

Prodeinextra

Paracetamol and codeine phosphate hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Prodeinextra.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Prodeinextra is used for

Prodeinextra is a type of analgesic intended for short term use to relieve moderate pain and fever.

Prodeinextra contains paracetamol and codeine. Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Paracetamol also acts in the brain to help reduce fever.

Your doctor or pharmacist may have given you Prodeinextra for another purpose.

If you want more information ask your doctor or pharmacist.

Before you take it

When you must not take it

Do not take Prodeinextra if you have:

- unstable asthma or emphysema
- bronchitis
- liver failure
- Glucose-6-phosphate-dehydrogenase deficiency (an enzyme deficiency)
- known CYP 2D6 ultra-rapid metaboliser (a fast metaboliser of codeine by the CYP 2D6 enzyme)
- a history of intolerance to this medicine
- Diarrhoea caused by antibiotics or poisoning

Do not take Prodeinextra if you have alcohol dependence.

Do not take Prodeinextra during the third trimester of pregnancy.

Do not take it if you are in labour, especially if the baby is premature.

Prodeinextra contains codeine, which may produce withdrawal effects in the newborn baby.

Do not take Prodeinextra if you are allergic to it or any of the ingredients listed at the end of this leaflet, morphine or oxycodone.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Prodeinextra to children under 12 years.

Do not give Prodeinextra to children aged between 12-18

years who have undergone tonsillectomy and/or adenoidectomy to treat sleep apnoea.

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

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

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is damaged or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes
- aspirin or any other NSAID medicine.

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

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

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- heart, lung, liver or kidney problems
- difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions

- **compromised respiratory function (due to emphysema, kyphoscoliosis or obesity)**
- **known analgesic intolerance**
- **a history of drug dependence, including alcohol dependence**
- **pre-existing opioid dependence**
- **chronic alcohol use including recent cessation of alcohol intake**
- **stomach, gallbladder, urinary or bowel conditions**
- **chronic constipation**
- **recent stomach, intestines or urinary tract surgery**
- **prostate problems**
- **problems with your adrenal gland or thyroid**
- **Multiple sclerosis**
- **head injury or trauma**
- **convulsions, fits or seizures**
- **are under 18 and have undergone adenoidectomy and/or tonsillectomy**
- **if you know you are a CYP 2D6 ultra-rapid metaboliser**

Tell your doctor or pharmacist if you plan to have surgery.

Tell your doctor or pharmacist if you drink large quantities of alcohol.

If you have not told your doctor or about any of the above, tell them before you take Prodeinextra.

Taking other medicines

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

Some medicines may affect how Prodeinextra works. These include:

- medicines causing sleepiness or drowsiness
- tranquilisers (medicines for anxiety and nerves)
- benzodiazepines (medicines used as sedatives or to treat anxiety)

- medicines containing alcohol (ethanol), e.g. some cough syrups
- medicines used to treat depression
- anticholinergics (medicines for stomach cramps/spasms, travel sickness, Parkinson's disease)
- antipsychotics (medicines used to treat mental illnesses)
- medicines which thin the blood
- medicines to treat epilepsy
- other pain relief medication
- medicines used to treat high blood pressure
- medicines used to relax muscles
- medicines used to treat diarrhoea, nausea or vomiting
- cholestyramine (medicine used to treat bile problems and/or high cholesterol)
- chelating resin
- buprenorphine
- naltrexone
- chloramphenicol (medicine used to treat ear and eye infections)
- flucloxacillin, zidovudine or rifampicin (medicines used to treat infections)

These medicines may be affected by Prodeinextra, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Prodeinextra.

How to take it

How much to take

The standard dose for adults and children aged 12 years and over for this medicine is 2 caplets, taken every 4 to 6 hours if necessary.

You should not take more than 8 caplets in a 24 hour period.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Prodeinextra may not work as well and your problem may not improve.

How to take it

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

When to take it

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

Do not take this medicine for longer than 48 hours (for children aged 12-17 years) or for more than 3 days, except on medical advice.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Prodeinextra.

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

You may need urgent medical attention.

If you take too much Prodeinextra, you will probably feel nauseous, light-headed, dizzy, or drowsy.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Prodeinextra.

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking given this medicine, stop taking it and tell your doctor or pharmacist immediately.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Adults and children over 12 years should not take more than 8 caplets a day.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

Taking more than the recommended dose may cause liver damage.

Codeine may be habit forming.

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

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

It may cause dizziness, drowsiness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy or drowsy.

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

The effects of alcohol could be made worse while taking Prodeinextra. It is not recommended that you drink alcohol while taking Prodeinextra.

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

Approximately 8% of people cannot metabolise codeine properly and are likely to obtain less pain relief with codeine containing medicines compared with other people who are not poor metabolisers.

Do not take more than the recommended dose of this medicine, even if you feel it is not working. Talk to your pharmacist or doctor.

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

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- stomach problems such as nausea, vomiting, stomach pain and/or constipation
- drowsiness
- dizziness
- skin rashes
- sweating

If you are taking Prodeinextra regularly, you may also need to take laxatives to prevent constipation.

These are mild side effects of this medicine and usually short-lived.

Tell your doctor or pharmacist immediately if you notice any of the following:

- shortness of breath
- mouth ulcers, fever and sore throat
- bleeding, bruising more easily
- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face
- painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)

These may be serious side effects of Prodeinextra. You may need urgent medical attention. Serious side effects are uncommon.

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 Prodeinextra. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

Other side effects not listed above may occur in some consumers.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

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

If you take the caplets out of the box or the blister pack they may not keep well.

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

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp 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 Prodeinextra, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Prodeinextra is a white, scored, capsule shaped tablet (caplet), marked 'PRO 15.'

Prodeinextra is available in boxes of 24 and 40 caplets.

Ingredients

Active Ingredient (s):

- Paracetamol 500 mg
- Codeine phosphate hemihydrate 15 mg

Inactive Ingredients:

- maize starch
- purified talc
- pregelatinised maize starch
- povidone
- stearic acid
- potassium sorbate
- magnesium stearate
- microcrystalline cellulose

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

Manufacturer/Sponsor

Prodeinextra is supplied in Australia by:

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

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