

# COPAN TABLET

Hyoscine butylbromide (10mg)

## What is in the leaflet

1. What COPAN is used for
2. How COPAN works
3. Before you use COPAN
4. How to use COPAN
5. While you are using it
6. Side effects
7. Storage and Disposal of COPAN
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What COPAN is used for

COPAN is known as an anticholinergic medicine. It relieves the pain of stomach and bowel cramps by helping your digestive system to relax. It is also used to help relax biliary tract (gall bladder, bile duct, sphincters), genital and urinary tract spasms.

## How COPAN works

COPAN reduces the peristalsis (wave-like contractions) of smooth muscle resulting in relief from spasms in certain organs in the digestive system.

Your doctor may have prescribed COPAN for another reason.

Always consult your doctor or pharmacist if the pain does not improve or if pain worsens after treatment.

## Before you use COPAN

- When you must not use it

Do not take COPAN if you are allergic to hyoscine butylbromide or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take COPAN if you have:

- myasthenia gravis - a condition in which the muscles become weak and tire easily.
- glaucoma – high pressure in the eye
- megacolon – a very enlarged colon
- tachyarrhythmia – a fast irregular heart rate
- enlarged prostate gland with urinary retention

COPAN must not be used when there is a blockage in the stomach or bowel or in certain conditions when there is reduced bowel activity.

These conditions are best explained by your doctor or pharmacist.

Do not take it 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.

If you are not sure whether you should be given this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you are pregnant especially during the first trimester, or plan to become pregnant or are breast-feeding.

There is limited information on the use of COPAN during pregnancy and breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

## Children:

For all anticholinergics – Infants and young children are especially susceptible to the toxic effects of anticholinergics. Close supervision is recommended for infants and children with spastic paralysis (paralysis with muscle spasm) or brain damage since an increased response to anticholinergics has been reported in these people and dosage adjustments are often required.

When anticholinergics are given to children where the environmental temperature is high, there is risk of a rapid increase in body temperature because of these medications' suppression of sweat gland activity. A paradoxical reaction characterized by hyperexcitability may occur in children taking large doses of anticholinergics.

## Elderly:

Elderly may respond to usual doses of anticholinergics with excitement, agitation, drowsiness or confusion. Elderly are especially susceptible to the anticholinergic side effects such as constipation, dryness of mouth, and urinary retention (especially in males). If these side effects occur and continue or are severe, medication should probably be discontinued. Caution is also recommended when anticholinergics are given to elderly because of the danger of precipitating undiagnosed glaucoma. Memory may

become severely impaired in elderly especially those who already have memory problems, with the continued use of anticholinergics since these medicines block the actions of acetylcholine which is responsible for many functions of the brain, including memory functions.

Dental:

Prolonged use of anticholinergics may decrease or block salivary flow thus contributing to the development of tooth decay, gum diseases, oral fungal infection (oral thrush) and discomfort.

If you have not told your doctor about any of the above, tell him/her before you start taking COPAN.

- Taking other medicines

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.

Some medicines and COPAN may interfere with each other. These include:

- medicines to treat irregular heart beat such as disopyramide
- medicines used to treat malaria such as quinine
- medicines used to treat the symptoms of Parkinson's disease such as amantadine
- medicines used to treat some mental conditions such as tricyclic antidepressants and phenothiazines
- medicines used to treat allergies such as antihistamines

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

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

**How to use COPAN**

Swallow COPAN with a full glass of water.

- How much to use

Take COPAN as your doctor has prescribed.

Your doctor will tell you how many tablets you will need to take each day.

*Adult and children over 6 years:*  
3-5 times daily, 1 to 2 tablets

- When to use it

Take COPAN as your doctor has prescribed.

- How long to use it

Worsening or persistent stomach pain should be investigated by your doctor to determine the cause of the pain.

- If you forget to use it

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

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much COPAN Tablet.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include: drowsiness, dry mouth, fast heart rate and sight disturbances.

**While you are using it**

- Things you must do

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

Cramps in the stomach or bowel may be temporary or may signal the presence of a more serious problem.

- Things you must not do

Do not take COPAN 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

Be careful driving or operating machinery until you know how COPAN affects you.

**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.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

- dry mouth
- fast heart rate
- reduced sweating
- rash
- difficulty with passing urine

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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

**Storage and Disposal of COPAN**

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

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

Do not store your medicine, 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

COPAN Tablet is a round 7mm diameter white tablet with markings “DUOMA/DUOMA” and “d”.

- Ingredients

Active ingredient:

- hyoscine butylbromide

Inactive ingredients:

- Primogel
- Magnesium stearate
- PVP
- Cornstarch
- Aerosil
- Lactose

- MAL number  
MAL20000832AZ

**Manufacturer**

Duopharma (M) Sdn. Bhd.  
(42491-M)  
Lot. 2599, Jalan Seruling 59,  
Kawasan 3, Taman Klang Jaya,  
41200 Klang, Selangor Darul  
Ehsan, Malaysia.

**Product Registration Holder**

Duopharma (M) Sdn. Bhd.  
(42491-M)  
Lot. 2599, Jalan Seruling 59,  
Kawasan 3, Taman Klang Jaya,  
41200 Klang, Selangor Darul  
Ehsan, Malaysia.

**Date of Revision**

24/02/2016

**Serial Number**

BPFK(R4/1)170216/00042