

Combolieve Night Pain Relief

Active ingredient(s): *Paracetamol, Diphenhydramine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Combolieve Night Pain Relief. **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 Combolieve Night Pain Relief.**

Where to find information in this leaflet:

- [1. Why am I using Combolieve Night Pain Relief?](#)
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1. Why am I using Combolieve Night Pain Relief?

Combolieve Night Pain Relief contains the active ingredients, paracetamol and diphenhydramine hydrochloride. Combolieve Night Pain Relief is used to give temporary relief of pain when associated with sleeping difficulty.

Combolieve Night Pain Relief is useful for headache, migraine, backache, arthritis, rheumatic and muscle pain, neuralgia, toothache or period pain.

Paracetamol is an analgesic. It works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Diphenhydramine hydrochloride is an antihistamine that helps you sleep.

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given you this for another reason.

This medicine is only available from your pharmacist.

2. What should I know before I use Combolieve Night Pain Relief?

Warnings

Do not take more than the recommended dose as it may cause serious harm to your liver.

Do not give Combolieve Night Pain Relief to children under 12 years of age.

Do not use Combolieve Night Pain Relief if you have an allergy to:

- Any medicine containing paracetamol or diphenhydramine hydrochloride.
- Any of the 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 use this medicine if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Always read and follow the label.

Do not take Combolieve Night Pain Relief if you have or have had any of the following medical conditions:

- Glaucoma (high pressure in the eyes)
- Stomach or duodenal ulcer or other stomach problems
- Prostate problems
- Bladder problems

Do not take Combolieve Night Pain Relief if you are taking monoamine oxidase inhibitors (MAOIs), a type of medicine used to treat depression.

Do not take Combolieve Night Pain Relief if you have taken other medicine containing paracetamol in the last 4 hours.

Do not take this medicine after the expiry date (EXP) printed on the pack. If you take it after the expiry has passed, it may not work as well.

Do not take Combolieve Night Pain Relief 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 start taking this medicine, talk to your pharmacist or doctor.

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

- Liver or kidney disease
- Underweight or malnourished
- You have a severe infection, are severely malnourished or are a chronic heavy alcohol user as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- deep, rapid, difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite

Contact a doctor immediately if you get a combination of these symptoms:

- Epilepsy
- Myasthenia gravis (a muscle dysfunction)
- Prostate gland enlargement or difficulty urinating
- Glaucoma
- Asthma
- Bronchitis or chronic lung disease

Tell your pharmacist or doctor if you take sedatives.

Consider taking the lowest effective dose for the shortest period of time.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking Combolieve Night Pain Relief.

Please see your doctor if your symptoms do not improve.

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

Do not take Combolieve Night Pain Relief 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.

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

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

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 Combolieve Night Pain Relief and affect how it works. These include:

- Warfarin, a medicine used to prevent blood clots
- Metoclopramide, a medicine used to control nausea and vomiting
- Medicines used to treat epilepsy or fits
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Alcohol
- Medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- Medicines used to help you sleep or relax (sedatives and hypnotics)
- Opioid analgesics, medicines used to treat pain
- Other antihistamine medicines including cough and cold medicines and those you use on your skin
- Medicines which make you drowsy or give you a dry mouth (sometimes called anticholinergics). Taking

such medicines while you are taking this medicine may increase the chances of side effects

- Probenecid, a medicine used to treat gout or sometimes given with an antibiotic
- Cholestyramine, a medicine used to treat high cholesterol levels in the blood

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Combolieve Night Pain Relief.

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

This product contains paracetamol. If you are taking any other medicine containing paracetamol, you must make sure you do not take more than 4000 mg paracetamol (including this product) in any 24-hour period. If in doubt, consult your doctor or pharmacist.

4. How do I use Combolieve Night Pain Relief?

Do not exceed the stated dose.

Use the smallest dose that you need to treat your symptoms and use the medicine for the shortest period of time necessary.

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

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

How much to take

- Take 1-2 tablets.
- Do not take more than the stated dose.
- If you are over 65 years of age, talk to your pharmacist or doctor about how much to use. Elderly patients are more likely to have side effects from taking this medicine. Carers should be aware that this medicine should not be given to elderly patients with confusion.

When to take Combolieve Night Pain Relief

Take the tablets at bed-time.

How to take Combolieve Night Pain Relief

Take with water or other fluid.

How long to take Combolieve Night Pain Relief

- Adults should not take this medicine for more than a few days at a time unless your doctor tells you to take it for longer.

- Children aged 12 to 17 years should not take this medicine for more than 48 hours unless on the advice of a doctor.
- Children under 12 years of age should not be given Combolieve Night Pain Relief unless a doctor has told you to.

If you forget to take Combolieve Night Pain Relief at bedtime

If you forget to take Combolieve Night Pain Relief at bedtime, you may take it through the night. Do not take a second dose.

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 use too much Combolieve Night Pain Relief

If you think that you (or anyone else) have used too much Combolieve Night Pain Relief, you may need urgent medical attention.

You should immediately:

- phone the National Poisons Centre (0800 POISON (0800 764766)), 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.

5. What should I know while using Combolieve Night Pain Relief?

Things you should do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Use Combolieve Night Pain Relief exactly as your pharmacist or doctor has told you to.

Remind any doctor, dentist or pharmacist you visit that you are using Combolieve Night Pain Relief.

Things you should not do

Children 12 to 17 years:

Do not give paracetamol for more than 48 hours unless a doctor has told you to.

Adults:

Do not take for more than a few days at a time unless your doctor tells you to. This medicine should not be taken for more than 3 consecutive days at a time except on medical advice.

Do not use this medicine to treat any other complaint unless your pharmacist or doctor tells you to.

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

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

Do not drink alcohol while taking Combolieve Night Pain Relief. The sedation effect of alcohol may be increased.

Driving or using machines

This product may cause dizziness, drowsiness, difficulty concentrating or blurred vision. If you experience any of these symptoms, do not drive or operate machinery. Be careful before you drive or use any machines or tools until you know how Combolieve Night Pain Relief affects you.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

Looking after your medicine

Keep your medicine in the original pack until it is time to take it.

If you keep the caplets out of their packaging, they will not keep well.

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

Store below 25 °C. Protect from light.

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?

This medicine helps most people with pain when associated with sleeping difficulty, but it may have unwanted side effects in a few people. 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.

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Combolieve Night Pain Relief.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

Less serious/common side effects

Less serious side effects	What to do
<p>Digestion related:</p> <ul style="list-style-type: none"> • Nausea or dyspepsia • Constipation <p>Alertness/ behaviour related:</p> <ul style="list-style-type: none"> • Nervousness and irritability • Drowsiness or sleepiness • Hallucinations • Dizziness • Difficulty concentration • Unsteadiness • Anxiety <p>General body related:</p> <ul style="list-style-type: none"> • Twitching or jerking muscles • Fast heart beat • Dry mouth, nose and throat • Tiredness 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p> <p>This list includes the more common side effects of your medicine. They are usually mild.</p>

Serious/rare side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Difficult or painful urination • Seizures (fits) 	<p>Tell your doctor as soon as possible if you notice any of these side effects.</p> <p>These side effects may require medical attention. These side effects are rare.</p>

Very serious/very rare side effects

Very serious side effects	What to do
<p>Breathing related:</p> <ul style="list-style-type: none"> • Shortness of breath • Wheezing or difficulty breathing • Previous breathing problems with aspirin or non-steroidal anti-inflammatories, and you experience a similar reaction with this product. <p>Allergy related:</p> <ul style="list-style-type: none"> • Swelling of the face, lips, tongue, throat or other parts of the body • Rash, peeling, itching or hives on 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>You may need</p>

<p>the skin or mouth ulcers</p> <p>Bleeding related:</p> <p>Unexplained bruising or bleeding</p>	<p>urgent medical attention or hospitalization. These side effects are very rare.</p>
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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 at <https://nzphvc.otago.ac.nz/reporting/>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Combolieve Night Pain Relief contains

Active ingredient (main ingredient)	Paracetamol, Diphenhydramine hydrochloride
Other ingredients (inactive ingredients)	Maize starch, microcrystalline cellulose, povidone, talc, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, colouring material (Wincoat WT-AQ-01736 Blue)

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

What Combolieve Night Pain Relief looks like

Combolieve Night Pain Relief is a light blue coloured, film coated caplet plain on both side.

Who distributes Combolieve Night Pain Relief

AFT Pharmaceuticals Ltd.

Auckland

Email: customer.service@aftpharm.com

This leaflet was prepared in June 2023.

Helpful advice on managing night pain

Managing pain at night can often be complicated by affecting your ability to get to sleep. When your sleep pattern is affected, pain at night can seem stronger than normal. For this reason, we have included some helpful advice on managing pain and getting to sleep.

Pain management

1. Application of gentle heat to the painful area. This increases the blood flow to the affected area which works to relieve the sensation of pain and aids the healing process. Hot water bottles, hot showers and heat bags can be useful.
2. Pain as a result of inflammation can also be treated by the application of cold to the affected area. Cold packs can often be more effective in the early stages of an injury than heat. See your doctor or pharmacist for advice on the best way to treat your pain.
3. For some people, massage can also help to increase blood flow to an area and contribute to increasing flexibility of joints and muscles. Massage oils may help.

Sleep routines

1. Avoid alcohol, caffeine products and nicotine before bedtime.
2. Avoid large meals before bedtime.
3. Develop a regular bed time routine. This helps signal to your mind that it is time to go to sleep.
4. Practice relaxation techniques. There are many useful books and courses available to instruct you on simple, effective techniques.
5. Ensure your bed is comfortable. Sometimes changing a mattress or pillows can increase your comfort and ability to get to sleep, particularly if you suffer from muscle or joint pain.

NOTE

Suffering from night time pain can be a lonely experience if it also stops you sleeping. Just remember, many people suffer from night time pain, you are not alone. Try some of the above techniques which could help you manage your night time pain.