

Trust Analgesic Calmative

Paracetamol 500mg, codeine phosphate 10mg and doxylamine succinate 5.1mg

Consumer Medicine Information

WARNINGS AND PRECAUTIONS

Limitations of use

Because of the risks associated with the use of opioids, TRUST ANALGESIC CALMATIVE should only be used in patients for whom other treatment options, including non-opioid analgesics, are ineffective, not tolerated or otherwise inadequate to provide appropriate management of pain

During treatment with TRUST ANALGESIC CALMATIVE, tell your doctor straight away if:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Other medicines and paracetamol

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)

Hazardous and harmful use

TRUST ANALGESIC CALMATIVE poses risks of hazardous and harmful use which can lead to overdose and death. Assess the patient's risk of hazardous and harmful use before prescribing and monitor the patient regularly during treatment

Life threatening respiratory depression

Serious, life-threatening or fatal respiratory depression may occur with the use of TRUST ANALGESIC CALMATIVE. Be aware of situations which increase the risk of respiratory depression, modify dosing in patients at risk and monitor patients closely, especially on initiation or following a dose increase

Concomitant use of benzodiazepines and other central nervous system (CNS) depressants, including alcohol

Concomitant use of opioids with benzodiazepines, gabapentinoids, antihistamines, tricyclic antidepressants, antipsychotics, cannabis or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Limit dosages and durations to the minimum required; and monitor patients for signs and symptoms of respiratory depression and sedation. Caution patients not to drink alcohol while taking TRUST ANALGESIC CALMATIVE.

Please read this information before you start taking this medicine.

What is in this CMI

This leaflet answers some common questions about Trust Analgesic Calmative.

It does not contain all the available information. It does not take the place of talking to your doctor. All medicines have risks and benefits. Your doctor has weighed the risks of taking this medicine against the

benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor.

Keep this leaflet with this medicine.

You may need to read it again.

What is Trust Analgesic Calmative used for

The name of your medicine is Trust Analgesic Calmative.

It contains the active ingredients paracetamol, codeine phosphate

hemihydrate and doxylamine succinate.

Paracetamol, an analgesic with antipyretic action also reduces fever.

Doxylamine succinate is an antihistamine with pronounced sedative effects.

Codeine phosphate hemihydrate is an analgesic, and in combination with paracetamol and doxylamine produces greater analgesia than any of these drugs alone and avoids the side effects associated with large doses of these components.

Trust Analgesic Calmative is used to provide temporary relief of acute

moderate pain and fever associated with

- neck and back pain,
- headache
- tension headache,
- toothache,
- backache,
- migraine headache,
- muscle pain,
- nerve pain,
- arthritis,
- rheumatics,
- osteoarthritis
- period pain,
- symptoms of
 - cold,
 - sore throat,
 - flu
- trauma
- surgery
- dental procedures
- and other pain

where a combined calmative and analgesic action is required.

It also reduces fever.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you take Trust Analgesic Calmative

When you must not take it

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

- any medicine containing paracetamol, codeine, doxylamine or other antihistamines or
- any of the inactive ingredients listed at the end of this leaflet.

Signs of an allergic reaction may include:

- rash,
- itching of the skin,
- shortness of breath and

- swelling of the tongue or face.

Do not take this medicine if you have or have had any of the following medical conditions:

- respiratory depression
- liver failure
- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer, or other stomach problems
- prostate problems
- bladder problems
- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- diarrhoea caused by antibiotics or poisoning
- If you are a Ultra rapid metaboliser of CYP2D6
- If you are aged below 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.

Do not take this medicine if you have alcohol dependence.

Do not give this medicine to a child under 12 years.

Do not take this medicine during the third trimester of pregnancy.

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

The medicine may produce withdrawal effects in the newborn baby.

Do not take this medicine if you are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression.

Do not take this medicine if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

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

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

Before you start to take it

Tell your doctor if you have allergies to:

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

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

Like most medicines of this kind, Trust Analgesic Calmative is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are pregnant.

Do not take Trust Analgesic Calmative during labour, especially if the baby is premature.

This medicine may produce withdrawal effects in the newborn baby.

Your doctor will discuss the possible risks and benefits of using this medicine during pregnancy and breastfeeding.

Do not use Trust Analgesic Calmative if you are breastfeeding or planning to breastfeed. This medicine passes into breast milk and may affect the baby.

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

- kidney or liver problems
- heart problems
- difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
- compromised respiratory function (due to emphysema, kyphoscoliosis or obesity)

- known analgesic intolerance
- you are a CYP 2D6 ultra-rapid metaboliser
- glaucoma
- 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
- have problems with the adrenal glands
- convulsions, fits or seizures
- pre-existing opioid dependence
- chronic constipation
- head injury or trauma
- a history of drug dependence, alcohol dependence
- Caution is particularly recommended for use in adolescents and young adults with a history of drug and/or alcohol abuse.
- recent surgery on the stomach or intestines
- prostate problems
- low blood pressure
- underactive thyroid

Tell your doctor if you plan to have surgery. If you have not told your doctor about any of the above, tell them before you use this medicine.

Taking other medicines

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

Do not take with other medicines containing paracetamol, unless your doctor says you can.

Some medicines may interact with this medicine.

These include:

- antihistamines
- sleeping tablets or sedatives

- tranquillisers (medicines used for anxiety or nerves)
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- medicines containing alcohol (ethanol), e.g. some cough syrups
- any medicine which thins the blood
- other opioid analgesics used to treat pain
- monoamine oxidase inhibitors, medicine used to treat depression, taken within the last 14 days
- antihypertensives (medicines used to help lower blood pressure)
- medicines to treat epilepsy
- metoclopramide or domperidone, medicines used to control nausea and vomiting
- propantheline, a medicine used to treat stomach ulcers
- chloramphenicol (antibiotic used to treat ear and eye infections)
- flucloxacillin, zidovudine or rifampicin, medicines used to treat infections
- antidepressants
- antipsychotics (medicines used to treat mental illnesses)
- chelating resin
- medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone, buprenorphine or methadone)
- CYP 2D6 inhibitors such as quindine, fluoxetine, paroxetine, bupropion, cinacalcet, methadone
- CYP 3A4 inducers such as rifampin.

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

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

How to take Trust Analgesic Calmative

Follow all directions given to you by your doctor carefully and keep to the recommended dose.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor for help.

How to take it

Swallow the tablets with a full glass of water.

When to take it

It does not matter if you take this medicine before or after food.

How long to take it

This medicine is for short term use only.

Adults and children over 12 years:

The usual dose is one to two tablets to be taken every four to six hours, as needed for pain relief, up to four times daily. Do not exceed 8 tablets in 24 hours period. Keep to the recommended dose.

Adults (over 18 years): Do not take this medicine for longer than a few days at a time unless advised by a doctor.

Adolescents (12-17 years): Do not take this medicine for longer than 48 hours at a time unless advised by a doctor.

If pain persists for more than three days, please see your doctor.

If you forget to take it

There is no need to take extra doses if the pain has gone away.

If the pain is still present, take your next dose if required.

Do not double a dose to make up for the dose you have missed.

If you are not sure what to do, ask your doctor.

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 the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning because of the risk of delayed, serious liver damage.

You may need urgent medical attention. Large amounts of paracetamol can cause liver damage.

If children take too many Trust Analgesic Calmative they can suffer from nightmares, hallucinations, fitting or have difficulty sleeping.

While you are taking Trust Analgesic Calmative

Things you must do

Tell all doctors and dentists who are treating you that you are taking this medicine.

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

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

Tell your doctor if:

- you develop a skin rash or hives while taking **this medicine**
- you become pregnant while taking **this medicine**

Things you must NOT do

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

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

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

Things to be careful of

This medicine may cause drowsiness or lightheadedness in some people especially after the first dose.

Do not drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

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

Be careful if you are over 65 and 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.

Drinking alcohol increases the likelihood of becoming drowsy while taking this medicine.

Drinking alcohol and taking paracetamol at the same time can cause liver damage. It is not recommended that you drink alcohol while taking this medicine.

Trust Analgesic Calmative may be habit forming if taken at high doses for extended periods of time.

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

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine.

This medicine helps most people with pain, but may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor any questions you may have.

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

- drowsiness
- dizziness
- nausea
- vomiting
- stomach pain
- constipation
- skin rashes
- sweating
- diarrhoea
- dry mouth
- indigestion
- ringing in the ear
- headache
- loss of appetite, weight loss
- depression

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
- 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)
- difficulty breathing
- flushing of the face
- unusual or extreme mood swings
- feeling confused
- dizziness, light-headedness
- fast heartbeat

Frequency "Not known" (frequency cannot be estimated from the available data): "A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)"

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

- 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 Trust Analgesic Calmative. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Trust Analgesic Calmative

Storage

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

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

Keep your medicine in a cool, dry place where it stays below 30°C.

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

Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep this medicine 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

Return any unused medicines to your pharmacist.

Product Description

What it looks like

Tablets are white capsule shaped, biconvex, bevel edged, uncoated tablets with break line on one side and plain on other side.

It is available in packs of 10 tablets, 12 tablets, 20 tablets, 24 tablets, 30 tablets, 36 tablets and 40 tablets.

Active ingredients:

Each tablet contains:

Paracetamol 500mg

Codeine phosphate hemihydrate 10mg

Doxylamine Succinate 5.1mg

Other ingredients:

Lactose monohydrate, Starch-Maize, Povidone, Ethanol, Crospovidone, Cellulose-microcrystalline, Stearic Acid, Magnesium Stearate.

Name and Address of the Sponsor

Trust Analgesic Calmative tablets are supplied in Australia by:

Pharmacor Pty. Ltd.

Suite 803, Tower A, The Zenith,
821 Pacific Highway,
Chatswood NSW 2067

Australia

Web: www.pharmacor.com.au

Phone: 1300 138 805

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