

Active ingredients- Each film-coated tablet contains Paracetamol 250 mg, Guaifenesin 100 mg and Phenylephrine Hydrochloride 5 mg.

Other ingredients microcrystalline cellulose (Ph101), croscarmellose sodium, povidone (PVP-K30), microcrystalline cellulose (PH102), stearic acid, macrogol (E1521) and hypromellose (E464).

What this medicine looks like and contents of the pack

Flamingo All-in-one tablets are white, capsule shaped, film coated tablet, embossed with "PGP" on one side and plain on the other. The tablets are 17.6mm in length, 7.3mm in width and 6.1 mm in thickness.

Tablets are available in cartons containing aluminium-PVC/PVDC and aluminium-PVC white opaque film child-resistant blister packs of 8, 12 and 16 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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