FLUCOR NIGHT PE SOFT GELATIN CAPSULE

Paracetamol (250 mg), Phenylephrine HCl (5 mg) and Chlorpheniramine maleate (2 mg)

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What Flucor Night PE Soft Gelatin Capsule is used for

Used to temporary relieve running nose and sneezing, minor aches and pains, headaches, fever and nasal congestion associated with the common cold.

How Flucor Night PE Soft Gelatin Capsule works

Paracetamol relieves pain by blocking the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Phenylephrine hydrochloride acts as a decongestant by clearing the nose, nasal passages and sinuses so that it is easier to breathe. It narrows the blood vessels in the affected areas.

Chlorpheniramine maleate is sedating anti-histamine that gives a drying effect on the nasal mucosa. The nasal mucosa is a moist tissue that produces mucus (a thick slippery substance) in the nose.

Before you use Flucor Night PE Soft Gelatin Capsule

- When you must not use it

Do not take this medicine if:

- you are allergic to paracetamol, phenylephrine hydrochloride, chlorpheniramine maleate and any of the excipients
- you have taken monoamine oxidase inhibitors in the last 14 days or within 14 days of stopping it
- you have very high blood pressure or coronary heart disease
- you are taking any other medicine that contains paracetamol
- you are pregnant or breastfeeding.

- Before you start to use it

Tell your doctor if:

- you have asthma, bronchitis or a chronic lung disorder
- you are breastfeeding or plan to become pregnant
- you drink alcohol regularly
- you have kidney problems
- you have liver problems
- you have high blood pressure
- you have heart disease
- you have prostrate problems
- you have breathing problems
- you have thyroid disease
- you have persistent or chronic cough
- you cough with excessive phlegm
- you have epilepsy
- you have diabetes
- you have glaucoma (high pressure in the eyes).

- Taking other medicines

Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtained without a prescription.

Some medicines interfere with the active ingredients in Flucor Night PE Soft Gelatin Capsule. They include:

- alcohol
- medicines used to treat depression
- medicines used to treat high blood pressure

- amphetamine (to treat attention deficit hyperactivity disorder (ADHD) and narcolepsy)
- appetite suppressants
- medicines that induces liver enzyme (e.g. antiepileptic drugs and rifampin)
- medicines that can be toxic to liver (e.g. non-steroidal antiinflammatory drugs (NSAIDs), isoniazid and others)
- monoamine oxidase inhibitors

Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to use Flucor Night Soft PE Soft Gelatin Capsule

- How much to use

Oral

Adults and children aged 12 years and above take 2 softgels every 4 hours.

Do not take more than 8 softgels in 24 hours. Swallow the softgels with fluid.

- When to use it

Take your medicine every 4 hours as needed.

- How long to use it

You are advised to take Flucor Night PE Soft Gelatin Capsule as long as your doctor tells you to.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much may cause vomiting, abdominal pain, sweating and low blood pressure.

While you are using it

- Things you must do

Tell your doctor:

- As soon as possible if there is no change in your condition or if you feel worse.
- If you experience allergic reactions/ any of the unwanted side effects while taking the medicine.
- If you become pregnant while taking this medication

Tell all the doctors, dentists and pharmacists treating you that you are taking Flucor Night PE Soft Gelatin Capsule.

Take your medicine exactly as your doctor has told you.

- Things you must not do

Do not:

- give this medicine to anyone else and to children under 12 years even if their symptoms seem similar to yours
- take your medicine to treat any other complaints unless you are told by your doctor or pharmacist
- change the recommended dosage on your own.

- Things to be careful of

Alcohol

Be careful when drinking alcohol while taking this medicine. You may increase the risk of liver side effects.

Driving and using machines
You may feel dizzy. Stop driving or
using machines if you experience
dizziness.

Side effects

Like all medicines, Flucor Night PE Soft Gelatin Capsule can cause side effects, although not everybody gets them. These effects can be serious but most of the time, they are mild and temporary.

Tell your doctor immediately if you think you are experiencing any of the following possible unwanted side effects while taking the medicine.

Haematological reactions:

- thrombocytopenia (reduced platelet count)
- leukopenia (reduced white blood cell count)
- pancytopenia (reduced red and white blood cells, and platelets)
- neutropenia (reduced number of neutrophils, a type of white blood cell)
- agranulocytosis (severe reduction in white blood cell count).

Common side effects associated with phenylephrine:

- anxiety
- palpitations
- irregular heartbeats
- headache
- cold extremities/gangrene
- high blood pressure
- nausea and vomiting
- sweating
- · weakness
- fear
- restlessness
- difficulty in sleeping
- confusion
- irritability
- psychotic states
- difficulty in breathing
- loss of appetite
- extravasation causing tissue necrosis and sloughing
- widening of the pupil
- difficulty in urination and urinary retention
- goosebumps
- increased salivation
- high blood sugar
- lactic acidosis

Less frequent or rare side effects associated with chlorpheniramine:

- difficult/painful urination
- drowsiness
- · increased sweating

- loss of appetite
- paradoxical reaction (a reaction that is an opposite effect of which is normally expected).

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Other unwanted side effects not listed may occur. Tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)"

Storage and Disposal of Flucor Night PE Soft Gelatin Capsule

- Storage

Keep out of reach of children. Store below 30°C. Protect from moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like

Flucor Night PE Soft Gelatin Capsule is a green transparent soft gelatin capsule printed with "Flucor". The capsule is oblong shaped filled with transparent green liquid.

- Ingredients

• Active Ingredients

Each liquid gel contains:

Paracetamol 250 mg Phenylephrine hydrochloride 5mg Chlorpheniramine maleate 2 mg

• Inactive ingredients

Polyethylene Glycol Polyvinylpyrrolidone FD&C Blue No1 Quinoline Yellow Purified Water Gelatin Gelatin-Sorbitol Mixture Polysorbate

- <u>MAL Number</u>: MAL14055161AZ

Manufacturer and Product Registration Holder HOVID Berhad 121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar), 30010 Ipoh, Perak, Malaysia.

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