

Package Leaflet: Information for the user

Remedeine® and Remedeine Forte® tablets Paracetamol
and Dihydrocodeine tartrate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What *Remedeine* and *Remedeine Forte* tablets are and what they are used for

These tablets have been prescribed for you to relieve severe pain over a period of 4 to 6 hours. They contain the active ingredients dihydrocodeine and paracetamol which belong to a group of medicines called strong analgesics or 'painkillers'. The other ingredients are listed in section 6 of this leaflet.

2. Before you take *Remedeine* or *Remedeine Forte* tablets

Do not take *Remedeine* or *Remedeine Forte* tablets if you:

- are allergic (hypersensitive) to dihydrocodeine, paracetamol or any of the other ingredients of the tablets (see section 6 'Further Information');
- have breathing problems, such as breathing more slowly or weakly than expected, or obstructive airways disease;
- are having an asthma attack.

Children under 12 years of age should not take these tablets.

Take special care with *Remedeine* and *Remedeine Forte* tablets Before treatment with these tablets tell your doctor or pharmacist if you:

- have asthma or any allergies;
- have an under-active thyroid gland (hypothyroidism);
- have kidney or long-term liver problems;
- have a severe headache or feel sick due to a head injury or increased pressure in your skull (for instance due to brain disease). This is because the tablets may make these symptoms worse or hide the extent of a head injury;
- have prostate problems;
- are addicted to alcohol;
- are or have ever been addicted to drugs.

Taking other medicines

Tell your doctor or pharmacist if you are taking:

- any other medicines containing paracetamol (you should not take these tablets if you are already taking another medicine containing paracetamol);
- medicines to help you sleep (for example tranquillisers, hypnotics or sedatives);
- medicines to treat psychiatric or mental disorders;
- a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromide, phenelzine, isocarboxazid, moclobamide and linezolid), or you have taken this type of medicine in the last two weeks;
- medicines to treat depression or anxiety;
- metoclopramide or domperidone to stop you feeling or being sick;
- cholestyramine to treat high blood pressure or diarrhoea;
- medicines such as warfarin to prevent your blood clotting or to help thin your blood.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

Taking *Remedeine* or *Remedeine Forte* with alcohol

Drinking alcohol during your treatment with these tablets may make you sleepy. If you are affected you should avoid drinking alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding do not take these tablets until you have spoken to your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel sleepy when taking these tablets. If you are affected you should not drive or use machinery.

3. How to take *Remedeine* and *Remedeine Forte* tablets

Two different strengths of tablets are available. Your doctor will decide which strength of tablet will suit you best.

Always take these tablets exactly as your doctor has told you. The label on your medicine will tell you how many tablets to take and how often. Do not take for longer than directed by your doctor. You should check with your doctor or pharmacist if you are not sure.

Swallow your tablets whole with a glass of water.

The usual starting dose for adults and children over 12 years of age is one or two tablets every 4 to 6 hours. If you are elderly your doctor may suggest a lower starting dose. Your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these tablets discuss this with your doctor.

Do not take more than eight tablets in 24 hours.

Do not take these tablets if you are already taking another medicine containing paracetamol.

If you take more *Remedeine* or *Remedeine Forte* tablets than you should or if someone accidentally swallows your tablets

Call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy and sick, and have abdominal pain. They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. You should contact your doctor immediately even if

you feel well as there is a risk of serious liver damage. When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show the doctor.

If you forget to take *Remedeine* or *Remedeine Forte* tablets

If you miss a dose you should take it as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten tablet.

If you stop taking *Remedeine* or *Remedeine Forte* tablets

You should not stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, these tablets can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are rare. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

As with all strong painkillers, there is a risk you may become addicted or reliant on these tablets.

Taking a painkiller for headaches too often or for too long can make your headaches worse.

Common side effects (Probably affecting more than 1 in 100 people taking these tablets)

Most people will have constipation when they take these tablets. Your doctor can prescribe a laxative to overcome this problem.

You may feel sick or vomit (be sick) when you take your tablets, this should normally wear off after a few days however your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.

You may find that you feel more sleepy than normal when you start taking your tablets or when your dose is increased. This should wear off after a few days.

The following side effects have also been commonly reported in patients treated with these tablets:

- Headache. □ Rash or itchy skin.

Uncommon side effects (Probably affecting fewer than 1 in 100 people taking these tablets)

- An unpleasant or uncomfortable mood.
- Hallucinations.
- A feeling of dizziness or 'spinning'.
- Difficulty in passing urine.
- A need to take increasingly higher doses to obtain the same level of pain relief (tolerance).
- Withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking the tablets.

Rare side effects (Probably affecting fewer than 1 in 1,000 people taking these tablets)

- Inflammation of the pancreas (which causes severe pain in the abdomen and back).
- Abnormal cells in the blood (blood dyscrasias).

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Remedeine and Remedeine Forte tablets

Keep out of the reach and sight of children.

Do not use any tablets after the expiry date which is stated on the carton. EXP 08 2010 means that you should not take the tablets after the last day of that month i.e. August 2010.

Do not store your tablets above 30°C. Keep the bottle tightly closed to protect the tablets from moisture.

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. Further information

What *Remedeine* and *Remedeine Forte* tablets contain

The active ingredients are paracetamol and dihydrocodeine tartrate. Each *Remedeine* tablet contains 500 mg of paracetamol and 20 mg of dihydrocodeine tartrate. Each *Remedeine Forte* tablet contains 500 mg of paracetamol and 30 mg of dihydrocodeine tartrate.

The other ingredients are:

- Magnesium stearate
- Maize starch

What *Remedeine* and *Remedeine Forte* tablets look like and the contents of the pack

Remedeine tablets are white and marked PD/20. *Remedeine Forte* tablets are white and marked PD/30.

In each bottle there are 56 or 112 tablets.

Marketing Authorisation Holder and Manufacturer

The tablets are made by Bard Pharmaceuticals Limited for the marketing authorisation holder Napp Pharmaceuticals Limited, both at Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

This leaflet was last approved in July 2008

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