

**PATIENT INFORMATION LEAFLET
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.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after a few days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- 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 do 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
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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 do 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.

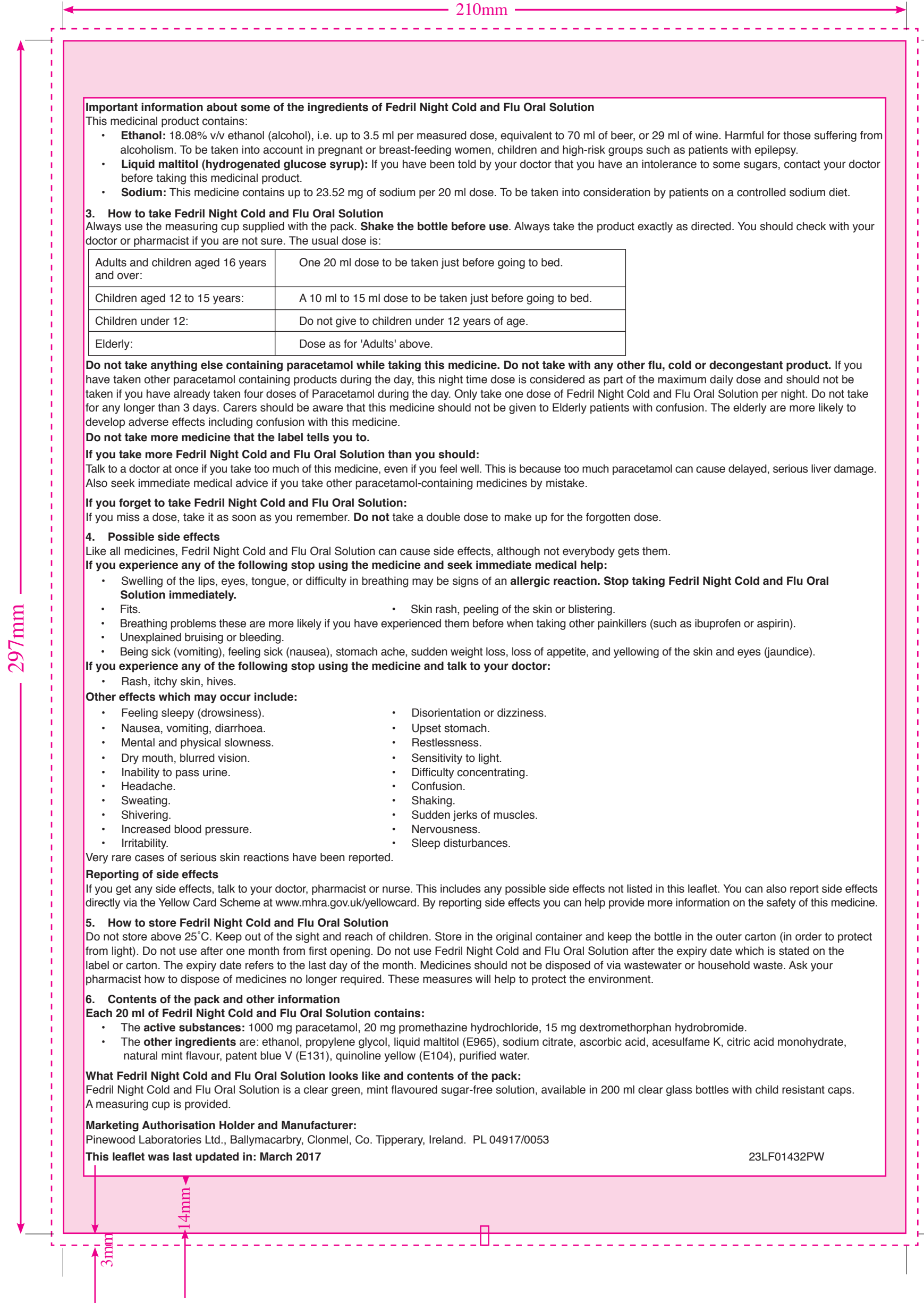
Do not take with any other paracetamol containing products. Do not take with any other flu, cold or decongestant product.
Warnings and Precautions
Tell your doctor if you:
• have kidney or liver problems
• have a chronic or persistent cough such as occurs with asthma or produces a lot of mucus (phlegm).
• are taking any other cough and cold medicines.
• have difficulty in passing urine (urinary retention).
• have prostate problems.
• have epilepsy.
• have an intolerance to some sugars.
• if you have a history of drug abuse.
• have alcohol dependence.
• have glaucoma.
• have heart problems.
• are elderly and suffer from confusion.
• 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 do not get better, talk to your doctor.
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, prephenazine and thioridazine.

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 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.
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>.

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Important information about some of the ingredients of Fedril Night Cold and Flu Oral Solution
This medicinal product contains:
• **Ethanol:** 18.08% v/v ethanol (alcohol), i.e. up to 3.5 ml per measured dose, equivalent to 70 ml of beer, or 29 ml of wine. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with epilepsy.
• **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.
• **Sodium:** This medicine contains up to 23.52 mg of sodium per 20 ml dose. To be taken into consideration by patients on a controlled sodium diet.

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 that the label tells you to.
If you take more Fedril Night Cold and Flu Oral Solution than you should:
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.
• 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).
• Rash, itchy skin, hives.
• Skin rash, peeling of the skin or blistering.

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

Very rare cases of serious skin reactions have been reported.
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. 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., Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 04917/0053
This leaflet was last updated in: March 2017

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