

Package leaflet: Information for the patient
FEDRIL NIGHT COLD AND FLU ORAL SOLUTION
Paracetamol 1000 mg/20 ml,
Promethazine Hydrochloride 20 mg/20 ml,
Dextromethorphan Hydrobromide 15 mg/20 ml

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription, however, you still need to take Fedril Night Cold and Flu Oral Solution carefully to get the best results from it. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after a few days.

What is in this leaflet:

1. What Fedril Night Cold and Flu Oral Solution is and what it is used for
2. What you need to know before you take Fedril Night Cold and Flu Oral Solution
3. How to take Fedril Night Cold and Flu Oral Solution
4. Possible side effects
5. How to store Fedril Night Cold and Flu Oral Solution
6. Contents of the pack and other information

1. What Fedril Night Cold and Flu Oral Solution is and what it is used for

Fedril Night Cold and Flu Oral Solution provides night time relief from cold and flu symptoms consisting of headache, shivers, sore throat pain, runny nose, tickly cough, aches and pains. It contains paracetamol to reduce fever, promethazine to dry up a runny nose, aids restful sleep and dextromethorphan which relieves a dry irritating tickly cough.

2. What you need to know before you take Fedril Night Cold and Flu Oral Solution

Do not take Fedril Night Cold and Flu Oral Solution

- if you are allergic (hypersensitive) to paracetamol, promethazine hydrochloride, dextromethorphan hydrobromide or any of the other ingredients of Fedril Night Cold and Flu Oral Solution (*Section 6 below*).
- if you suffer from lung disease.
- if you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs).
- if you are taking selective serotonin re-uptake inhibitors (used to treat depression and anxiety such as fluoxetine, paroxetine and sertraline).
- if your child is under 12 years old.

Do not take with any other paracetamol containing products.

Do not take with any other flu, cold or decongestant product.

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

Warnings and Precautions

Tell your doctor if you:

- have kidney or liver problems.
- have a chronic or persistent cough such as occurs with asthma or produces a lot of mucus (phlegm).
- are taking any other cough and cold medicines.
- have difficulty in passing urine (urinary retention).
- have glaucoma.
- have prostate problems.
- have heart problems.
- have epilepsy.
- are elderly and suffer from confusion.
- have an intolerance to some sugars.
- if your child is susceptible to developing certain allergic reactions.
- if you have been told by your doctor that you are a slow metabolizer of CYP2D6.
- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

Check with your doctor or nurse before having Fedril Night Cold and Flu Oral Solution if:

- You have any serious heart problems.
- You have any personal or family history of heart disease.
- You have an irregular heartbeat.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Only use this medicine as described in the leaflet.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Speak to your doctor if you experience withdrawal symptoms.

If you do not get better, talk to your doctor.

During treatment with Fedril Night Cold and Flu Oral Solution tell your doctor straight away:

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 Fedril Night Cold and Flu Oral Solution

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even medicines obtained without a prescription.

In particular, tell your doctor if you are taking medicines which:

- thin the blood (e.g. warfarin).
- control nausea or vomiting (e.g. domperidone or metoclopramide).
- reduce levels of cholesterol and other fats in the blood (e.g. cholestyramine).
- have been prescribed by your doctor to improve sleep, for anxiety or depression (including monoamine oxidase inhibitors (MAOIs) and antimuscarinic drugs).
- medicines to control your heart rhythm e.g. quinide, amiodarone, flecainide or propafenone.
- antifungal medicines e.g. terbinafine.
- medicines to help with quitting smoking e.g. bupropion.
- medicines to help with certain addictions or treat pain e.g. methadone.
- medicines to help with overactive parathyroid e.g. cinacalcet.
- antipsychotic medicines e.g. haloperidol, perphenazine and thioridazine.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Talk to your doctor or pharmacist before taking Fedril Night Cold and Flu Oral Solution:

- If you are taking medicines such as certain antidepressants or antipsychotics. Fedril Night Cold and Flu Oral Solution 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).

Also tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following:

- medicines that can affect your heart rhythm.

Do not consume alcoholic drinks while you are taking Fedril Night Cold and Flu Oral Solution.

Promethazine may interfere with pregnancy tests to produce false results.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicines during pregnancy. If necessary, Fedril Night Cold and Flu Oral Solution can be used during pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible.

Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Driving and using machines

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:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - o 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. There is further information for patients who are intending to drive in the UK - go to <https://www.gov.uk/drug-driving-law>.

Important information about some of the ingredients of Fedril Night Cold and Flu Oral Solution

This medicinal product contains:

- **Ethanol:** 2916 mg of alcohol (ethanol) in each 20 ml of this medicine, which is equivalent to 18.08 v/v %. The amount in 20 ml of this medicine is equivalent to 73 ml of beer or 29 ml of wine. The alcohol in this preparation is likely to affect children. These effects may include feeling sleepy and changes in behaviour. It may also affect their ability to concentrate and take part in physical activities. The amount of alcohol in this medicine can affect your ability to drive or use machines. This is because it may affect your judgement and how fast you react. If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine. The amount of alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.
- **Liquid maltitol (hydrogenated glucose syrup):** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May have a mild laxative effect.
- **Sodium:** This medicine contains 23.52 mg of sodium (main component of cooking salt) in each 20 ml dose. This is equivalent to 1.2% of the recommended maximum daily dietary intake of sodium for an adult.

- **Propylene glycol:** 5180 mg propylene glycol in each 20 ml of this medicine, which is equivalent to 259 mg/ml or 220 mg/g. If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine. If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Propylene glycol in this medicine can have the same effects as drinking alcohol and increase the likelihood of side effects. Your doctor may carry out extra checks while you are taking this medicine.

3. How to take Fedril Night Cold and Flu Oral Solution

Always use the measuring cup supplied with the pack. **Shake the bottle before use.** Always take the product exactly as directed. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults and children aged 16 years and over:	One 20 ml dose to be taken just before going to bed.
Children aged 12 to 15 years:	A 10 ml to 15 ml dose to be taken just before going to bed.
Children under 12:	Do not give to children under 12 years of age.
Elderly:	Dose as for 'Adults' above.

Do not take anything else containing paracetamol while taking this medicine. Do not take with any other flu, cold or decongestant product. If you have taken other paracetamol containing products during the day, this night time dose is considered as part of the maximum daily dose and should not be taken if you have already taken four doses of paracetamol during the day. Only take one dose of Fedril Night Cold and Flu Oral Solution per night. Do not take for any longer than 3 days. Carers should be aware that this medicine should not be given to Elderly patients with confusion. The elderly are more likely to develop adverse effects including confusion with this medicine.

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

If you take more Fedril Night Cold and Flu Oral Solution 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. Other signs may include dizziness, restlessness, nervousness or irritability.

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.

Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

Also seek immediate medical advice if you take other paracetamol-containing medicines by mistake.

If you forget to take Fedril Night Cold and Flu Oral Solution:

If you miss a dose, take it as soon as you remember. **Do not** take a double dose to make up for the forgotten dose.

4. Possible side effects

Like all medicines, Fedril Night Cold and Flu Oral Solution can cause side effects, although not everybody gets them.

If you experience any of the following stop using the medicine and seek immediate medical help:

- Swelling of the lips, eyes, tongue, or difficulty in breathing may be signs of an **allergic reaction. Stop taking Fedril Night Cold and Flu Oral Solution immediately.**
- Fits.
- Skin rash, peeling of the skin or blistering.
- Breathing problems these are more likely if you have experienced them before when taking other painkillers (such as ibuprofen or aspirin).
- Unexplained bruising or bleeding.
- Being sick (vomiting), feeling sick (nausea), stomach ache, sudden weight loss, loss of appetite, and yellowing of the skin and eyes (jaundice).

If you experience any of the following stop using the medicine and talk to your doctor:

- Rash, itchy skin, hives.

Other effects which may occur include:

- Feeling sleepy (drowsiness).
- Upset stomach.
- Sensitivity to light.
- Headache.
- Shaking.
- Increased blood pressure.
- Sleep disturbances.
- Disorientation or dizziness.
- Mental and physical slowness.
- Inability to pass urine.
- Confusion.
- Shivering.
- Nervousness.
- Nausea, vomiting, diarrhoea.
- Dry mouth, blurred vision.
- Difficulty concentrating.
- Sweating.
- Sudden jerks of muscles.
- Irritability.

Very rare cases of serious skin reactions have been reported.

Unknown frequency: dependence and addiction (see section "How do I know if I am addicted?").

Not known frequency (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).
- Abnormal electrical activity of the heart that affects its rhythm, including life-threatening rhythm disturbance.
- A serious reaction with fever, rigid muscles, changing blood pressure and coma (neuroleptic malignant syndrome).
- Low levels of blood platelets (which can lead to bleeding and bruising).
- Restlessness.
- Hallucinations.
- Aggression.

Drug Withdrawal

When you stop taking Fedril Night Cold and Flu Oral Solution, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Fedril Night Cold and Flu Oral Solution, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than those indicated
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to 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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fedril Night Cold and Flu Oral Solution

Do not store above 25°C.

Keep out of the sight and reach of children.

Store in the original container and keep the bottle in the outer carton (in order to protect from light). Do not use after one month from first opening.

Do not use Fedril Night Cold and Flu Oral Solution after the expiry date which is stated on the label or carton. The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

Each 20 ml of Fedril Night Cold and Flu Oral Solution contains:

- The **active substances:** 1000 mg paracetamol, 20 mg promethazine hydrochloride, 15 mg dextromethorphan hydrobromide.
- The **other ingredients** are: ethanol, propylene glycol, liquid maltitol (E965), sodium citrate, ascorbic acid, acesulfame K, citric acid monohydrate, natural mint flavour, patent blue V (E131), quinoline yellow (E104), purified water.

What Fedril Night Cold and Flu Oral Solution looks like and contents of the pack:

Fedril Night Cold and Flu Oral Solution is a clear green, mint flavoured sugar-free solution, available in 200 ml clear glass bottles with child resistant caps.

A measuring cup is provided.

Marketing Authorisation Holder and Manufacturer:

Pinewood Laboratories Ltd., Ballymacbray, Clonmel, Co. Tipperary, Ireland.
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