

UPHAMOL PLUS CODEINE TABLET

Paracetamol / Codeine phosphate (500mg / 8mg)

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What Uphamol Plus Codeine is used for

Uphamol Plus Codeine is used to relieve pain such as headache, stomach pain, conditions involving musculoskeletal pain and to relieve discomfort and fever in cold and viral infections. It is also used to manage pain associated with dental work and tooth extractions.

How Uphamol Plus Codeine works

Uphamol Plus Codeine contains paracetamol and codeine. Paracetamol is used to relieve pain and reduce fever.

Codeine is used to relieve pain and suppress cough.

Paracetamol and codeine work together to provide additional pain relief.

Before you use Uphamol Plus Codeine

- When you must not use it

Do not take this medicine if you have an allergy to:

- paracetamol
- codeine
- any of the ingredients listed at the end of this leaflet.

Do not take this medicine:

- in children below 12 years old for symptomatic treatment of colds
- in all pediatric patients (0-18 years old) who undergo surgery to remove tonsils and/or adenoid for sleep disorder syndrome
- in woman who are pregnant or breastfeeding

- in patients who are CYP2D6 ultra-rapid metabolisers.

Codeine may depress neonatal respiration and cause withdrawal effects in neonates of dependent mothers. As precautionary, Uphamol Plus Codeine should be avoided during the third trimester of pregnancy and labor.

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.

- Before you start use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have ever had any other health problems / medical conditions, including:

- Liver disease
- Kidney disease
- Head injury
- Addison's disease (a disorder of insufficient production of certain hormones by adrenal glands)

- Taking other medicines

Taking Uphamol Plus Codeine with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine.

Seek medical attention immediately if you or the person taking this medication experience symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are using any other medicines, including any of the following medicines:

- Medicine or substance which may depress central nervous system including alcohol
- Serotonergic drugs used for weight loss that contains serotonin

Your doctor or pharmacist will tell you what to do if you are taking any of these medicines.

How to use Uphamol Plus Codeine

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

- How much to use

Adult and children above 12 years:

Take 1 to 2 tablets every 4 to 6 hours.

Do not take more than 6 tablets in one day.

Children aged less than 12 years:

Codeine should not be used in children below the age of 12 years due to risk of toxicity.

Uphamol Plus Codeine is contraindicated in children below 12 years for symptomatic treatment of colds.

Children aged 12 years to 18 years:

Uphamol Plus Codeine is not recommended for use in children aged 12 years to 18 years with compromised respiratory function.

- When to use it

Take Uphamol Plus Codeine as your doctor has prescribed.

May be taken with or without food.

- How long to use it

Continue taking Uphamol Plus Codeine for as long as your doctor recommends.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

- If you use too much (overdose)

Early symptoms (nausea, vomiting, and weakness) usually occur after ingestion of paracetamol overdose large enough to cause liver toxicity.

Immediately telephone your doctor for advice or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much Uphamol Plus Codeine.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Uphamol Plus Codeine.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Uphamol Plus Codeine.

- Things you must not do

Do not take Uphamol Plus Codeine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Uphamol Plus Codeine may cause dizziness or drowsiness in some people, especially after the first dose.

If affected, do not drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or drowsy.

Children should not ride bikes if affected and should be supervised to avoid potential harm.

Do not drink alcohol. Drinking alcohol increases the likelihood of becoming drowsy.

Uphamol Plus Codeine may be habit forming if taken in high doses for extended periods of time.

Ask your doctor or pharmacist if you are concerned about this.

This preparation contains Paracetamol. Do not take any other paracetamol containing medicines at the same time.

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.

Serotonin syndrome: Uphamol Plus Codeine may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

Adrenal insufficiency: Long-term use of Uphamol Plus Codeine may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

Infertility: Long-term use of Uphamol Plus Codeine may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

The following side effects are common:

- Nausea
- Vomiting
- Dizziness
- Drowsiness
- Light-headedness

The following side effects are rare:

- Skin reactions such as urticaria (hives)

The following side effects have been reported:

- skin rashes,
- angioedema (swelling of area beneath the skin)
- Stevens Johnson Syndrome (severe skin reaction with flu-like symptoms and painful red rashes)
- Toxic Epidermal Necrolysis (TEN) (potentially life threatening severe skin reaction)

Long-term use of opioids (codeine) may cause reduced fertility in females and males. It is not known whether these effects on fertility are reversible.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835490, or visiting the website www.npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Uphamol Plus Codeine Tablet

- Storage

Keep your medicine in the original container. If you take it out of its original container it may not be kept well. Keep the container tightly closed.

Keep your medicine in a dry place where the temperature stays below 30°C. Protect from light.

Do not store Uphamol Plus Codeine 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.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

- What it looks like

Uphamol Plus Codeine is a 12mm, round, flat, scored and yellow tablet.

- Ingredients

- Active ingredients:

- Paracetamol
- Codeine Phosphate

- Inactive ingredients:

- P.V.P 30
- Sodium Starch Glycolate
- Gelatin Bloom 200
- Corn starch
- Magnesium stearate
- Ariavit Quinoline Yellow

- MAL number:

MAL19871075AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn. Bhd.

Lot 2&4, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi
Selangor Darul Ehsan.

Product Registration Holder

Duopharma Manufacturing (Bangi) Sdn. Bhd.

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