

Panalgesic capsules

Paracetamol, Codeine Phosphate Hemihydrate & Doxylamine Succinate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Panalgesic capsules. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

Keep this information with the capsules. You may need to read it again.

What is Panalgesic used for

Panalgesic is a type of analgesic intended for short term use to relieve moderate pain.

Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Doxylamine is an antihistamine with calmative effects.

Your doctor may have prescribed this medicine for another use. If you want more information, ask your doctor or pharmacist.

Codeine is addictive.

Before you take Panalgesic

When you must not use it

You should not take Panalgesic if you are allergic to paracetamol, codeine, doxylamine or any of the ingredients listed under "Product Description".

The symptoms of an allergic reaction may include a rash, itching, swelling of the face, lips or tongue,

which may cause difficulty in swallowing or breathing, asthma attack or hayfever.

Do not take Panalgesic if you are a CYP 2D6 ultra-rapid metaboliser (a fast metaboliser of codeine by the CYP 2D6 enzyme).

Do not take Panalgesic if you have glucose-6-phosphate-dehydrogenase deficiency.

Do not take Panalgesic if you have impaired lung, liver or kidney function.

Panalgesic should not be used in children who are aged between 12-18 years who undergo tonsillectomy and/or adenoidectomy.

Do not give Panalgesic to children under 12 years of age.

Do not take Panalgesic during the third trimester of pregnancy.

Do not take Panalgesic during labour, especially if the baby is premature.

This medicine may produce withdrawal effects in the newborn baby.

Do not take Panalgesic if you are breastfeeding or planning to breastfeed.

Panalgesic passes into breast milk and there is a possibility your baby may be affected.

Do not use Panalgesic after the expiry date (EXP) printed on the pack.

If you take it after the expiry date it may have no effect at all, or worse, have an entirely unexpected effect.

Do not use Panalgesic if the packaging is torn or shows signs of tampering.

Do not use this medicine to treat any other complaint unless your

doctor says it is safe. Do not give this medicine to anyone else.

Before you start to take it

You must tell your doctor if:

- **You have allergies to any ingredients listed under "Product Description" at the end of this leaflet.**
- **You have allergies to aspirin or any other NSAID medicine**
- **You have any of these conditions:**
 - Lung problems, such as asthma or respiratory depression; compromised respiratory function (due to emphysema, kyphoscoliosis or obesity)
 - Impaired heart, liver or kidney function
 - G6PD deficiency, a human enzyme deficiency
 - Are between 12-18 years and have undergone adenoidectomy and/or tonsillectomy
 - Head injury or trauma
 - If you know you are a CYP 2D6 ultra-rapid metaboliser
 - Known analgesic intolerance
 - Pre-existing opioid dependence
- **You have a history of drug dependence, including alcohol dependence**
- **You drink large amounts of alcohol.**
- **Chronic alcohol use including recent cessation of alcohol intake**
- **Low glutathione reserves**
- **Gilbert's syndrome**
- **Prostate problems**
- **Thyroid problems**
- **Multiple sclerosis**

- **Urinary, bowel or gallbladder conditions**
- **Chronic constipation**
- **Addison's disease**
- **Convulsions, fits or seizures**

Tell your doctor if you are pregnant or intend to become pregnant.

Your pharmacist or doctor will discuss the risks and benefits of taking it if you are pregnant.

Taking other medicines

You should talk with your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and Panalgesic may interfere with each other.

These include:

- Any medicines causing sleepiness
- Tranquillisers (medicines for anxiety or nerves)
- Benzodiazepines (medicines used as sedatives or to treat anxiety)
- Medicines containing alcohol (ethanol), e.g. some cough syrups
- Any medicines which thin the blood
- Medicine to treat epilepsy
- Antihypertensives (medicines used to help lower blood pressure)
- Metoclopramide or domperidone, a medicine used to control nausea and vomiting
- Propantheline, a drug used to treat stomach ulcers
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Flucloxacillin, zidovudine or rifampicin, drugs used to treat infections
- Antidepressants
- Antipsychotics (medicines used to treat mental illnesses)

- Chelating resin
- Buprenorphine
- Naltrexone

These medicines may be affected by Panalgesic or may affect the way Panalgesic works.

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

If you have not told your doctor about any of these things, tell him/her before you take Panalgesic.

How to take Panalgesic

How much to take

The label on your pack of Panalgesic will tell you how to take your medicine and how often. If you are unsure about the directions ask your doctor or pharmacist.

The usual dose is:

Adults and Children over 12 years: 2 capsules.

This dosage may be repeated in 4 hours if necessary.

You should not take more than 8 capsules in 24 hours.

If Panalgesic is not adequately controlling your pain, do not increase the dose. Please see your doctor.

Do not give Panalgesic to children under 12 years of age.

How to take it

Swallow the capsules whole with a little water or other liquid.

The directions given to you by your doctor or pharmacist may be different from the information in this leaflet.

If you are unsure what dose to take ask your pharmacist or doctor.

If you forget to take it

If you miss a dose, take it as soon as you remember. 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 of Panalgesic to make up for the dose missed.

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

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much Panalgesic.

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

Keep telephone numbers of these places handy.

If you take too many capsules you may feel nauseous, lightheaded, dizzy or drowsy. Fits can occur in children.

While you are taking Panalgesic

Things you must do

Take Panalgesic exactly as your doctor has prescribed.

Tell all your doctors, dentists and pharmacists that you are taking Panalgesic.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Panalgesic.

Tell your doctor if you become pregnant while taking Panalgesic.

If you plan to have surgery that needs a general anaesthetic, tell

your doctor or dentist that you are taking this medicine.

Things to be careful of

Panalgesic 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 bicycles if affected and should be supervised to avoid potential harm.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Do not drink alcohol.

Drinking alcohol increases the likelihood of becoming drowsy. It is not recommended that you drink alcohol while taking Panalgesic.

Panalgesic may be habit forming if taken in high doses for extended periods of time.

Please ask your doctor or pharmacist if you are concerned about this.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Panalgesic.

Like other medicines, Panalgesic can cause some side effects. If they occur, they are most likely minor and temporary. However, sometimes they are serious and need medical treatment.

Ask your doctor or pharmacist any questions you may have.

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

Stomach problems such as:

- Nausea
- Vomiting

- Stomach pain
- Constipation

Difficulty thinking or working because of:

- Dizziness
- Drowsiness

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

Other problems include:

- Skin rashes
- Sweating
- Difficulty breathing

Tell your doctor as soon as possible if you notice any of the following:

- painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills
- hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- hives
- fainting
- yellowing of the skin and eyes (jaundice)

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Panalgesic. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

If you believe Panalgesic is not working well for you do not increase the dose. Please see your doctor.

Some people may get other side effects not listed above.

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

After taking Panalgesic

Storage

Keep your capsules in the blister pack until it is time to take them.

If you take the capsules out of the box or the blister pack they will not keep well.

Keep Panalgesic in a cool, dry place where the temperature stays below 30°C.

Heat and dampness can destroy some medicines. Do not leave Panalgesic in the car on hot days.

Do not store Panalgesic or any other medicine in the bathroom or near a sink.

Keep Panalgesic where young 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 tells you to stop taking the capsules, ask your pharmacist what to do with any capsules that are left over.

This is not all the information that is available on Panalgesic. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Panalgesic comes as a yellow and white capsule marked 'PANALGESIC' in black ink on the body and cap of the capsule.

A box contains 24 capsules.

Product description

Active Ingredient:

Each Panalgesic capsule contains:

- Paracetamol 500 mg
- Codeine Phosphate Hemihydrate
8 mg
- Doxylamine Succinate 5 mg

Other ingredients:

- Sodium starch glycollate
- Purified talc
- Purified water
- Magnesium stearate
- Gelatin
- Titanium dioxide
- Quinoline Yellow
- Erythrosine
- Opacode S-1-8152 HV Black
(PI 1560)

Panalgesic does not contain any
gluten, lactose, sucrose, tartrazine
or any azo dyes.

Manufacturer

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

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