

REMEDEINE® AND REMEDEINE FORTE® TABLETS

Paracetamol and Dihydrocodeine tartrate

This medicine contains dihydrocodeine tartrate which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Remedeine Tablets are and what they are used for
2. What you need to know before you take Remedeine Tablets
3. How to take Remedeine Tablets
4. Possible side effects
5. How to store Remedeine Tablets
6. Contents of the pack and other information

1. What Remedeine Tablets are and what they are used for

The name of this medicine is Remedeine and Remedeine Forte Tablets.

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'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your doctor should have explained how long you will be taking it for, when it is appropriate to stop and how to do this safely. The other ingredients are listed in section 6 of this leaflet.

2. What you need to know before you take Remedeine Tablets

Do not take Remedeine Tablets if you:

- are allergic to dihydrocodeine, paracetamol or any of the other ingredients of this medicine (listed in section 6)
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Remedeine Tablets, if you suffer from any of the following:

- 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 or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- Have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- Feel you need to take more Remedeine Tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.
- Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Sleep-related breathing disorders

Remedeine Tablets can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

During treatment with Remedeine Tablets, tell your doctor straight away if:

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).

Tolerance, dependence, and addiction

This medicine contains dihydrocodeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to

person. You may have a greater risk of becoming dependent on or addicted to Remedeine and Remedeine Forte Tablets if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Remedeine and Remedeine Forte Tablets, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Remedeine Tablets).

Other special warnings:

- **Do not take anything else containing paracetamol while taking this medicine.**
- **Do not take for longer than directed by your prescriber.**
- **Taking dihydrocodeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets. Your doctor should have explained how long you will be taking it for, when it is appropriate to stop and how to do this safely.**
- **Taking a painkiller for headaches too often or for too long can make them worse.**

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

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. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Other medicines and Remedeine Tablets

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

If you take these tablets with some other medicines, the effect of these or the other medicine may be changed.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- 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 tranylcypromine, phenelzine, isocarboxazid, moclobemide 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 (for lowering cholesterol levels);
- medicines such as warfarin to prevent your blood clotting or to help thin your blood.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

Concomitant use of Remedeine Tablets and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Remedeine Tablets together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.



Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.



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Product:	Remedeine and Remedeine Forte Tablets - Crescent Medical
Item Code:	P3836T
Size:	210 x 380 mm
Min. Point size:	8pt
O. Artwork	23/02/26
Proof No.	1
Amendment Date:	

Colours Used	
	Process Black
	Keyline - Does not print

Remedeine Tablets 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 breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. **Do not** take these tablets until you have spoken to your doctor.

If you use Remedeine Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Remedeine Tablets while you are breastfeeding as dihydrocodeine tartrate passes into breast milk and will affect your baby.

Driving and using machines

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

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

- Do not drive whilst taking this medicine until you know how this medicine 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 the 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.

3. How to take Remedeine Tablets

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

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Remedeine and Remedeine Forte Tablets, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Remedeine Tablets).

Remedeine Tablets should be taken orally. Swallow your tablets whole with a glass of water.

The recommended dose is:

Adults: 1 or 2 tablets every four to six hours when necessary. Do not take more than 8 tablets in 24 hours.

Elderly: If you are elderly your doctor may suggest a lower starting dose.

Use in children and adolescents:

Adolescents 16 to 18 years: 1 or 2 tablets every six hours when necessary. Do not take more than 8 tablets in 24 hours.

Children 12 to 15 years: 1 tablet every six hours when necessary. Do not take more than 4 tablets in 24 hours.

Children under 12 years of age: Not recommended.

Remedeine Tablets should be used for the shortest duration necessary to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a physician.

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 these tablets if you are already taking another medicine containing paracetamol.

If you take more Remedeine Tablets than you should

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. 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.

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 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 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.

Effects of withdrawal - abrupt withdrawal precipitates a withdrawal syndrome. Symptoms may include tremor, insomnia, nausea, vomiting, sweating and increase in heart rate, respiratory rate and blood pressure. NOTE - tolerance diminishes rapidly after withdrawal so a previously tolerated dose may prove fatal.

Regularly prolonged use of dihydrocodeine is known to lead to addiction and tolerance. Symptoms of restlessness and irritability may result when treatment is then stopped.

Prolonged use of a painkiller for headaches can make them worse.

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

4. Possible side effects

Like all medicines, this medicine 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.

Tell your doctor or pharmacist if you notice any of the side effects listed in the sections below:

Common side effects: (may affect up to 1 in 10 people)

- Most people will have constipation when they take these tablets. Your doctor will 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 (may affect up to 1 in 100 people)

- 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 (may affect up to 1 in 1,000 people)

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

Very rare cases of serious skin reactions have been reported.

Not known (frequency cannot be estimated from the available data):

- Abdominal pain
- Dependence and addiction (see section 'How do I know if I am addicted?').
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).
- problem affecting a valve in the intestines (sphincter of Oddi dysfunction)
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Remedeine Tablets, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your doctor
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- 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.

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 Remedeine Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, after EXP. The expiry date refers to the last day of that month.

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

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Remedeine Tablets contain

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

Each **Remedeine Forte Tablet** contains 500mg paracetamol and 30mg of dihydrocodeine tartrate.

The other ingredients are: Magnesium stearate, maize starch and povidone.

What Remedeine Tablets and Remedeine Forte Tablets look like and contents of the pack

Remedeine Tablets are white and marked PD/20.

Remedeine Forte Tablets are white and marked PD/30.

This medicine is available in containers with 56 or 112 tablets or in blister packs of 2, 8, 12, 28, 56, 112 or 200 tablets. (Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.

Manufacturer



Crescent Medical UK Ltd, Bolton BL5 2AL, UK

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