

COVONIA NIGHT TIME FORMULA

Covonia Night Time Formula is for night time relief of the symptoms of dry coughs and congestion from colds. **SHAKE THE BOTTLE.** Take the solution by mouth.

Adults, the elderly and children over 12 years:

Take 3 x 5ml spoonfuls at bedtime. Repeat after 6 hours if required.

Do not give to children under 12 years old.

Do not take more medicine than the label tells you to.

Do not take with any other cough and cold medicine.

Avoid alcoholic drink. This medicine can lead to dependence. Therefore the treatment should be of short duration.

Peel where shown for further precautions.

If symptoms persist consult your doctor.

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

Keep out of the sight and reach of children.

Active ingredients per 5ml:

dextromethorphan hydrobromide 6.65mg,

diphenhydramine hydrochloride 10mg.

Also contains: ethanol, glycerol (E422), sorbitol (E420), sodium benzoate, maltitol liquid, propylene glycol.

Alcohol 7.3 vol%.

See reverse for full list.



5 011309 017212

P

Do not store above 25°C.
Protect from light.

MA holder and manufacturer

Thomson and Ross Ltd., Huddersfield, HD7 5QH, UK
PL 00240/0042 92768591909

MA065/00503

COVONIA is a registered Trade Mark.

150ml e

Peel here



Peel here

Covonia Night Time Formula contains dextromethorphan which reduces the desire to cough and diphenhydramine (an antihistamine) which dries up your runny nose and relieves congestion. **P1**

1. Before you use this medicine

Do not use the medicine if you have....

- An allergy to any of the ingredients listed in section 3
- Taken MAOIs (monoamine oxidase inhibitors) for depression within the last two weeks or are taking SSRIs for depression
- Shortage of breath
- Liver problems
- Porphyria
- Asthma or a cough which produces phlegm.

Talk to your doctor if you have....

- Glaucoma
- Difficulty passing urine
- Prostate trouble
- A blocked intestine
- Epilepsy
- Heart problems
- A cough which lasts a long time
- Or you are prone to allergies

Talk to your doctor or pharmacist if you are taking....

- medicines such as certain antidepressants or antipsychotics - Covonia Night Time may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).
- Alcohol
- Cimetidine for stomach ulcers
- Medicines for Parkinson's disease (e.g. rasagiline, moclobenide, venlafaxine)
- Medicines for anxiety or to help you sleep (e.g. diazepam)
- Memantine for Alzheimer's disease
- Medicines for irregular heartbeat (e.g. amiodarone, propafenone, quinidine, beta blockers)
- Antihistamines
- Betahistine for vertigo or histamine for some types of cancer
- Strong pain killers (e.g. codeine)
- Medicine for a runny nose or to control the bladder, or atropine used to treat eye problems.

Turn Over ↗
92768591909

Driving and using machines....

P2

This medicine causes drowsiness and you should not drive or operate machinery until the effects have worn off.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

• Do not drive while taking this medicine until you know how it affects you.

• It is an offence to drive if this medicine affects your ability to drive.

• However, you would not be committing an offence if:

- The medicine has been prescribed to treat a medical or dental problem and
- You have taken it according to the instructions given by the prescriber or in the information provided with this medicine and
- It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Pregnant or breastfeeding....

Ask your doctor or pharmacist for advice before using if you are pregnant, might be pregnant or are breastfeeding. This medicine should not be used unless the doctor has told you to do so.

Important ingredient information

• Contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'. • Contains 18mg sodium benzoate per dose. • Contains maltitol liquid and 3.675g sorbitol in each 15ml dose. If you have been told by your doctor that you or your child have an intolerance to some sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, contact your doctor before you or your child take or receive this medicine. • It contains 7.3 vol% of ethanol (alcohol), i.e. up to 870mg per dose, equivalent to 22ml of beer or 9ml of wine per dose. Harmful for those suffering from alcoholism. To be taken into account in children and high risk groups such as patients with liver disease or epilepsy.

2. Possible side effects

P3

Like all medicines, Covonia Night Time Formula can have side effects, although these don't affect everyone.

Important side effects. If you get any of these side effects stop use immediately and see a doctor as soon as possible:

• Swelling of the lips, mouth, eyes or tongue • Difficulty breathing • Fits.

Other possible side effects: Drowsiness and lack of concentration • Dizziness • Feeling excited or confused • Feeling depressed • Sleeping problems • Headache • Muscle twitching • Trembling • Blurred vision • Stomach upsets (e.g. feeling sick, being sick, diarrhoea) • Rash • Skin blisters • Pins and needles • Dry mouth • Thick saliva • Low blood pressure, palpitations or irregular heartbeat • Difficulty passing urine • Blood or liver problems • Eye problems (glaucoma) • Sweating • Muscle pain • Ringing in the ears • Hair loss.

If you notice these or any other side effects not listed, stop use and tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the following national reporting systems:

United Kingdom

Yellow Card Scheme – www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

Malta

www.medicinesauthority.gov.mt/adportal

By reporting side effects you can help provide more information on the safety of this medicine.

3. Further information

■ If you take more Covonia Night Time than you should, you may experience the following symptoms: nausea and vomiting, involuntary muscle contractions, agitation, confusion, somnolence, disturbances in consciousness, involuntary and rapid eye movements, cardiac disorders (rapid heart beating), coordination disorders, psychosis with visual hallucinations, and hyperexcitability.

P4

Other symptoms in case of massive overdose may be: coma, severe breathing problems, and convulsions.

Contact your doctor or hospital straight away if you experience any of the above symptoms.

Take the pack with you to show which medicine you have swallowed.

• Do not use after the expiry date. The expiry date refers to the last day of that month. • Return any unused medicine to the pharmacy for disposal.

The active ingredients per 5ml are: dextromethorphan hydrobromide 6.65mg, diphenhydramine hydrochloride 10mg.

The other ingredients are: ethanol, glycerol (E422), sorbitol (E420), sodium benzoate (E211), maltitol liquid (containing maltitol (E965) and sorbitol (E420)), hydroxyethylcellulose, povidone (E1202), saccharin sodium, capsicum tincture (capsicum oleoresin), menthol, peppermint oil, anise oil, citric acid (E330), macrogol cetostearyl ether, caramel (E150), blackcurrant flavour (containing propylene glycol (E1520)) and purified water.

What the medicine looks like

Covonia Night Time Formula is a brown syrupy liquid.

It is supplied in 150ml bottles.

This label was last revised in December 2019