Comfarol Forte®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I taking Comfarol Forte?

Comfarol Forte contains the active ingredients paracetamol and codeine phosphate hemihydrate. Comfarol Forte is used to relieve severe pain. For more information, see Section 1. Why am I using Comfarol Forte? in the full CMI.

2. What should I know before I take Comfarol Forte?

Do not use if you have ever had an allergic reaction to Comfarol Forte or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

You may develop addiction, dependence and tolerance.

For more information, see Section 2. What should I know before I use Comfarol Forte? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Comfarol Forte and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Comfarol Forte?

The standard dose for adults is 1 or 2 tablets for severe pain, taken every 4 to 6 hours if necessary. More instructions can be found in Section 4. How do I use Comfarol Forte? in the full CMI.

5. What should I know while taking Comfarol Forte?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Comfarol Forte.

	• Talk to your doctor about pain control if the medicine is not helping. • Tell your doctor if you become pregnant while taking Comfarol Forte.
Things you should not do	• Do not take more than the recommended dose unless your doctor tells you to. • Do not take more than 8 tablets a day. • Do not give Comfarol Forte to children under 12. • Do not take high doses of the medicine for long periods of time unless your doctor tells you to.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how Comfarol Forte affects you. Comfarol Forte may cause dizziness, drowsiness or light-headedness in some people, especially after the first dose.

Drinking alcohol	• Do not drink alcohol while taking Comfarol Forte.
Looking after your medicine	• Store below 25°C. • Store in a cool, dry place away from young children.

For more information, see Section 5. What should I know while using Comfarol Forte? in the full CMI.

6. Are there any side effects?

- Tell your doctor or pharmacist immediately if you notice any of the following side effects 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. They may be the signs of an allergic reaction.
- Tell your doctor or pharmacist if you notice any of the following and they worry you: nausea or vomiting; constipation; drowsiness or dizziness. These are more common side effects of your medicine. They are usually mild.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING:

Limitations of use

Comfarol Forte should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Comfarol Forte poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Comfarol Forte can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Comfarol Forte and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate

Use of other medicines while using Comfarol Forte

Using Comfarol Forte with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentanoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs

and symptoms of breathing difficulties and sedation.
You must not drink alcohol while using Comfarol Forte.

Comfarol Forte®

Active ingredient(s): *paracetamol and codeine phosphate hemihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Comfarol Forte. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Comfarol Forte.**

Where to find information in this leaflet:

1. Why am I using Comfarol Forte?
2. What should I know before I use Comfarol Forte?
3. What if I am taking other medicines?
4. How do I take Comfarol Forte?
5. What should I know while taking Comfarol Forte?
6. Are there any side effects?
7. Product details

1. Why am I using Comfarol Forte?

Comfarol Forte contains the active ingredients paracetamol and codeine phosphate hemihydrate.

Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Your doctor may have prescribed this medicine for another use.

Comfarol Forte is used to relieve severe pain for which other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain.

2. What should I know before I use Comfarol Forte?

Warnings

Do not use Comfarol Forte if:

- you are allergic to paracetamol or codeine phosphate hemihydrate, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you have acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- you have Glucose-6-phosphatedehydrogenase deficiency (an enzyme deficiency)
- you are a CYP 2D6 ultra-rapid metaboliser (a fast metaboliser of codeine by the CYP 2D6 enzyme)
- you have diarrhoea caused by antibiotics or poisoning
- you have liver failure.

Do not take Comfarol Forte if you have a history of drug dependence, including alcohol dependence.

Do not take Comfarol Forte if you have experienced systemic allergy (generalised rash or shortness of breath) to morphine or oxycodone.

Do not take Comfarol Forte if you have a history of intolerance to paracetamol and/or codeine.

Do not take Comfarol Forte if you are under 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.

Do not take Comfarol Forte during the third trimester of pregnancy.

Do not take Comfarol Forte during labour especially if the baby is premature.

Do not use Comfarol Forte if you are breastfeeding or planning to breastfeed.

Do not take this medicine 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 take this medicine 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.

Comfarol Forte is not recommended for children under 12 years.

Check with your doctor if you have or have had any of the following medical conditions:

- lung, heart, liver or kidney problems
- problems with your pancreas
- low blood pressure
- difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- sleep problems such as sleep apnoea
  Comfarol Forte can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.
- a history of drug dependence, including alcohol dependence
- you drink large quantities of alcohol
- mild-to-moderate hepatocellular insufficiency
- severe renal insufficiency and sepsis
- chronic alcohol use including recent cessation of alcohol intake
- malnutrition and other sources of low glutathione reserves
- Gilbert's syndrome
- gall bladder problems or your gall bladder has been removed
- multiple sclerosis
- recent stomach, intestine or urinary tract surgery

- irritable bowel syndrome or other bowel problems
- prostate problems
- under active thyroid gland or problems with your adrenal glands
- fits or seizures
- head injury
- brain tumours.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take Comfarol Forte during the third trimester of pregnancy.

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

This medicine can cause breathing problems and may produce withdrawal effects in the newborn baby.

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

The medicine passes into breast milk and may affect the baby.

Addiction

You can become addicted to Comfarol Forte even if you take it exactly as prescribed. Comfarol Forte may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking Comfarol Forte. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Comfarol Forte suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to Comfarol Forte may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

3. What if I am taking other medicines?

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

Some medicines may interfere with Comfarol Forte and affect how it works.

These include:

- any medicine causing sleepiness or drowsiness

- tranquillisers (medicines for anxiety and nerves)
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- gabapentin and pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).
- medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone, buprenorphine or methadone)
- medicines containing alcohol (ethanol), e.g. some cough syrups
- cough suppressants or antitussives
- antihistamines (medicines used to treat allergies)
- medicines used to treat depression
- medicines used to treat mental illness
- monoamine oxidase inhibitors (medicines used to treat depression) taken within the last 10 days
- salicylates or non-steroidal anti-inflammatory drugs (NSAIDS), such as aspirin or ibuprofen
- 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
- propantheline, a drug used to treat stomach ulcers
- cholestyramine (medicine used to treat bile problems and/or high cholesterol
- chelating resin

- chloramphenicol (antibiotic used to treat ear and eye infections)
- flucloxacillin, zidovudine or rifampicin (medicines used to treat infections)
- medicines used to control electrolytes levels in kidney disease

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Comfarol Forte.

4. How do I take Comfarol Forte?

How much to take

- The recommended dose of Comfarol Forte is:
  Adults: 1 or 2 tablets for severe pain. This dosage may be repeated in 4-6 hours if necessary.
- Follow the instructions provided.
- Do not take more than 8 tablets in 24 hours.
- Do not take more than the recommended dose.

Taking more than the recommended dose may cause liver damage.

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.

Talk to your doctor about pain control if the medicine is not helping.

Depending on your body's individual ability to break down codeine, you may be getting reduced benefit or experience signs of overdose even when you take Comfarol Forte as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

How to take Comfarol Forte

- Swallow the tablets with water.

How long to take it for

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

If you forget to take Comfarol Forte

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 you missed.

This may increase the chance of you getting an unwanted side effect.

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

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

If you take too much Comfarol Forte

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Comfarol Forte that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits
- Mental impairment

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

If you think that you have used too much Comfarol Forte, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while taking Comfarol Forte?

Things you should do

Take Comfarol Forte exactly as your doctor has prescribed.

Tell your doctor if you become pregnant while taking Comfarol Forte.

Remind any doctor, dentist or pharmacist you visit that you are using Comfarol Forte.

If your pain gets worse after you take this medicine do not take more without first talking to your doctor.

Talk to your doctor, if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking this medicine.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated

with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Things you should not do

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

Adults should not take more than 8 tablets 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 can cause liver damage.

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

- **Do not give this medicine to anyone else.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Comfarol Forte affects you.

Comfarol Forte may cause dizziness, light-headedness, drowsiness and problems with vision in some people, especially after the first dose.

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

Drinking alcohol

Do not drink alcohol while taking Comfarol Forte.

Drinking alcohol increases the likelihood of becoming drowsy.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- Nervousness, restlessness, agitations, trouble sleeping or anxiety
- Body aches, weakness or stomach cramps
- Loss of appetite, nausea, vomiting or diarrhoea
- Increased heart rate, breathing rate or pupil size
- Watery eyes, runny nose, chills or yawning
- Increased sweating

Comfarol Forte given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn. Withdrawal symptoms in the newborn can also occur with long-term use during pregnancy.

Looking after your medicine

- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: • nausea or vomiting • indigestion • constipation • stomach pain • severe abdominal pain • have difficulty swallowing, regurgitation, chest pain	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
that is not related to your heart, especially if you have been using this medicine for a long time **Head and neurology related:** • dry mouth • drowsiness or sleepiness • headache • ringing in the ears **Skin related:** • sweating **Reproductive related:** • low libido • impotence or Erectile dysfunction • loss of menstrual cycle • infertility **Sleep related:** • sleep apnoea **General:** • weakness • anorexia • fatigue	

Less serious side effects	What to do
• low blood pressure	

Serious side effects

Serious side effects	What to do
Allergy related: • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • skin rash, itching or hives on the skin • flushing of the face **Heart related:** • fast heartbeat **Skin related:** • severe blisters and bleeding in the lips, eyes, mouth, nose and genitals • painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• yellowing of the skin and eyes (jaundice) **Infection related:** • mouth ulcers, fever and sore throat **Bleeding related:** • bleeding, bruising more easily **Head and neurology related:** • dizziness, light-headedness • unusual or extreme mood swings • confusion • seizures **Liver related:** • hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine) **Urinary related:** • problems passing urine • dark coloured urine	

Serious side effects	What to do
Eyes related: • blurred vision **Metabolism related:** • symptoms of rapid breathing, rapid heart rate, changes in consciousness, drowsiness, nausea or vomiting caused by pyroglutamic acidosis (an accumulation of pyroglutamic acid due to low levels of a protein called glutathione)	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Comfarol Forte contains

Active ingredient (main ingredient)	Paracetamol and codeine phosphate hemihydrate.
Other ingredients (inactive ingredients)	Maize starch, povidone, potassium sorbate, microcrystalline cellulose, stearic acid, magnesium stearate, purified talc, pregelatinized maize starch, and croscarmellose sodium.
Potential allergens	Contains potassium sorbate. Comfarol Forte does not contain gluten, lactose, sucrose, tartrazine or any azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Comfarol Forte looks like

Comfarol Forte is available as white to off-white capsule-shaped tablets, marked “P” and “F” either side of a score line on one side and plain on the other (AUST R 131137).

It comes in boxes of 20 tablets.

Who distributes Comfarol Forte

Distributor:
Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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